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# Biopharmaceutical Process – Contract Development Organization: Startup

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## Biopharmaceutical Process – Contract Development Organization: Startup

## Abstract

Due to their high specificity and the wide range of treatments they can provide, monoclonal antibodies (MAbs) from mammalian cell cultures have gained increasing popularity in therapeutics. As a result, treatments have become cheaper and easier to manufacture while maintaining their natural effectiveness, further increasing their appeal. Building MAb manufacturing facilities can be costly for biopharmaceutical companies, especially smaller biotech firms, and current production capacities are limited. As a result, there is an everincreasing demand for contract development organizations (CDOs). The CDO being proposed targets demand within this regime specific to MAbs entering clinical trials. It has the capability to screen clones, grow MAb-producing cells up to a 2500 L culture, and purify the MAb to clinical standards. By employing the newest technology available, the facilities will provide flexibility necessary for producing a myriad of different MAb therapeutics in Chinese Hamster Ovary (CHO) cells. Microbioreactors can screen dozens of clones at the millileter scale, saving time and money. Disposable bioreactors in the upstream process allow for variance in the production capacity due to the range of sizes they are available in. Finally, the purification process has been designed to allow for flexibility depending on the size and needs of every client's product to maximize value to the costumer as well as the company.

The current market for MAb production has an astounding worldwide value of approximately \$27.5 billion and continues to expand as the number of MAbs entering clinical trials increases (Cowen 2006). It is estimated that within the next four years that the worldwide market value will reach \$50 billion ("Preclinical Development", 2010). The profitability of this proposal is based on running 39 batches a year at 4.326 kg MAb/batch or 168.71 kg MAb/year. By charging a reasonable average of \$1,125,000/kg MAb, a profitability profile can be created. Assuming a 70% production capacity and a ten year plant life, the ROI, NPV and IRR of the project are 115.83%, \$111,907,800 and 52.96% respectively. However, using a 70% production capacity also leaves room for even higher profit margins. The plant design also has space allotted for future expansion within the mammalian suite as well as room for a future microbial suite.

#### Disciplines

Biochemical and Biomolecular Engineering | Chemical Engineering | Engineering

# Biopharmaceutical Process – Contract Development Organization: Startup

CBE 459 - Spring 2010

Andrew Chaffkin, Melissa Hedberg, Louise Jacobovitz, Matthew Louie

Project Advisor: Dr. Matthew Lazzara Project Recommendation: Dr. Tiffany Rau

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#### **1.0 Abstract**

Due to their high specificity and the wide range of treatments they can provide, monoclonal antibodies (MAbs) from mammalian cell cultures have gained increasing popularity in therapeutics. As a result, treatments have become cheaper and easier to manufacture while maintaining their natural effectiveness, further increasing their appeal. Building MAb manufacturing facilities can be costly for biopharmaceutical companies, especially smaller biotech firms, and current production capacities are limited. As a result, there is an everincreasing demand for contract development organizations (CDOs). The CDO being proposed targets demand within this regime specific to MAbs entering clinical trials. It has the capability to screen clones, grow MAb-producing cells up to a 2500 L culture, and purify the MAb to clinical standards. By employing the newest technology available, the facilities will provide flexibility necessary for producing a myriad of different MAb therapeutics in Chinese Hamster Ovary (CHO) cells. Microbioreactors can screen dozens of clones at the millileter scale, saving time and money. Disposable bioreactors in the upstream process allow for variance in the production capacity due to the range of sizes they are available in. Finally, the purification process has been designed to allow for flexibility depending on the size and needs of every client's product to maximize value to the costumer as well as the company.

The current market for MAb production has an astounding worldwide value of approximately \$27.5 billion and continues to expand as the number of MAbs entering clinical trials increases (Cowen 2006). It is estimated that within the next four years that the worldwide market value will reach \$50 billion ("Preclinical Development", 2010). The profitability of this proposal is based on running 39 batches a year at 4.326 kg MAb/batch or 168.71 kg MAb/year. By charging a reasonable average of \$1,125,000/kg MAb, a profitability profile can be created. Assuming a 70% production capacity and a ten year plant life, the ROI, NPV and IRR of the project are 115.83%, \$111,907,800 and 52.96% respectively. However, using a 70% production capacity also leaves room for even higher profit margins. The plant design also has space allotted for future expansion within the mammalian suite as well as room for a future microbial suite.

### **2.0 Introduction**

Antibodies are a class of proteins that are produced or secreted by the B cells of the immune system in response to foreign substances, or antigens. As shown in Figure 2.1, the structure of an antibody allows for the binding between the antibody and an antigen to be highly specific. (Cohen)

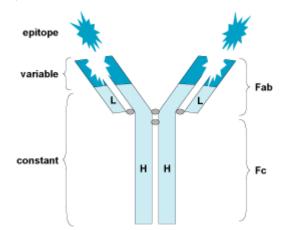


Figure 2.1: Typical antibody molecule. Consists of two heavy chains (H) and two light chains (L), which are held together by disulfide bonds. The two epitopes that bind to the molecule are identical given its symmetry. Fc is the constant region and Fab is the antigen-binding region in the molecule. The variable region allows for highly-specified binding (Cohen)

A monoclonal antibody is produced by a single B cell clone, making it specific to only one kind of antigen. Due to their high specificity, MAbs are becoming increasingly popular in therapeutics, especially in the treatment of autoimmune diseases, inflammatory conditions, viral diseases and cancer (Brodsky).

Because MAb production can be extremely costly, exceeding the budget of about twothirds of biopharmaceutical companies, there is high demand for contract manufacturing organizations (CMOs), as well as contract development organizations. These companies can specialize in the production and development of different kinds of MAbs. Despite the high initial investment cost, by the end of 2007, MAbs were generating global revenues of around \$20 billion and represented the fastest-growing segment within the pharmaceutical industry. Table 2.1 lists the MAb therapeutics approved until 2005 (Reichert 2005). The expected compound annual growth rate is 14% between the years 2006-2012. In order to rectify the high demand for MAbs and the high initial investment cost, CDOs and CMOs are currently the best solution for small biopharmaceutical companies. (Andersson 2001)

Generic	Company/location	Trade	Description	Therapeutic category	Approval date
Muromonab-CD3	Johnson & Johnson New Brunswick, New Jersey	Orthoclone OKT3	Murine, IgG2a, anti-CD3	Immunological	06/19/86 (US)
Abciximab	Centocor	ReoPro	Chimeric, IgG1, anti-GPIIb/IIIa; Fab	Hemostasis	12/22/94 (US)
Rituximab	Genentech	Rituxan	Chimeric, IgG1x, anti-CD20	Oncological	11/26/97 (US) 06/02/98 (EU)
Daclizumab	Hoffmann-La Roche Basel	Zenapax	Humanized, IgG1ĸ, anti-CD25	Immunological	12/10/97 (US) 02/26/99 (EU)
Basiliximab	Novartis Basel	Simulect	Chimeric, IgG1ĸ, anti-CD25	Immunological	05/12/98 (US) 10/09/98 (EU)
Palivizumab	MedImmune Gaithersburg, Maryland	Synagis	Humanized, IgG1x, anti-respiratory syncytial virus	Anti-infective	06/19/98 (US) 08/13/99 (EU)
Infliximab	Centocor	Remicade	Chimeric, IgG1κ, anti-tumor necrosis factor (TNFα)	Immunological	08/24/98 (US 08/13/99 (EU
Trastuzumab	Genentech	Herceptin	Humanized, IgG1x, anti-HER2	Oncological	09/25/98 (US) 08/28/00 (EU)
Gemtuzumab ozogamicin	Wyeth Madison, New Jersey	Mylotarg	Humanized, IgG4x, anti-CD33; immunotoxin	Oncological	05/17/00 (US)
Alemtuzumab	Genzyme Cambridge, Massachusetts	Campath-1H	Humanized, IgG1x, anti-CD52	Oncological	05/07/01 (US) 07/06/01 (EU)
Ibritumomab tiuxetan	Biogen Idec	Zevalin	Murine, IgG1x, anti-CD20; radiolabeled (Yttrium 90)	Oncological	02/19/02 (US
Adalimumab	Abbott Deerfield Park, Illinois	Humira	Human, IgG1x, anti-TNF $\alpha$	Immunological	12/31/02 (US) 09/1/03 (EU)
Omalizumab	Genentech	Xolair	Humanized, IgG1x, anti-IgE	Immunological	06/20/03 (US)
Tositumomab-1131	Corixa Seattle	Bexxar	Murine, IgG2aλ, anti-CD20; radiolabeled (lodine 131)	Oncological	06/27/03 (US)
Efalizumab	Genentech	Raptiva	Humanized, IgG1x, anti-CD11a	Immunological	10/27/03 (US) 09/20/04 (EU)
Cetuximab	Imclone Systems New York	Erbitux	Chimeric, IgG1x, anti-Epidermal growth factor receptor	Oncological	02/12/04 (US) 06/29/04 (EU)
Bevacizumab	Genentech	Avastin	Humanized, IgG1, anti-vascular endothelial growth factor	Oncological	02/26/04 (US) 01/12/05 (EU)
Natalizumab <sup>a</sup>	Biogen Idec	Tysabri	Humanized, IgG4κ, anti-α4-integrin	Immunological	11/23/04 (US)

Table 2.1: Summary of MAb therapeutics approved by the FDA until February 2005. The growth rate of MAb approval, as well as production, has grown consistently ever since. (Reichert 2005)

As opposed to CMOs that focus on manufacturing only, CDOs specialize in manufacturing, cell optimization, and process development. To optimize production, Chinese hamster ovary cells were selected to produce the MAbs. CHO cells have been widely used to create MAbs because they offer consistent growth and protein production. Additionally, CHO cells are mammalian cells, and they can therefore produce antibodies with proper posttranslational modifications (PTMs) such as glycosylation and protein folding. Such flexibility for MAb with PTMs is crucial since the PTMs can extend the function of the protein and are therefore a popular demand for biopharmaceutical companies. CHO cells also allow for production at lower costs because they can grow at large scale without the presence of expensive serum. Finally, CHO cells can grow quickly and can survive in dense populations, which is crucial to large-scale production, and it allows for a recovery of 2 g of MAb per liter of culture or more. (Gerson 2008)

The production process begins with the screening of 100 CHO clones provided by the client. This number of clones is chosen for the selection process because it is a manageable number that shortens the screening time, while maintaining a high likelihood of finding an ideal clone. An ideal clone is determined by the growth and production parameters chosen for each process. One may note, however, that if there is no clone with ideal properties from the initial set of clones, then more clones may have to be generated, either in-house or from their original source. As these are both costly and time-consuming options, the clone with the best properties can be selected from the original set. This decision will be at the discretion of the client.

The facility also includes an area for cell culture and purification, where cells in vials of few hundred milliliters can be expanded into a 2500 L reactor, and the product can be purified according to the required standards. The latest technologies utilized by this company include disposable bioreactors in the upstream process and disc stack centrifugation in the downstream. Disposable bioreactors were selected because these are less costly than other reactors, remove the bottleneck of cleaning and sterilizing the reactors between batches, and are considered environmentally friendly. Disc stack centrifugation was selected in the downstream process because it significantly increases the speed of the purification by making the centrifugation into a continuous process rather than batch (Morrow 2007). By using the latest technologies, the key factors of cost and speed are optimized in the delivery process.

Finally, since Massachusetts is a popular location for biopharmaceutical companies, Cambridge is a great fit as a location for the manufacturing facility. By being so close to other biopharmaceutical companies, the facility will be following the location of its customers. It is also in an area that contains a large talent pool from cutting-edge academic universities, as well as from other biopharmaceutical companies, within reasonable proximity. This location is also near an international airport, decreasing the cost and increasing the speed associated with shipping. Given the conditions that the materials need to be stored in, speed and reliability in the

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transportation process is of crucial importance. Thus, the location of the CDO will not only meet the demands of today but also the demands and promises of tomorrow.

## **2.1 Project Charter**

Project Name: Biopharmaceutical Process- Contract Development Organization: Startup

Project Champions: Business Director of Biopharmaceutical Companies

Project Leaders: Andrew Chaffkin, Melissa Hedberg, Louise Jacobovitz, Matthew Louie

Specific Goals: Design a biopharmaceutical facility and process to produce monoclonal

antibodies of varying scales

## **Project Scope In-scope:**

- Facility must accommodate cell line screening, cell culture and purification processes
- Facility may be used to produce various kinds of monoclonal antibodies
- Facility and product meet current safety and health regulations
- Maintain profit margin

## **Out-of-scope:**

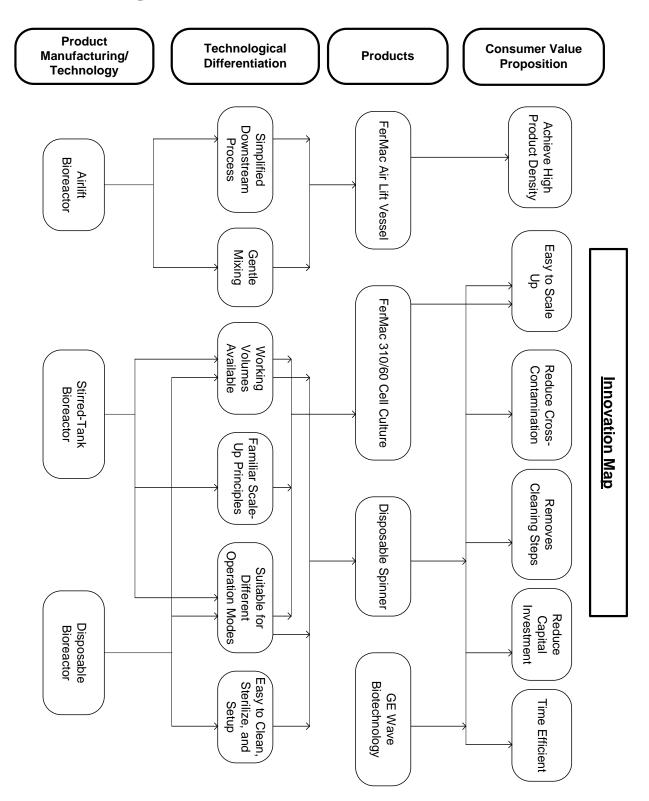
- Equipment for quality control
- Clinical Trials
- Distribution of product
- Research and development of monoclonal antibodies
- Air flow of the laboratory facility

## Deliverables

- Business opportunity assessment:
  - How great is the business opportunity for biopharmaceutical contract development organizations?
  - What is the market space for monoclonal antibodies?

- Technical feasibility assessment:
  - Is it technically feasible to manufacture monoclonal antibodies in the designed facility?
  - Is it technically feasible to manufacture MAbs at different scales?
- Manufacturing capability assessment:
  - Can this facility be built and can this process be executed without significant capital investment?
- Product life-cycle assessment:
  - Would the facility and process satisfy current regulatory requirements?
- Time Line:
  - Facility and process design within 3 months
  - Construction of the facility within 1.5 years

## 2.2 Innovation Map



#### **3.0 Concept Stage**

#### **3.1 Total Market and Competitive Analysis**

The specific segment of the market being targeted by the company is the production of monoclonal antibodies entering clinical trials. In a 2005 market analysis, it was projected that the worldwide monoclonal antibody market would increase from an estimated \$15 billion to \$26 billion by 2010, an annual average growth rate of 11.5% ("World Antibody Market", 2005). Compellingly, a more recent analysis by Cowen & Co. projected in October 2006 that the total sales in cancer, Alzheimer's, and respiratory treatments alone would be in excess of \$27.5 billion in 2010, surpassing the previous year's projected market value. Also, in a March 2010 report it was stated that within the next four years it is predicted that the worldwide monoclonal antibody market value will increase to nearly \$50 billion ("Preclinical Development", 2010), reflecting a major growth in the monoclonal antibody industry.

As of 2004 there were 121 novel therapeutics in the clinic, 61 were monoclonal antibodies or 50.41% of novel therapeutics. However, within two years, that number grew to 130 monoclonal antibodies out of 216 total novel therapeutics of such kind or 60.19% (Lubiniecki 2006). It can be seen that within these years there was an extraordinary growth in the number of monoclonal antibodies being tested, such growth has existed for quite some time. Between 1995 and 2007, the number of monoclonal antibodies entering clinical trials more than tripled and such growth continues today ("Preclinical Development", 2010). However, the current production capacity for cell culture seems to be the limiting factor for the expansion of the market as the current capacity seems to be operating at a maximum as manufacturers feign away from conditions otherwise. At the same time, many runs for products entering clinical trials are small and too expensive for large production facilities to start up their large 5000 L or more reactors.

As a result of the lack of room for production of new products, the proposal of this project ventures on this opportunity. The plan is to create a facility that is flexible in size and small enough to produce amounts for clinical trials rather than mass retail production while taking into account the expansion of the market while leaving room within the facility for later expansion within the primary mammalian suite. Space within the facility has also been left for an eventual venture in a microbial suite where therapeutics produced by microbial cells will be made as well. This would allow the company to tap into the microbial regime of the biopharmaceutical market, which is already well established. Therefore the venture plans to take advantage of the current market's demand in a manner that is twofold by concentrating on the need for manufacturing capacity as well as the growth of the monoclonal antibody market.

## 3.2 Principle Competition Production Level and Sales

The major competitors within the biopharmaceutical market by far are large, wellestablished companies such as Amgen, J&J Centocor, Roche, Pfizer and Abbott along with their subsidiaries such as Roche's Genentech. The revenue expectations of those companies are exceedingly high in comparison to our company's predicted revenues exceeding billions of dollars. However, this is mostly due to the fact that their facilities are much greater in size and the products they produce are mostly for retail. As the market segment being targeted is specific to monoclonal antibodies entering clinical trials, it is expect by the nature of this segment that revenues will be lower since the companies developing these therapies have a strong desire to cut losses in the case that these projects fail. However, the niche within the market that the facility will fall under is specific to lower volumes of production since clinical trials target significantly lower treatment populations, enough product for approximately 20,000 doses, where as commercial products will produce enough product for the masses. As a result, companies seeking production of monoclonal antibodies for clinical trials will employ a facility whose capacity is fitted to those needs at a affordable rate. Conversely, companies with facilities of a larger scale will not target such clients as their main goal is to maximize the usage of their capacity or charge a premium for lower scale production.

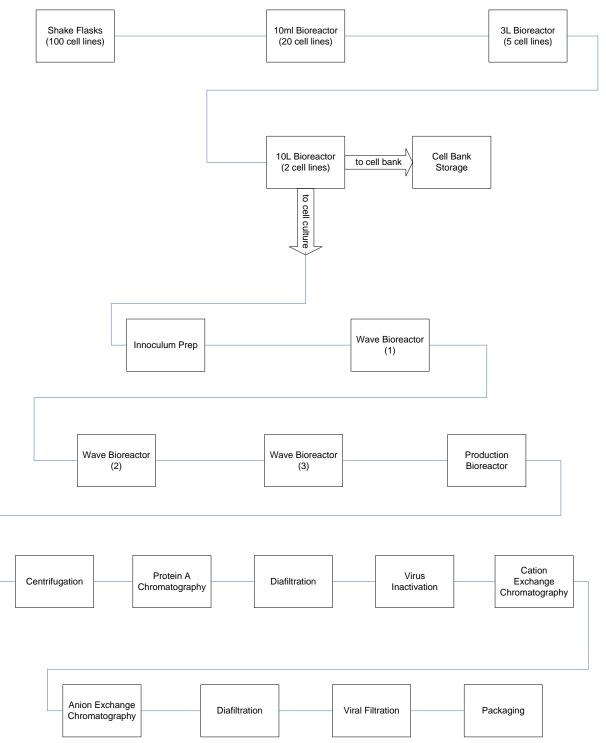
## **3.3 Customer Requirements**

Given the flexibility of the proposed facility in conjunction with the variability that is inherent with MAb production, customer requirements will vary on a case by case basis. However, our goal is to provide services and technology most befitting to those needs while maintaining quality and stability of the product. As a result, the customer requirements for the proposed facility fall under new-unique-and-difficult or new to the world. First and foremost, the technology within the facility and the processes that go along with it must be able to supply product that meets FDA standards for clinical trials and eventual commercialization such as 99.99% purity of the end product and strict product composition at packaging. The process must also have been developed by the client as research and development is not within the scope of the CDO. Also given the goal of the facility design and the ever evolving nature of medicine and process improvements, flexibility must be inherent in order to accommodate for advances in monoclonal antibody therapies. That being said, the newest technology available on the market will be employed. Using disposable bag bioreactors allows for a clean transfer of product between each stage of the process. This will permit the necessary standards and flexibility that is desired while allowing for the most efficient processes available to clients. To summarize, main goal in meeting the customer requirements is to provide cutting edge technology in conjunction with sound engineering and science to make available flexibility in production of both established and innovative therapies while not lowering the integrity of the final product.

## 3.4 Block flow Diagram

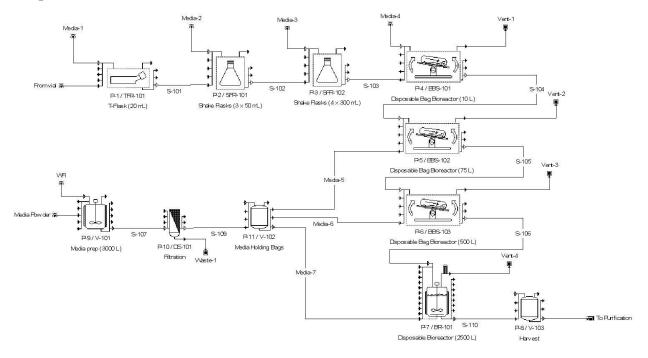
The following is an illustration of the overall process, including the cell selection,

upstream and downstream procedures.



## 4.0 Process Flow Diagrams

## 4.1 Upstream Process

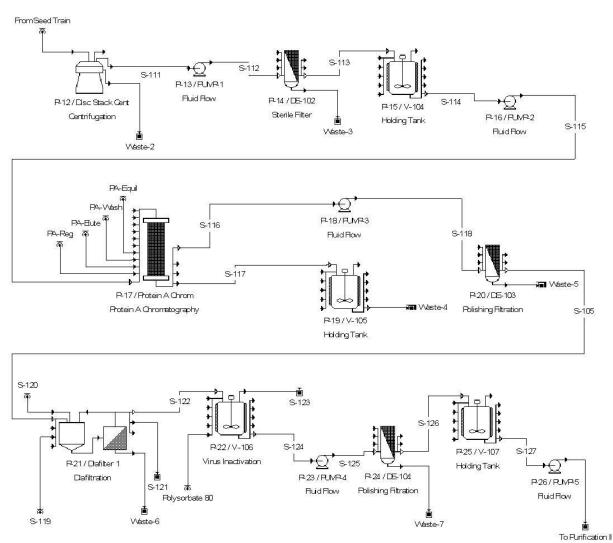


Note: Volumes shown are working volumes. Pumps are not included in the diagram. One pump is shared between the three bag bioreactors, and one is dedicated to the media preparation, as described in the unit descriptions (section 6.2).

COMPONENT	INITIAL	INPUT	OUTPUT	FINAL	OUT-IN
Amino acids	0.00	1.33	0.08	0.12	(1.13)
Biomass	0.00	0.00	4.26	0.00	4.26
Dead Biomass	0.00	0.00	10.28	0.00	10.28
Glucose	0.00	3.89	0.23	0.35	(3.315)
Inorganic salts	0.00	17.41	1.02	1.57	(14.82)
MAb	0.00	0.00	5.01	0.00	5.01
Nitrogen	14.61	0.00	0.00	14.61	0.00
Other media comp	0.00	0.25	0.02	0.02	(0.215)
Oxygen	4.44	0.00	0.00	4.44	0.00
Vitamins	0.00	0.08	0.01	0.01	(0.066)
WFI	0.00	2950.25	2704.62	245.63	0.00
TOTAL	19.05	2973.21	2725.52	266.74	0.00

4.1.1 Overall Material Balance for Upstream Process

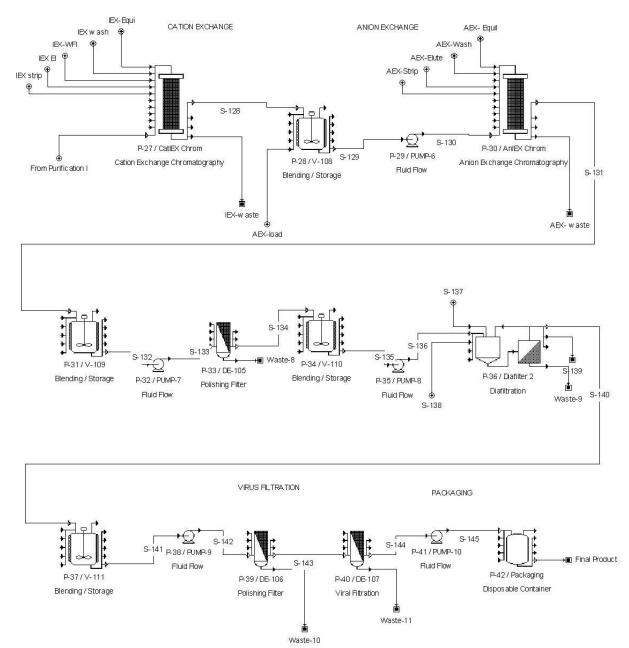
## 4.2 Downstream Process Part 1



4.2.1 Overall Material Dalance for Downstream Process Part 1					
COMPONENT	INITIAL	INPUT	OUTPUT	FINAL	OUT-IN
Amino Acids	0.00	0.08	0.08	0.00	0.00
Biomass	0.00	4.26	4.26	0.00	0.00
Citric Acid	0.00	2.88	2.88	0.00	0.00
Dead Biomass	0.00	10.29	10.29	0.00	0.00
Ethyl Alcohol	0.00	1307.38	1307.38	0.00	0.00
Glucose	0.00	0.23	0.23	0.00	0.00
<b>Inorganic Salts</b>	0.00	1.02	1.02	0.00	0.00
MAB	0.00	5.00	5.00	0.00	0.00
Nitrogen	13.05	0.08	0.08	13.05	0.00
<b>Other Media Comp</b>	0.00	0.02	0.02	0.00	0.00
Oxygen	3.96	0.02	0.02	3.96	0.00
Phosphoric Acid	0.00	182.70	182.70	0.00	0.00
Polysorbate 80	0.00	0.01	0.01	0.00	0.00
Sodium Hydroxide	0.00	30.92	30.92	0.00	0.00
TRIS Base	0.00	0.77	0.77	0.00	0.00
TRIS HCl	0.00	2.30	2.30	0.00	0.00
Vitamins	0.00	0.01	0.01	0.00	0.00
Water	0.00	12698.02	12698.02	0.00	0.00
WFI	0.00	17106.25	17106.25	0.00	0.00
TOTAL	17.01	31352.21	31352.21	17.01	0.00

**4.2.1 Overall Material Balance for Downstream Process Part 1** 

## 4.3 Downstream Process Part 2



COMPONENT	INITIAL	INPUT	OUTPUT	FINAL	OUT-IN
Citric Acid	0.00	0.00	0.00	0.00	0.00
MAb	0.00	4.33	4.33	0.00	0.00
Nitrogen	1.09	0.00	0.00	1.09	0.00
Oxygen	0.33	0.00	0.00	0.33	0.00
Phosphoric Acid	0.00	438.03	438.03	0.00	0.00
Polysorbate 80	0.00	0.01	0.01	0.00	0.00
Sodium Chloride	0.00	382.87	382.87	0.00	0.00
Sodium Hydroxide	0.00	40.23	40.23	0.00	0.00
Sodium Phosphate	0.00	751.41	751.41	0.00	0.00
<b>TRIS Base</b>	0.00	1.49	1.49	0.00	0.00
Water	0.00	3373.89	3373.89	0.00	0.00
WFI	0.00	9176.86	9176.86	0.00	0.00
TOTAL	1.42	14169.10	14169.10	1.42	0.00

**4.3.1 Overall Material Balance for Downstream Process Part 2** 

## **5.0 Process Descriptions**

## **5.1 Buffer Preparation**

The buffers required in the process are prepared in sterile disposable containers in the buffer preparation room. By making the buffers in-house, the cost for the buffer decreases. Buffers are made in disposable containers in order to reduce the time and work required for steam and clean in place, and their respective validations. All buffers are made using WFI, so that it can be used in the purification process, and when process is completed, the buffers are tested and verified to make sure that they are at their appropriate pHs. Before use, the buffers go through a  $0.2 \,\mu\text{m}$  sterile filter to ensure that any bacteria or other contaminants have been properly removed.

## 5.2 Cell Screening and Selection

#### 5.2.1 Shake Flasks

First, the provided vials of cells containing the 100 cell lines are removed from a liquid nitrogen freezer and stored in a biosafety cabinet until fully thawed. Once thawed, the cells are centrifuged, the supernatant is discarded, and the cells are resuspended in fresh media. 125 mL shake flasks are inoculated with 25 million cells and 50 mL of serum free media using serological pipettes. Each shake flask thus has a working volume of 40% to allow for proper agitation as recommended by Corning (see Appendix for flask brochure), from which these flasks are being purchased. The shake flasks are stored in an incubated orbital shaker with CO<sub>2</sub> at 37° C and an agitation of 75-125 rpm, which are conditions commonly used for CHO cells. Since this is an uncontrolled and unmonitored system, fluctuations in the pH and dissolved oxygen levels will occur. The pH will fluctuate around a neutral pH of 7.0. Vented caps are used to allow for sterile gas exchange while minimizing contamination. After 3 or 4 days, the cells are passaged. A sterile serological pipette is used to transfer cell culture to a new flask for each of the 100 clones. Fresh serum free media is added to each flask such that the shake flasks have a working volume of 40%. The exact volume of culture used for seeding will be determined based on the measured viable cell density using a ViCell or hemocytometer to obtain a target seeding density of around 5 x  $10^5$  cells/ml.

After five passages, the 20 best cell lines will be selected based on their growth, production level, and stability. To measure the production level, 120  $\mu$ L of culture is spun down in eppendorf filter tubes and sent to the analytical department at the end of each passage. From these samples, the titer and titer binding, the MAb's binding capacity to the target antigen, will be determined. Analytical method details for these measurements are left for the analytical department. Throughout the passaging regime, at least 100  $\mu$ L samples are removed, diluted with trypsin, and analyzed on the ViCell to determine the cell density, viability and cell size. Stability will be established if the growth and production level of the cell line does not decrease and/or change with each passage. The 20 cell lines continue to be passaged while further experiments are conducted to monitor their stability. Throughout the passaging of cells, a development bank will be formed. Approximately every 4 passages, the cells will be counted, spun down, and resuspended in freezing media to a final concentration of 5 x 10<sup>6</sup> cells/ml, as recommended by Millipore. Then, 1 ml of cell suspension is aliquotted per tube into 10-15 cryo-vials. The cell culture should be frozen while growing in log phase with viability greater than 90%.

#### 5.2.2 10 ml Bioreactor

Next, the 20 best cell lines are grown in a micro-bioreactor system manufactured by Pall Corporation with 24 individually controlled reactors. Each reactor is inoculated with a culture containing 5 x 10<sup>5</sup> cells/ml in fresh serum free media using a serological pipette to yield a total working volume of 5 ml. The final working volume of each cassette is thus 50% of the total reactor volume to allow for proper agitation. Process control of each reactor is achieved through a standard laptop/PC. Typically, the dissolved oxygen is kept at 30-40%, the pH is maintained at 7.0, and the temperature is held at 37° C, which are typical operating parameters for CHO cells. Designs of experiment (DOE's) can be conducted to determine the optimum temperature, pH, and/or dissolved oxygen settings for each cell line as requested by the client.

The reactor is operated for a maximum of 3 weeks, depending on client requirements. Samples are removed every 4-7 days. Again, 100  $\mu$ l samples are analyzed on the ViCell and 120  $\mu$ l samples are sent to analytical. An additional 90  $\mu$ l is measured with a blood gas analyzer with enhanced features to determine the pH, the dissolved oxygen and carbon dioxide levels, and the electrolyte and metabolite levels, particularly glucose and lactose. This is used to monitor the metabolic state of the culture. The culture is fed based on client specifications. Between 5 and 6 cell lines will be selected based on their production levels, growth, and metabolic profile during the micro-bioreactor experiments. These cell lines will continue to be passaged and banked so that their stability can be monitored while further experiments are conducted.

## 5.2.3 3 L Bioreactors

Once the cell lines are screened in the Micro-24 bioreactor, the remaining cell lines are grown in a 3 L disposable bioreactor system for a maximum of 3 weeks, depending on client specifications. The following seed train is used to inoculate the bioreactor starting with cell culture from the most recent passage. All flasks are stored in an incubated orbital shaker with

250 ml flask	31.25 ml of culture from 125 ml flask	68.75 ml of serum free media
500 ml flask	62.5 ml of culture from 250 ml flask	137.5 ml of serum free media
1L flask	125 ml of culture from 500 ml flask	275 ml of serum free media
2L flask	250 ml of culture from 1L flask	550 ml of serum free media

 $CO_2$  for four days at 37° C and an agitation of 75-125 rpm. Culture and media are transferred to the new flask under a biosafety cabinet using a seriological pipette.

At the end of the seed train, approximately 667 ml of culture is transferred from the 2 L flask to the 3 L bioreactor in the biosafety cabinet. Fresh media is added to obtain a working volume of 2 L. This is within the range of working volumes of 0.6-2.4 L recommended by Applikon, from which this system was purchased. Again, these volumes are calculated for a doubling time of approximately 30 hours. Precise volumes will be calculated based on cell count for a target density of 5 x  $10^5$  viable cells/ml. The temperature and pH probes and the tubing is connected under the biosafety cabinet to ensure a sterile connection. The 3 L bioreactor is operated for 3-4 days to increase the cell count enough to seed 2 or 3 additional 3 L bioreactors at 1 x  $10^6$  viable cells/ml so the cell lines may be run head to head.

The pH, dissolved oxygen, and temperature parameters are set to the optimum values determined from the DOE's in the 10 ml bioreactor. Measurements are taken using pH, dissolved oxygen, and temperature probes and the info is sent to the ez-Control system. These parameters are maintained at their set value using a PID control loop. The agitation is controlled by setting the stirrer between 75 and 125 rpm and the liquid height is measured to monitor the foam level. Every other day 5-10 ml samples are removed and analyzed on the ViCell, blood gas analyzer, and by the analytical department as described for the 10 ml bioreators. After 3 or 4 weeks, or when the viability has dropped to 30-40%, the final harvest is sent to purification, where it is used to optimize the purification process.

Based on the experiments in the 3 L bioreactors, the two best clones are selected based on their production levels, growth, and metabolic profiles. Final clone selection and design of experiment may be left up to client specifications. For example, with more time and resources a lot more development screening of the final clones at the 10 ml scale may be done but this will require a greater financial commitment. A master cell bank of 20 vials or more, if client requests, is formed using the method of cell banking described above. The GMP master cell bank creation

will be made by an outside vendor. From this master cell bank, a single vial can be thawed, passaged several times, and used to form a working cell bank.

### **5.3 Upstream Section**

#### 5.3.1 T-Flask (P-1/TFR-101)

A vial of cells from the screening lab is thawed and 20 million cells are resuspended into 20 mL fresh serum-free media in a t-flask for a final target concentration of  $1 \times 10^6$  cells/mL. The media is added gradually over the course of a few minutes using a serological pipette. This allows the cells to slowly acclimate to their new environment, reducing the shock of thawing. The t-flask is stored in a 37° C, 30% O<sub>2</sub> incubator for approximately five days. The media will equilibrate to a pH of approximately 7.0. The pH will fluctuate over the course of the culture, but these fluctuations will not be enough to significantly affect the growth of the cells.

#### 5.3.2 250 mL Shake Flasks (P-2/SFR-101)

When the viable cell density (VCD) in the t-flask is greater than  $7.5 \times 10^6$  cells/mL, the culture is transferred into three 250 mL shake flask cultures using a serological pipette, with 50 million cells in each flask. Fresh media is added to reach the final culture volume, which is 50 mL per flask. The shake flasks are kept in a shaking incubator at  $37^\circ$  C for approximately 5 days. This will allow for proper aeration of the cultures. The media will equilibrate to a pH of approximately 7.0, but there will be fluctuations similar to those in the t-flask.

## 5.3.3 1 L Shake Flasks (P-3/SFR-102)

When the average VCD in the small shake flasks is greater than  $8 \times 10^6$  cells/mL, the cultures are transferred into four 1 L shake flask cultures using a peristaltic pump, with 300 million cells in each flask. Fresh media is added to reach the final culture volume, which is 300 mL per flask. The shake flasks are kept in a shaking incubator at 37° C for approximately 6 days. The shaking allows for proper aeration of the cultures. The media will equilibrate to a pH of approximately 7.0, but there will be fluctuations similar to those in the t-flask.

#### **5.3.4 Bag Bioreactor 1 (P-4/BBS-101)**

When the average VCD in the large shake flasks is greater than 8.33 x  $10^6$  cells/mL, the cultures are transferred into a 20 L WAVE<sup>TM</sup> bioreactor, with a final working volume of 10 L.

Fresh serum-free media is added to reach the final volume. The bag is kept on a rocking platform. The process is monitored using temperature, pH and DO probes. The culture is kept at  $37^{\circ}$  for approximately five days. The pH is controlled using a CO<sub>2</sub> source, and DO is controlled by adjusting the air flow rate into the reactor.

## 5.3.5 Bag Bioreactor 2 (P-5/BBS-102)

When the VCD in the first WAVE<sup>TM</sup> bioreactor is greater than 7.5 x  $10^6$  cells/mL, the culture is transferred into a 200 L WAVE<sup>TM</sup> bioreactor, with a final working volume of 75 L. Fresh serum-free media is added to reach the final volume. The bag is kept on a rocking platform. The process is monitored using temperature, pH and DO probes. The culture is kept at 37° for approximately four days. The pH is controlled using a CO<sub>2</sub> source, and DO is controlled by adjusting the air flow rate into the reactor.

#### **5.3.6 Bag Bioreactor 3 (P-6/BBS-103)**

When the VCD in the second WAVE<sup>TM</sup> bioreactor is greater than 6.67 x  $10^6$  cells/mL, the culture is transferred into a 1000 L WAVE<sup>TM</sup> bioreactor, with a final working volume of 500 L. Fresh serum-free media is added to reach the final volume. The bag is kept on a rocking platform. The process is monitored using temperature, pH and DO probes. The culture is kept at 37° for approximately four days. The pH is controlled using a CO<sub>2</sub> source, and DO is controlled by adjusting the air flow rate into the reactor.

### 5.3.7 Production Reactor (P-7/BR-101)

When the VCD in the third WAVE<sup>TM</sup> bioreactor is greater than 5 x 10<sup>6</sup> cells/mL, the cells are transferred into a custom 2500 L Xcellerex XDR single-use bioreactor. Fresh serum-free media is added to reach the final volume. Alternatively, a different production media can be used at the request of the client. In either case, the culture is kept at 37° until the viability of the culture falls to 30%. This occurs in approximately 10 days, but could vary depending on the growth characteristics of the individual cell lines. The XDR is a jacketed vessel, so temperature

is controlled by heating the jacket. The pH and DO parameters are controlled by adjusting the composition of the sparge gas, which is used to aerate the culture.

#### 5.3.8 Harvest Bags (P-8/V-103)

The harvested material is stored in five 500 L disposable bags until it is ready for purification. By using disposable bags in this step, the need for CIP or SIP procedures is eliminated.

#### 5.3.9 Media Prep (P-9/V-101)

Media is prepared in a large 3000 L mixing tank. Powdered CD-CHO media is dissolved in WFI. The media composition is proprietary, so a comparable, non-proprietary media was used for the simulation. After mixing, the liquid media is passed through a sterile filter (P-10/DE-101) and stored in 500 L bags until it is needed for the reactors. The tank and filter are sterilized using standard CIP and SIP procedures after each batch.

#### 5.3.10 Media Holding Bags (P-11/V-102)

The media is stored in six 500 L disposable bags until it is required by the bioreactors. These bags are identical to those used for the final harvest, but they are stored separately.

#### **5.3.11** Alternate Media Production (not pictured)

A client may wish to use a different media for the production reactor than for the rest of the process. One reason for this is that some cells grow well in one media but have better production in another. Prior to the production reactor, the primary goal is cell growth and reaching the required cell density for transferring to the next reactor. In the production reactor, the goal is to make product. The incorporation of a second media would require another set of media preparation equipment, which would be identical to those described earlier.

#### **5.4 Downstream Process**

#### 5.4.1 Centrifugation (P-12/Disc Stack Cent)

A Disc-Stack Centrifuge (P-12/Disc Stack Cent) is used to remove biomass and dead biomass from the upstream process. The centrifuge is operated at 25° C with a throughput of 2000 L/h. In the process, 2% of MAb is lost in the waste stream, resulting in a product yield of 98%. 98% of the biomass and dead biomass is removed. The centrifuge is sterilized through by SIP before the operation and CIP after each batch.

#### 5.4.2 Depth Filtration (P-14/DE-102)

The product, which is in the supernatant, is then passed through a series of filters (P-14/DE-102), where 99.99% of the biomass and dead biomass is removed. The supernatant is split and passes through four 1.2 µm depth filtration units. These filters remove particles in the liquid that could be harmful to downstream membranes. The product stream is then filtered through five 0.2 µm sterile filtration units. The filter membranes are disposed and replaced after each batch. (Shukla 2006)

#### 5.4.3 Protein A Chromatography (P-17/Protein A Chrom)

This step removes the bulk of the proteins that are not desired in the product. While the product is being loaded to the column, MAb binds to the Protein A resin and the impurities are washed through. Before loading the product, the resin must be prepared using equilibration buffer. Following this step, a column testing is performed, whereby the column's performance is analyzed. At this point, the product stream is loaded into the column at a linear velocity of 200 cm/h with a resin binding capacity of 50 g/L. The column is then washed with wash buffer, and is then eluted isocratically with elute buffer at a volume of 5 bed volumes per cycle per unit. Finally, in preparation for its next use, the column is regenerated using a regeneration buffer and then cleaned in place using 0.1 M NaOH and WFI. Though the binding of MAb to the column is 95%, the typical yield is 90%. (Shukla 2006)

As conservative estimates are being used, all wastes are drained into a holding tank (P-19/V-105) for 10 hours in order to allow for enough recovery time in case the column malfunctions and the MAb is removed in the waste stream. The product stream, on the other hand, is filtered through a polishing filter (P-20/DE-103). There is no holding tank between the column and the filter because the flow-rates and duration of the operation of both the column and the filter are equal. SIP and CIP is also performed before and after the column and tank are used with NaOH and WFI in the cleaning procedure for the column and WFI, NaOH and  $H_3PO_4$  for the tank. The filter membranes are disposed after each batch.

#### 5.4.4 Diafiltration (P-21/Diafilter 1)

After passing through a polishing filtration unit (P-20/DE-103), where any bacteria potentially present in the stream will be removed, the stream is then passed into a diafiltration system. In diafiltration, molecules are separated according to the difference in molecular weight, without concentrating the product stream. The filter membranes have a molecular weight cutoff of 30 kDa, preventing any monoclonal antibody from passing through the membrane. The concentration process also removes any unwanted component that is still present in the solution, including the media components and the acetic acid used in the buffers from the Protein A column. Denaturation of monoclonal antibody results in a product yield of 97%. The system is operated at 25° C with a feed pressure of 2.74 bar. The diafiltration system, including the reusable membranes, is sterilized after every batch with SIP and CIP processes. Reusable membranes are sterilized with 40 M NaOH at 40° C for 30 min. (Shukla 2006)

#### 5.4.5 Virus Inactivation (P-22/V-106)

The concentrated protein solution is pumped into a blending tank where it is chemically treated for 90 minutes with polysorbate 80 to inactivate enveloped viruses. Polysorbate 80 is an oil-in-water emulsifier and solubilizer and is used to inactivate viruses as it disrupts the interactions between molecules in the lipid coat of viruses. By disrupting these interactions, the coat becomes dysfunctional and prevents the virus from replicating (Roberts 2008). The process operates at 25° C and is sterilized after each batch with standard CIP and SIP procedures for stirred tanks. After the inactivation process, the stream once again passes through a polishing filter (P-24/DE-104) to remove any potential bacteria in the stream. (Shukla 2006)

#### 5.4.6 Cation Exchange Chromatography (P-25/CatIEX Chrom)

In Cation Exchange Chromatograhy, positively charged molecules bind to the negatively charged resin. Before loading the product stream, the column is equilibrated with 5 bed volumes of Cation Buffer of Sodium Phosphate, thus significantly lowering the pH of the column to about 4.5. As the MAb is positively charged, it binds to the equilibrated resin, while the other less positively charged impurities are washed out to the waste stream. Before dispensing the product stream into the column, a column testing is performed for 2 hours, where the resin's performance is tested. After the testing, the stream is loaded, and MAb binds to the resin, which has a 45 g/L binding capacity at a binding factor of 98%, and a yield of 95%. The column is then washed with 5 bed volumes of buffer containing phosphoric acid and sodium chloride to remove the impurities that did not bind to the resin. The MAb is then eluted using the elute buffer, which also contains sodium chloride, causing a disruption of the ionic binding between the MAb and the resin. The elution strategy is through a gradient of the elute buffer diluted through WFI. After the product is retrieved, a stripping step is performed, where the column in regenerated and all remaining products in the resin is completely removed. The column is then rinsed and a CIP is performed, using a wash of NaOH and WFI. (Shukla 2006)

#### 5.4.7 Anion Exchange Chromatography (P-30/AnIEX Chrom)

In anion exchange chromatography, the negatively charged molecules bind to the positively charged resin The resin is composed of ion exchange groups that are coupled to a highly cross-linked agarose matrix through ether bonds, as specified by the vendor (GE Life Sciences). In this case, the MAb is washed through the column, while DNA, endotoxins and other negatively charged molecules bind to the resin. Before entering the column, the MAb stream is combined with an anion load stream, containing tris base and sodium chloride (P-28/V-108). By adding the anion load, the MAb becomes slightly basic, which helps it avoid binding to the resin. Before loading the MAb stream into the column, the resin in the column is equilibrated with 5 bed volumes of the anion buffer also containing tris base and sodium chloride. After the equilibration step, the column is tested for 2 hours to check test the resin. The column is then loaded with the MAb containing stream, which automatically flows through and is collected to be further processed with a yield of 95%. The resin is then washed and eluted isocratically using

5 bed volumes to remove all the impurities from the negatively charged molecules. The column is then stripped using 3 bed volumes of stripping buffer, which has a higher concentration of NaCl than the other anion buffer to ensure that the ionic reactions between any remaining impurities and the resin is removed. Finally, CIP is performed using 0.1M NaOH and WFI. The process is finalized after passing the stream through a Polishing Filter (P-33/DE-105), removing any bacteria in the stream, and temporarily stored in a blending tank (P-34/V-110), which is cleaned by SIP and CIP using WFI, NaOH and H<sub>3</sub>PO<sub>4</sub>. (Shukla 2006)

#### **5.4.8 Diafiltration (P-36/Diafilter 2)**

Following anion exchange, the product stream is passed through a sterile filtration unit (P-33/DE-105), where any bacteria potentially present in the stream is removed. Diafiltration is performed before viral filtration in order to keep the product stream neutralized before it is finally filtered out. It is used to remove unwanted materials of smaller molecular weight, especially the buffers used in the previous chromatographic columns. The cassette is diafiltered twice with WFI and is concentrated 5 times. A denaturation of 3% of the MAb occurs, thus giving a product yield of 97%. For this step, WFI is used in the diafiltration as opposed to any other buffers since the MAb will eventually be lyophilized before its final formulization step. SIP is performed before using the system and CIP after, where the CIP uses WFI, 0.5M NaOH, H<sub>3</sub>PO<sub>4</sub> and again WFI.

#### 5.4.9 Viral Filtration (P-40/DE-107)

Though some viruses may have been removed from the product stream in previous purification steps, a final viral filtration is needed to remove any remaining viruses. The viruses can be either coming from the mammalian cell lines that produced the MAb (these can very easily be carrying endogenous viruses, though they are supposed to be virus-free) or from other sources throughout the process. As the MAb is usually approximately 10 nm large, and parvoviruses are larger than 20 nm (retroviruses are 50 nm or larger), the filter must be a 20 nm filter in order to allow for the MAb to pass through while retaining the viruses. The operation is performed in a normal flow filtration, where the fluid flows perpendicularly to the filter and the desired material is passed through the filter while the viruses are retained. After the filter is

setup, the stream passes through the filter, and the waste is collected as biowaste. Like all other filters, new filters are used for every batch. (Shukla 2006)

#### 5.4.10 Packaging (P-42/Packaging)

Once the purification procedure is finalized, the product contains MAb in WFI at a purity level of 99.99%. The product is packaged into 2 separate disposable plastic 50L bags and then stored at -80° C until it is sent out to another facility to be formulated. No other buffers are necessary in the storing, as the product is kept in such low temperature, and it will be eventually lyophilized before it is actually formulated. (Bhambhani 2008)

#### **6.0 Major Unit Descriptions**

#### 6.1 Cell Screening and Selection

#### 6.1.1 Shake Flasks

The 125 mL shake flasks are used for the passaging of the cell lines and seeding the 10 ml micro-bioreactor. The 250 mL, 500 mL, 1 L, and 2 L shake flasks are used for seeding the 3 L bioreactors. These flasks are individually packaged and radiation sterilized so that cells will not be contaminated in any way when they come into contact with the surface of the flask. The flasks are made of polycarbonate and can be purchased with a vented cap to allow continuous gas exchange while ensuring sterility. The flasks will be manipulated in a Biosafety hood and are easily disposed of after use.

#### 6.1.2 Micro-bioreactor System

The micro-bioreactor system is used in the second phase of cell line selection to mimic the controlled cell culture conditions that will be used in later development. The system used is the Micro $24^{\text{TM}}$ , purchased from Applikon for the cost of \$94,600 with an additional \$5,500 for installation and training. The Micro24 is a bench-top, computer controlled micro-bioreactor system. It comes with a pre-sterilized, disposable cassette with 24 individually controlled 10 ml reactors, allowing for easy set up and confidence in sterility. A working volume of 5 ml will be used. Each reactor has independent control of temperature, pH, and dissolved oxygen. The cassettes have a bottom membrane that forms an aseptic seal between the control system and the reactor. The gases enter the vessel through the sterile membrane. The system has a built in orbital shaker to control the agitation.

#### 6.1.3 3 L Bioreactor

The Mobius CellReady 3 L bioreactor platform is used for the last phase of cell selection. The 3L CellReady Bundle System is purchased from Applikon for \$26,063 with an additional \$1,080.00 for installation and training. It includes the ez-Control, 6 disposable 3 L CellReady bioreactors, a silicon heating blanket, reusable pH, dissolved oxygen and temperature sensors, and a stirrer motor for agitation. Additional 3L disposable bioreactors may be purchased from Millipore in cases of 2 for \$695. The Mobius CellReady bioreactor is a single-use, 3 L stirred tank bioreactor with a maximum working volume of 2.4 L. It comes pre-assembled and gamma irradiated. The materials in contact with the cell culture are polycarbonate, high-density polyethylene, silicon, and nitrile, which are proven to be non-toxic and chemically inert. The bioreactor is equipped with clear c-Flex tubing suitable for tube welding for addition, sample, and harvest lines. In addition, each line comes with a leur lock connector. There are two leur lock side sampling ports, which eliminate the need to purge the line prior to drawing the sample. The ez-Control has five control loops; pH, temperature, dissolved oxygen, level/anti-foam, and stirrer speed. PID control is used for the control of pH, temperature, and dissolved oxygen.

#### **6.2 Upstream Process**

#### 6.2.1 T-Flask (P-1/TFR-101)

The T-flasks are purchased from Corning Inc. and have a surface area of 75 cm<sup>2</sup>. They are sold in a case of 20 for \$90.20. The maximum volume is 60 mL, but the suggested working volume is 15-22.5 mL. For this process, the working volume is 20 mL. The flasks are certified nonpyrogenic and arrive sterilized by gamma irradiation. One flask is used per batch. The flask will be inoculated and sampled inside of a biosafety cabinet to avoid contamination.

#### 6.2.2 250 mL Shake Flasks (P-2/SFR-101)

The shake flasks are purchased from Corning. The flasks have a working volume of 50 mL. They are sold in a case of 50 for \$908.32. The flasks are made of clear polycarbonate, and they are sterilized by autoclaving. Three flasks will be used per batch. They will be inoculated and sampled in a biosafety cabinet.

#### 6.2.3 1 L Shake Flasks (P-3/SFR-102)

These flasks are a larger version of the shake flasks described earlier. The flasks are purchased from Corning. They have a working volume of 300 mL. They are sold in a case of 25 for \$1011.11. The flasks are made of clear polycarbonate, so they are sterilized in an autoclave. Four flasks are used per batch. They are inoculated and sampled in a biosafety cabinet.

#### 6.2.4 Pump 1 (not pictured)

This pump is used to passage the culture from the shake flask to the disposable bag bioreactor. It is a Cole-Palmer I/P Modular Digital Dispensing peristaltic pump, with a retail price of \$2,874. The pressure drop for the pump is 25 psi, and it has a maximum flow rate of 10.07 LPM. One pump is needed per batch. The pump is kept on a cart and reused for each of the subsequent transfer steps. In future runs, when staggered batches are utilized, more pumps may be required.

#### 6.2.5 Disposable Bag Bioreactor 1 (P-4/BBS-101)

This is a WAVE<sup>TM</sup> Bioreactor System 20/50EHT. The system allows for working volumes of 0.1-25 L. For this process, the working volume is 10 L. The purchase price for the system is \$21,903. The disposable bags cost \$197 each. Each bag has sterile ports for air, inoculation, sampling, and harvesting or passaging. The bags are securely attached to a rocking unit prior to inoculation. The rocking unit has controls for temperature, rocking speed, and rocking angle. Correct rocking speed and angle allows for proper aeration of the cells, promoting growth.

#### 6.2.6 Pump 2 (not pictured)

This is the same Cole-Palmer I/P Modular Digital Dispensing peristaltic pump as described earlier. It is used to transfer the cell culture from the first disposable bag bioreactor to the second.

### 6.2.7 Disposable Bag Bioreactor 2 (P-5/BBS-102)

This is a WAVE<sup>TM</sup> Bioreactor System 200EH. The system allows for working volumes of 10-100 L. This process utilizes a working volume of 75 L. The purchase price for the system is \$201,050. The disposable bags cost \$513 each. The reactor operates similarly to the smaller model, but the rocking unit has a full stainless steel enclosure. This can shield the culture from light, which can degrade media components.

#### 6.2.8 Pump 3 (not pictured)

This is the same Cole-Palmer I/P Modular Digital Dispensing peristaltic pump as earlier described. It is used to transfer the cell culture from the second disposable bag bioreactor to the third.

#### 6.2.9 Disposable Bag Bioreactor 3 (P-6/BBS-103)

This is a WAVE<sup>TM</sup> Bioreactor System 500/1000EH. The system allows for working volumes of 100-500 L. This process will have a working volume of 500 L. The purchase price for the system is \$395,740. The disposable bags cost \$1080 each. The unit operates similarly to the previous reactors, and it has an integrated aeration pump.

#### 6.2.10 Production Bioreactor (P-7/BR-101)

This unit is a custom 2500 L XDR single-use bioreactor, manufactured by Xcellerex. The system allows for working volumes of 500-2500 L. This process will operate with a 2500 L working volume. The purchase cost for the system is \$610,000. The disposable bags cost \$1500 each. The reactor consists of a disposable bag housed within a stainless steel jacket. Agitation is achieved with a magnetically driven bottom-mount impeller. The unit is controlled by an adjacent cabinet, which also contains mass flow controllers and peristaltic pumps.

#### 6.2.11 Media Prep (P-9/V-101)

This 3000 L tank is made of stainless steel 316. It is approximately 3 m tall and 1 m wide. It is purchased from Sharpsville Container for \$120,000. The tank operates at room temperature and 1 bar. After mixing, the media is passed through a sterile filter and packaged into 500 L bags for storage.

#### 6.2.12 Pump 4 (not pictured)

This pump is used to transfer the media from the 3000 L tank through the sterile filter. It is the same model, Cole-Palmer I/P Modular Digital Dispensing, as the pump described earlier for passaging the cell culture between reactors. The purchase price is \$2,874. The pressure drop for the pump is 25 psi, and it has a maximum flow rate of 10.07 LPM.

#### 6.2.13 Sterile Filter (P-10/DE-101)

This filter removes any particulate contaminant in the media stream. It is purchased from Sartorius Stedim for \$617. It is a 1.2  $\mu$ m glass fiber disposable filter that must be replaced after each batch.

#### 6.2.14 Harvest Bags (P-8/V-103)

The Flexel 3D Bioprocessing Bags for Drum manufactured by Sartorius Stedim are used. The Standard Thermoweldable TPE tubing provided can be used in conjunction with the BioWelder and BioSealer to make sterile connections and disconnections. The bags come gamma irradiated to ensure they are sterile for immediate use and can be purchased with an optional side bottom drain port. The 500 L sized bags are purchased in cases of 2 for \$960.84.

#### 6.2.15 Media Holding Bags (P-11/V-102)

The Flexel 3D Bioprocessing Bags for Drum manufactured by Sartorius Stedim are used. The Standard Thermoweldable TPE tubing provided can be used in conjunction with the BioWelder and BioSealer to make sterile connections and disconnections. The bags come gamma irradiated to ensure they are sterile for immediate use and can be purchased with an optional side bottom drain port. The 500 L sized bags are purchased in cases of 2 for \$960.84.

### 6.2.16 Alternate Media Production (not pictured)

Per client request, a separate media can be used for the production bioreactor. This would require an additional 3000 L mixing tank and sterile filter. In addition, the client may choose to purchase pre-made liquid media or use their own formulated media for the process.

#### **6.3 Downstream Process**

#### 6.3.1 Disc-Stack Centrifuge (P-12/Disc Stack Cent)

After the harvest is removed from the final bioreactor, biomass solids are removed using a Disc-Stack Centrifuge. The Culturefuge 100 produced by Alfa-Laval is the model chosen for this step and has a purchase cost of \$750,000. It is constructed from 316 stainless steel with an electropolish finish, has a volume of  $12 \text{ m}^2$ , and a net weight of 1,400 kg. The centrifuge is fully hermetic, meaning there is no air inside the rotating centrifuge bowl. This ensures that particle breakage due to shear stress remains at an absolute minimum, making the Culturefuge 100 ideal for shear sensitive mammalian cells. It is fully automated and has clean-in-place and sterilize-in-place capabilities. The maximum bowl speed is 9,650 rpm and the motor requires 7.5 W. It operates at 25° C and can process the 2500 L batch in approximately 4 hours.

#### 6.3.2 Pump 1 (P-13/PUMP-1)

This pump is used to transfer the supernatant of the centrifugation process to the depth filter. A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.3 Sterile Filtration (P-14/DE-102)

The supernatant of the centrifugation process is pre-filtered with a 1.2  $\mu$ m depth filter followed in series by a 0.2  $\mu$ m sterile filter to remove bacteria and other contaminants. The purpose of the depth filter is to prevent the premature blockage of the .2  $\mu$ m filter cartridges. For the depth filters, Sartopure GF Plus MaxiCaps are purchased from Sartorius Stedim for \$617 each. The capsule consists of a glass fiber filter in a polypropylene housing. Each 30" capsule has a filtration area of 1.8 m<sup>2</sup> and about 4 capsules are needed to filter a batch of this size. They are operated at 25°C with a maximum differential pressure of 4 bar. The pressure is adjusted to obtain a flow through of about 151 L/h. The entire capsule is disposable and must be replaced after every batch.

For the sterile filters, the Sartopore 2 XLG filter cartridges were selected. Each 30" filter cartridge has a filtration area of 2.4 m<sup>2</sup> and can be purchased from Sartorius Stedim for \$1,279 each. The cartridge contains a 0.8  $\mu$ m pre-filter membrane followed by a 0.2  $\mu$ m final filter membrane, both made of polyethersulfone (PES). This pore size combination improves the total throughput and the flow rate performance of the filter, ensuring highest process efficiency and minimized costs. The system operates at 25° C with a maximum differential pressure of 5 bar. Five cartridges are needed to filter a batch of this size. Each filter cartridge requires stainless steel housing for support, which can be purchased from Sartorius Stedim for \$6,000 each and is reusable. The filter cassettes are disposable and are replaced after every batch.

#### 6.3.4 Storage Tank (P-15/V-104)

The storage tank holds the product stream from sterile filtration (P-14/DE-102) until it is ready to be loaded onto the protein A chromatography column. The tank is constructed of 316L stainless steel with an electro-polish finish and holds up to 3,500 L. It can be purchased from DCI inc. for \$48,000. The tank is maintained at about 25° C and is sterilized after every batch using CIP and SIP procedures.

#### 6.3.5 Pump 2 (P-16/PUMP-2)

This pump is used to load the product stream onto the protein A chromatography column. A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.6 Protein A Chromatography (P-17/Protein A Chrom)

The Protein A affinity chromatography column is used for direct capture and purification of the MAb given its high specific binding between the Fc-region and the antibody itself. The column used is the Chromaflow Column, model 1000/100-300, produced by GE Life Sciences, as it is available in a variety of bed volumes varying in both bed height and diameter. The bed has very high longevity and chemical resistance to both pH and salt concentrations. The major components included are the column tube (316L stainless steel), column lids (316L stainless steel), distributor (polypropylene), bed support (316L stainless steel), patented nozzle (316L stainless steel), seals (FEP encapsulated silicone) and a stand (316L stainless steel). The column packing, nProtein A Sepharose 4 Fast Flow resin, is also a product of GE Life Sciences. The estimated resin binding capacity is of 50 g/L and working capacity of 300 cm/h and is operated at 25° C and 1 bar. The column is between 78.5 L and 235.5 L, thus satisfying the 96.2 L required as calculated by SuperPro Designer. The cost of the column is \$120,000 and the resin is \$93,014 per 10 liters.

#### 6.3.7 Storage Tank (P-19/V-105)

The storage tank holds the waste stream from the protein A chromatography column so that the monoclonal antibody will not be lost if the column malfunctions. The tank is constructed of 316L stainless steel with an electro-polish finish and holds up to 15,000 L. It is operated at about 25° C and sterilized after every batch using CIP and SIP procedures. The tank is manufactured by DCI inc and can be purchased for a cost of \$90,000.

#### 6.3.8 Pump 3 (P-18/PUMP-3)

This pump is used to transfer the protein A chromatography product stream from the storage tank (P-19/V-105) to the sterile filter (P-20/DE-103). A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$ 2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump

operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.9 Sterile Filtration (P-20/DE-103)

A .2  $\mu$ m sterile filter is used to remove bacteria and other contaminants from the product stream. The Sartopore 2 membrane filter MaxiCaps, purchased from Sartorius Stedim for \$1,357 each, are used. The capsule consists of a polyethersulfon (PES) membrane in a polypropylene housing. Each 30" MaxiCap has a filtration area of 1.8 m<sup>2</sup>. The system is operated at 25° C with a maximum differential pressure of 4 bar. The entire capsule is disposable and must be replaced after every batch.

#### **6.3.10 Diafiltration (P-21/Diafilter 1)**

Diafiltration is used to concentrate the product by a factor of 5. An automated diafiltration system, the SartoFlow 10/20 Auto Crossflow System, is purchased from Sartorius Stedim for \$25,965. The system is made of 316 stainless steel and electro-polished. All wetted surfaces have an electro-polished finish  $\leq 20\mu$  inch Ra. The system is designed to meet cGMP operating environments and has a clean-in-place protocol specified by the manufacturer.

The Hydrostart Ultrafilter Cassettes are used with the automated system. The Hydrostart cassette is a cellulose based membrane with a molecular weight cut-off of 30 kDa. Each Sartocube cassette has a filtration area of 3 m<sup>2</sup>. They can be used in combination with two Sartocon Cassettes, with a filter area of .6 m<sup>2</sup> each, to meet the required filtration area of 3.8 m<sup>2</sup>. The diafiltration process is operated at 25° C and a feed pressure of 2.74 bar. The Hydrostart Membrane shows minimal protein adsorption, resulting in high product yields. The cassette is disinfected with 1M NaOH at 40° C for 30 min after each bactch and re-used. Each Sartocube Cassette can be purchased from Sartorius Stedim for \$8,768 and each Sartocon cassette costs \$2,406. For stability, a stainless steel housing is needed to hold the cassettes in place. This requires a one-time purchase of \$10,000.

#### 6.3.11 Virus Inactivation (P-22/V-106)

This jacketed blending tank is used to mix the product stream with Polysorbate 80, which will inactivate any virus particles in the stream. The tank is constructed of 316L stainless steel with an electro-polish finish and holds a volume of up to 200 L. This tank is manufactured by DCI inc. and can be purchased for a cost of \$33,000. It is operated at about 25° C and if sterilized via CIP and SIP procedures after every batch.

#### 6.3.12 Pump 4 (P-23/PUMP-4)

This pump is used to transfer the product stream from the virus inactivation tank to the sterile filter (P-24/DE-104). A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$ 2,874. With the Masterflex I/P 26 Precision Pump Tubing (\$149 for a 25 ft. roll), flow rates under 0.4 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.13 Sterile Filtration (P-24/DE-104)

A .2  $\mu$ m sterile filter is used to remove bacteria and other contaminants from the product stream. The Sartopore 2 membrane filter MaxiCaps, purchased from Sartorius Stedim for \$452 each, are used. The capsule consists of a polyethersulfon (PES) membrane in a polypropylene housing. Each 10" MaxiCap has a filtration area of 0.6 m<sup>2</sup>. The system is operated at 25° C with a maximum differential pressure of 4 bar. The entire capsule is disposable and must be replaced after every batch.

#### 6.3.14 Holding Tank (P-25/V-107)

This storage tank is used to hold the product stream from sterile filtration (P-24/DE-104) until it is ready to be fed onto the cation exchange chromatography column. The tank is manufactured by DCI inc. and can be purchased for a cost of \$28,000. It is constructed with 316L stainless steel with an electro-polish finish and can hold up to 200 L. It is operated around 25° C and is sterilized after every batch with CIP and SIP procedures.

#### 6.3.15 Pump 5 (P-26/PUMP-5)

This pump is used to load product stream onto the cation exchange chromatography column. A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$ 2,874. With the Masterflex I/P 26 Precision Pump Tubing (\$149 for a 25 ft. roll), flow rates under 0.4 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.16 Cation Exchange Chromatography (P-27/CatEX Chrom)

The cation exchange chromatography column is mainly used for its effectiveness in reducing the leached protein A as it distinguishes the IgG and IgG-Protein A complexes based on the charge differentiation. The column used is once again the Chromaflow Column, model 1000/100-300, produced by GE Life Sciences as it is available in a variety of bed volumes varying in both bed height and diameter. The bed has very high longevity and chemical resistance to both pH and salt concentrations. The major components included are the column tube (316L stainless steel), column lids (316L stainless steel), distributor (polypropylene), bed support (316L stainless steel), patented nozzle (316L stainless steel), seals (FEP encapsulated silicone) and a stand (316L stainless steel). The column packing, SP Fast Flow Sepharose resin, is also a product of GE Life Sciences. The estimated resin binding capacity is of 30 g/L and working capacity of 300 cm/h and is operated at 25° C and 1 bar. The column and the packing can be washed using standard CIP procedures. The volume capacity of the column is between 78.5 L and 235.5 L, thus satisfying the 144.2 L required as calculated by SuperPro Designer. The cost of the column is \$120,000 and the resin is \$4,288 per 5 liters.

#### 6.3.17 Blending Tank (P-28/V-108)

This jacketed blending tank is used to mix the product stream from the cation exchange chromatography column with buffer solutions prior to loading the anion exchange chromatography column. The tank is manufactured by DCI inc. and can be purchased for a cost of \$50,000. It is constructed of 316L stainless steel with an electro-polish finish and can hold up to 1000 L. The tank is operated at 25° C and is sterilized after every batch with CIP and SIP procedures.

#### 6.3.18 Pump 6 (P-29/PUMP-6)

This pump is used to load the product stream onto the anion exchange chromatography column. A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.19 Anion Exchange Chromatography (P-30/AnIEX Chrom)

The anion exchange chromatography column is the last chromatography step due to its ability to scavenge endotoxins that may have entered the process through contaminated manufacturing materials. It effectively reduces neuclotides, viruses, and leached protein A. The column used is once again the Chromaflow Column, model 400/100-300, produced by GE Life Sciences as it is available in a variety of bed volumes varying in both bed height and diameter. The bed has very high longevity and chemical resistance to both pH and salt concentrations. The major components included are the column tube (316L stainless steel), column lids (316L stainless steel), distributor (polypropylene), bed support (316L stainless steel), patented nozzle (316L stainless steel), seals (FEP encapsulated silicone) and a stand (316L stainless steel). The column packing, Q Fast Flow Sepharose resin, is also a product of GE Life Sciences. The estimated resin binding capacity is of 25 g/L and working capacity of 300 cm/h and is operated at 25° C and 1 bar. The column and the packing can be washed using standard CIP procedures. The volume capacity of the column is between 12.6 L and 37.8 L, thus satisfying the 16.44 L required as calculated by SuperPro Designer. The cost of the column is \$82,000 and the resin is \$8,565 per 10 liters.

#### 6.3.20 Storage Tank (P-31/V-109)

This storage tank is used to hold the product stream from anion exchange chromatography before it is transferred to sterile filtration (P-33/DE-105). The tank, which is manufactured by DCI inc., is constructed of 316L stainless steel with an electro-polish finish and holds up to 1000 L. It is operated around 25° C and is sterilized after every batch with CIP and SIP procedures. The tank was purchased for a cost of \$40,000.

#### 6.3.21 Pump 7 (P-32/PUMP-7)

This pump is used to transfer the product stream from the storage tank (P-31/V-109) to the sterile filter (P-33/DE-105). A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$ 2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.22 Sterile Filtration (P-33/DE-105)

A .2  $\mu$ m sterile filter is used to remove bacteria and other contaminants from the product stream. The Sartopore 2 membrane filter MaxiCaps, purchased from Sartorius Stedim for \$1,357 each, are used. The capsule consists of a polyethersulfon (PES) membrane in a polypropylene housing. Each 30" MaxiCap has a filtration area of 1.8 m<sup>2</sup>. The system is operated at 25°C with a maximum differential pressure of 4 bar. The entire capsule is disposable and must be replaced after every batch.

### 6.3.23 Storage Tank (P-34/V-110)

This storage tank is used to hold the product stream from sterile filtration (P-33/DE-105) until it is transferred to the diafiltration unit (P-36/Diafilter 2). The tank is manufactured by DCI inc. and is purchased for a cost of \$40,000. It is constructed of 316L stainless steel with an electro-polish finish and holds up to 1000 L. The tank is operated around 25° C and sterilized after every batch with CIP and SIP procedures.

#### 6.3.24 Pump 8 (P-35/PUMP-8)

This pump is used to transfer the product stream to the diafiltration unit (P-36/Diafilter 2). A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### **6.3.25 Diafiltration (P-36/Diafilter 2)**

Diafiltration is used to concentrate the product by a factor of 5. An automated diafiltration system, the SartoFlow 10/20 Auto Crossflow System, is purchased from Sartorius Stedim for \$25,965. The system is made of 316 stainless steel and electro-polished. All wetted surfaces have an electro-polished finish  $\leq 20\mu$  inch Ra. The system is designed to meet cGMP operating environments and is easy to clean-in-place.

The Sartocube Hydrostart Ultrafilter Cassette used with the automated system. The Hydrostart cassette is a cellulose based membrane with a molecular weight cut-off of 30 kDa. Three cassettes, with a filtration area of 3 m<sup>2</sup> each, are used to provide the required 8.18 m<sup>2</sup> filtration area. The diafiltration process is operated at 25° C and a feed pressure of 1.686 bar. The Hydrostart Membrane shows minimal protein adsorption, resulting in high product yields. The cassette is disinfected with 1M NaOH at 40°C for 30 min after each bactch and re-used. Each Sartocube Cassette can be purchased from Sartorius Stedim for \$8,768 and requires a stainless steel housing, which can be purchased for an additional \$10,000.

#### 6.3.26 Storage Tank (P-37/V-111)

This storage tank is used to hold the concentrated product stream from the diafiltration unit (P-36/Diafilter 2) until it is transferred to the retrovirus filtration unit (P-39/DE-106). The tank is manufactured by DCI inc. and is purchased for a cost of \$24,000. It is constructed of

316L stainless steel with an electro-polish finish and holds up to 150 L. The tank is operated around 25° C and is sterilized after every batch with CIP and SIP procedures.

#### 6.3.27 Pump 9 (P-38/PUMP-9)

This pump is used to transfer the product stream from the storage tank (P-37/V-111) to the retrovirus filtration unit (P-39/DE-106). A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.28 Sterile Filtration (P-39/DE-106)

A .2  $\mu$ m sterile filter is used to remove bacteria and other contaminants from the product stream. The Sartopore 2 membrane filter MaxiCaps, purchased from Sartorius Stedim for \$452 each, are used. The capsule consists of a polyethersulfon (PES) membrane in a polypropylene housing. Each 10" MaxiCap has a filtration area of .6 m<sup>2</sup>. The system is operated at 25° C with a maximum differential pressure of 4 bar. The entire capsule is disposable and must be replaced after every batch.

#### 6.3.29 Parvovirus Filtration (P-40/DE-107)

Normal flow parvovirus (NFP) membranes are used to remove parvoviruses from the product stream by means of size exclusion while allowing proteins to pass through. The 10" Viresolve NFP cartridge filter, manufactured by Millipore, has a filtration area of .42 m<sup>2</sup>. The membrane is made out of modified PVDF and has a maximum operating pressure of 5.5 bar at 25° C. It has a pore size of 28 nm and allows proteins up to 160 Kda to pass through. Each cartridge can be purchased for \$4,201 and requires a one-time purchase of \$1,423 for the Series 3000 code 7 single-round T-line stainless steel housing. The cartridge will be replaced after each batch.

#### 6.3.30 Pump 10 (P-41/PUMP-10)

This pump is used to transfer the final product stream into a sterile disposable container. A low powered (0.2 hp) peristaltic pump is sufficient for this task. The I/P Modular Digital Dispensing Pump with Benchtop Controller can be purchased from Cole-Palmer for \$2,874. With the Masterflex I/P 82 Precision Pump Tubing (\$196 for a 25 ft. roll), flow rates up to 13 LPM can be achieved. The pump operates at room temperature with a pressure drop of 25 psi. The pump is sterilized via CIP and SIP after every batch.

#### 6.3.31 Disposable Container (P-42/Packaging)

After the final purification step, the final product stream is collected into a disposable container skid. The Flexel 3D Bioprocessing Bags for Drum manufactured by Sartorius Stedim are used. The Standard Thermoweldable TPE tubing provided can be used in conjunction with the BioWelder and BioSealer to make sterile connections and disconnections. The bags come gamma irradiated to ensure they are sterile for immediate use and can be purchased with an optional side bottom drain port. The 100 L sized bags are purchased in cases of 5 for \$1,731.96.

#### 7.0 Additional Equipment

#### 7.1 ViCell

The ViCell XR purchased from Beckman Coulter for \$48,500 is used to measure the total or viable cell concentration, the viability, and the mean cell size of cell culture for cells within the range of 2-70 µm. The ViCell provides automation of the standard trypan blue assay. A 12-position sample carrousel allows for improved sample throughput and automation. In addition, Beckman Coulter complies with current Good Manufacturing Practices and provides all the necessary documents for instrument validation.

#### 7.2 Incubated Orbital Shaker

For the passaging of cells, the shake flasks must remain within a narrow temperature range for the CHO cells to survive and proliferate. The I 26 Incubated Shaker, purchased from New Brunswick Scientific for \$11,195 each, is used to control the temperature of the shake flasks. Up to three shakers can be stacked for space saving using stacking kits. To accommodate the needs of the cell selection lab, three shakers are used. Two will have platforms for 125 ml flasks and the third will have a universal platform.

#### 7.3 Refrigerated Centrifuge

A refrigerated centrifuge is needed to spin cell culture samples in eppendorf filter tubes so the supernatant can be sent to the analytical department. The Sorvall Legend RT Plus Centrifuge was purchased from Thermo Scientific for \$8,938. The centrifuge is refrigerated with a maximum rpm of 15,000. A 24-Place Fixed-Angle Aluminum Rotor with Cover is purchased separately for \$1,379.22 and holds 24 1.5-5 ml tubes and additional rotors may be purchased.

#### 7.4 Biosafety Cabinet

A Biosafety Cabinet is needed to provide a sterile environment for the aeseptic transfer of cell culture to shake flasks and bioreactors. The Hamilton SafeAire II Constant-Volume/Bypass Fume Hoods is a class II biosafety cabinet purchased from Thermo Scientific for \$10,183.

#### 7.5 Blood Gas Analyzer (BGA)

A blood gas analyzer is used to analyze the content of the cell culture. The Rapidlab 1260 System, purchased from Siemens for \$33,170, is capable of measuring the pH, the dissolved oxygen and carbon dioxide levels, electrolyte levels, and metabolites such as glucose and lactate. This information is used to monitor the metabolic state of the culture and determine when to feed the cells. The Rapidlab 1240 system only requires a sample volume of 90  $\mu$ l and results are obtained within 60 seconds.

#### 7.6 Refrigeration

A liquid nitrogen freezer is needed to store cell banks. Since the temperature at which cells are frozen affects their viability after recovery, storing cell banks at a lower temperature will lengthen their viable storage period. The Thermo Scientific CryoPlus Storage System uses microprocessor technology and has 16 audible and visual alarms to ensure product protection. It has a 200 L capacity and can hold 13,000 2 ml vials with 10 square or 26 vertical racks.

When freezing down cells, the water present in the cell freezes and cellular metabolism can no longer take place. However, dehydration can also occur increasing the concentration of salts and metabolites in the cell. Dehydration and ice crystal formation during freezing can result in low cell recovery. These detrimental effects can be minimized by controlled rate freezing. The CryoMed Controlled-Rate Freezer, purchased from Thermo Scientific for \$17,862, is capable of precise freezing from -180° to +50°C for maximum accuracy of cell freezing and has a 1.7 cu. ft. capacity. There are 6 preset freezing profiles and 10 user-defined freezing profiles of 20 steps each. 120V 60Hz

A -20° C freezer will be used to store some reagents, samples, and analytical kits. The Fisher Scientific Isotemp Plus Lab Freezer is purchased from Thermo Scientific for \$11,062.50. Using microprocessor temperature control, it has a temperature range of -30° to -12° C with a  $\pm$ 3° C stability. It has a capacity of 46.6 cu.ft. and a recorder/alarm.

Harvests from the production bioreactor and experiments on the 3L scale need to be stored at -80°C. The Fisher Scientific Isotemp Ultrafreeze Upright Model Freezer is designed for the secure storage of biological products. It has a temperature range of -86° to -50° C and a capacity of 13.4 cu. ft.. The advanced microprocessor control and the alarm monitoring system ensure the precise temperature control.

Finally, a lab refrigerator will be used to store media and other reagents. The Fisher Scientific Lab Refrigerator with microprocessor temperature control and a temperature recorder/alarm was purchased from Thermo Scientific for \$10,236.52. It has 3 glass hinged doors, a 72 cu.ft. capacity, and a temperature range of 1° to 12°C.

#### 7.7 Neutralization Waste Tanks

During production, all liquid waste streams generated by the process must be neutralized to a pH of 7.0 before is can be disposed in the sewage system. Non-hazardous waste is sent directly to the non-biohazardous waste tank. The 15,000 L, 316 stainless steel tank can be purchased from Sharpsville Containers for \$90,000. From the holding tank, the waste is fed into a continuous neutralization system. The Totaltreat Continuous Neutralization System, manufactured by Siemens, has a three step neutralization process designed to accommodate the most extreme pH adjustments. The system is constructed of polypropylene to give superior corrosion resistance. The NS-50-3 model is permits a flow rate of up to 50 gpm and can be purchased for \$70,000.

#### 7.8 Pharmaceutical Sterilizer

Biohazardous waste is waste that requires biological inactivation prior to disposal. Disposable pieces of equipment that come into contact with mammalian cells will be sterilized in a depyrogenation oven in autoclavable waste containers prior to disposal. The S-Series Class 100 Pharmaceutical Sterilizer (model SC55H31.4SS) is purchased from Gruenberg for \$130,000. The S-Series Sterilizers are installed with HEPA filters to ensure a class 100 area throughout the interior chamber and are cGMP compliant. The sterilizer has a 304L stainless steel exterior and a 316L stainless steel interior chamber with dimensions of 32"Wx34"Dx50"H. The oven can reach temperatures up to 260°C.

#### 7.9 USP Water System

USP grade water is produced from tap water using a water treatment package. The water treatment package from Siemens has a total cost of \$132,210.98 for all equipment, shipping, and installation costs. The package includes an activated carbon filter, a duplex water softener, ultraviolet254nm lights, a reverse osmosis system, and a continuous deionization system.

#### 7.10 Multiple-Effect Stills for WFI

Pyrogen-free WFI is produced from USP grade water in a multiple-effect still. A multiple-effect still with a 150 gallon per hour capacity (model 6015-3) can be purchased from Paul Mueller Company for \$150,000.

#### 7.11 WFI Storage and Distribution System

The WFI Storage and distribution system is needed to keep the WFI sterile and pump it to various equipment units when needed. The system sterilizes the WFI by maintaining it at 80°C while continuously circulating it. The storage and distribution system from Paul Mueller Company has a purchase cost of \$200,000.

#### 7.12 Pure Steam Generator

Pyrogen-free steam is produced in a pure steam generate manufactured by Paul Mueller Company. The pure steam generator mode 7145 has a purchase cost of \$125,000.

#### 7.13 CIP Skid

A portable clean-in-place system is needed in the sterilization of equipment units. A two tank single pump CIP system is purchased from Sani-Matic for \$108,050. The system is constructed of 304L stainless steel and has a 300 gallon solution tank and a 300 gallon rinse tank. A multi-tank system was chosen because it permits the reuse of wash solution and rinse water, therefore reducing both the cycle time and water/waste water costs.

### 7.14 Oil-less Screw-Tight Compressors

Oil-less screw tight compressors are needed to produce clean air to sparge into the bioreactors. The oil-free rotary screw compressor produces ISO 8573-1 class 0 air (meaning there is no trace of oil in the outlet air flow) and can be purchased from Atlas Copco for \$57,500.

### 7.15 Integrity Filter Testing

The integrity of every filter must be checked before use to ensure the filter cartridge is not defective. The sartocheck 4 MultiUnit is used to check the integrity of any sterilizing grade filter. The unit can be purchased from Sartorius Stedim for \$25,000. For the virus filters, an airwater diffusion based integrity test has been developed and can be run in 15 minutes.

## 8.0 Unit Specification Sheets

## 8.1 Cell Screening and Selection

Shake Flasks

Function:	Non-treated, sterile flasks for the suspension and growth of cell cultures	
Vendor:	Corning	
Operation:	Batch	
Materials Handled:	<u>Input</u> Amino Acids Glucose Inorganic Salts Vitamins Other media components WFI	<u>Quantity (kg/ml)</u> 0.614 1.8 8.057 0.12 0.036 1000
Characteristics:	Model: Material of Construction: Cap: Vessel Type: Total Volume: Suggested Working Volume: Additional Features:	Disposable Erlenmeyer Flask Polycarbonate Vented Erlenmeyer 125ml, 250 ml, 500 ml, 1L, 2L 40% of the total volume disposable
Operating Conditions:	Temp: Pressure: Agitation: Duration:	37°C 1 bar 75-125 rpm 4 days
Purchase Cost:	125 ml flask 250 ml flask 500 ml flask 1L flask 2L flask	\$823.91 case of 50 \$908.32 case of 50 \$687.69 case of 25 \$1,011.11 case of 25 \$188.81 case of 6

### Micro-bioreactor

Function:	cassettes provide 24 simultaneo independent control of gas supp	A cell culture system using a pre-sterilized disposable cassette. The cassettes provide 24 simultaneous 10 ml experiments each with independent control of gas supply, temperature, and pH. The system is used to run designs of experiment.		
Vendor:	Applikon	Applikon		
Maufacturer:	Pall Corporation			
Operation:	Batch			
Materials Handled:	<u>Input</u> Amino Acids Glucose Inorganic Salts Vitamins Other media components WFI Total	<u>Quantity (kg/ml)</u> 0.614 1.8 8.057 0.12 0.036 1000		
Characteristics:	Model: Material of Construction: Cap: Flask Type: Reactor Volume: Suggested Working Volume: # reactors per cassette: Additional Features:	Micro-24 Polycarbonate cassettes Vented Erlenmeyer 10 ml 5 ml 24 disposable		
Operating Conditions:	Temp: Pressure: pH pO2 Agitation Duration:	varied based on process 1 bar varied based on process 30-40% 500-800 rpm <21 days		
Purchase Cost:	Micro-24 Installation/Training disposable cassettes	\$94,600 \$5,500 \$300.00		

### 3L Bioreactor

Function:	A pre-sterilized, disposable 3L bioreactor system equipt with PID control of temperature, pH, and dissolved oxygen as well as control of agitation and anti-foam. The bioreactor has two built in leur lock side sampling ports.		
Vendor:	Applikon and Millipore		
Operation:	Batch		
Materials Handled:	<u>Input</u> Amino Acids Glucose Inorganic Salts Vitamins Other media components WFI Total	<u>Quantity (kg/ml)</u> 0.614 1.8 8.057 0.12 0.036 1000	
Characteristics:	Model: Material of Construction: Reactor Volume: Maximum Working Volume: Additional Features:	Mobius CellReady 3L Platform polycarbonate, high-density polyethylene, silicon, and nitrile 3L 2.4L disposable	
Operating Conditions:	Temp: Pressure: pH: pO2: Impeller speed: Duration:	variable 1 bar variable 30-40% 75-125 rpm < 21 days	
Purchase Cost:	Mobius CellReady Bioreactor: ez-Control: installation and training:	\$695.00 case of 2 \$26,063 \$1,080	

## 8.2 Upstream Section

## T-Flask (P-1/TFR-101)

Function:	Non-treated, sterile flask for the growth of cell cultures.	
Vendor:	Corning	
Operation:	Batch	
Materials Handled:	<u>Input</u> Amino Acids Biomass Glucose Inorganic Salts WFI Total	<u>Quantity (kg/batch)</u> 0.00002 0.00003 0.00007 0.0003 0.0195 0.01992
Characteristics:	Model: Material of Construction: Cap: Vessel Type: Total Volume: Suggested Working Volume: Additional Features:	75 cm <sup>2</sup> t-flask Polypropylene Vented T-flask 60 mL 15-22.5 mL disposable
Operating Conditions:	Temp: Pressure: Agitation: Dissolved $O_{2:}$ Duration:	37°C 1 bar none 30% 5 days

Purchase Cost: \$90.20 for case of 20

### 250 mL Shake Flask (P-2/SFR-101)

Function:	Non-treated, sterile flask for the growth of cell cultures.	
Vendor:	Corning	
Operation:	Batch	
	Input	Quantity (kg/batch)
	Amino Acids	0.00016
	Biomass	0.00015
	Dead Biomass	0.00002
	Glucose	0.00048
Materials Handled:	Inorganic Salts	0.00215
	Other Media	0.00003
	Vitamins	0.00001
	WFI	0.14626
	Total	0.14926
	Model:	Disposable Erlenmeyer Flask
	Material of Construction:	Polycarbonate
	Cap:	Vented
Characteristics:	Vessel Type:	Shake Flask
	Total Volume:	250 mL
	Working Volume:	50 mL
	Additional Features:	disposable
	Temp:	37°C
<b>Operating Conditions:</b>	Pressure:	1 bar
	Agitation:	75-125 rpm
	Duration:	5 days

Purchase Cost: \$908.32 for case of 50

### 1 L Shake Flask (P-3/SFR-102)

Function:	Non-treated, sterile flask for the growth of cell cultures.		
Vendor:	Corning		
Operation:	Batch		
<u>Materials Handled:</u>	Input Amino Acids Biomass Dead Biomass Glucose Inorganic Salts Mab Other Media Vitamins WFI Total	Quantity (kg/batch) 0.0013 0.00124 0.00015 0.00381 0.01707 0.00001 0.000025 0.00008 1.17034 1.19425	
Characteristics:	Model: Material of Construction: Cap: Vessel Type: Total Volume: Suggested Working Volume: Additional Features:	Disposable Erlenmeyer Flask Polycarbonate Vented Shake Flask 1 L 300 mL disposable	
Operating Conditions:	Temp: Pressure: Agitation: Duration:	37°C 1 bar 75-125 rpm 6 days	

Purchase Cost: \$1011.11 for case of 25

### Wave Bioreactor 1 (P-4/BBS-101)

Function:	Disposable bag bioreactor	
Vendor:	GE Healthcare	
Operation:	Batch	
	<u>Input</u>	Quantity (kg/batch)
	Amino Acids	0.01081
	Biomass	0.01031
	Dead Biomass	0.0013
	Glucose	0.03174
Materials Handled:	Inorganic Salts	0.1419
	Mab	0.00012
	Other Media	0.00206
	Vitamins	0.00063
	WFI	9.74336
	Total	9.94223
	Model:	Wave 20/50EHT
	Vessel Type:	Disposable bag
Characteristics:	Total Volume:	50 L
	Suggested Working Volume:	0.1-25 L
	Additional Features:	disposable
	Temp:	37°C
	Pressure:	1 bar
<b>Operating Conditions:</b>	Agitation:	Rocking platform
	Dissolved $O_{2}$	30-40%
	Duration:	5 days
	pH	7.0

Purchase Cost:

\$21,903 \$197 per bag

# Wave Bioreactor 2 (P-5/BBS-102)

Function:	Disposable bag bioreactor	
Vendor:	GE Healthcare	
Operation:	Batch	
	<u>Input</u>	Quantity (kg/batch)
	Amino Acids	0.03763
	Biomass	0.772
	Dead Biomass	0.00988
	Glucose	0.11042
Materials Handled:	Inorganic Salts	0.49368
	Mab	0.00088
	Other Media	0.00717
	Vitamins	0.00218
	WFI	73.8729
	Total	75.30674
	Model:	Wave 200EH
	Vessel Type:	Disposable bag
Characteristics:	Total Volume:	200
	Suggested Working Volume:	10-100 L
	Additional Features:	disposable
	Temp:	37°C
	Pressure:	1 bar
<b>Operating Conditions:</b>	Agitation:	Rocking platform
-	Dissolved $O_{2i}$	30-40%
	Duration:	4 days
	pН	7.0
	-	

Purchase Cost:

\$201,050 \$513 per bag

#### Wave Bioreactor 3 (P-6/BBS-103)

Function:	Disposable bag bioreactor	
Vendor:	GE Healthcare	
Operation:	Batch	
	<u>Input</u>	Quantity (kg/batch)
	Amino Acids	0.21283
	Biomass	0.51536
	Dead Biomass	0.06714
	Glucose	0.62452
Materials Handled:	Inorganic Salts	2.79223
	Mab	0.00588
	Other Media	0.04059
	Vitamins	0.01236
	WFI	493.182
	Total	497.45291
	Model:	Wave 500/1000EH
	Vessel Type:	Disposable bag
Characteristics:	Total Volume:	1000 L
	Suggested Working Volume:	100-500 L
	Additional Features:	disposable
	Temp:	37°C
	Pressure:	1 bar
<b>Operating</b> Conditions:	Agitation:	Rocking platform
	Dissolved O <sub>2:</sub>	30-40%
	Duration:	4 days
	pН	7.0

Purchase Cost:

\$395,740 \$1080 per bag

## Production Bioreactor (P-7/BR-101)

Function:	Disposable 2500 L bioreactor	
Vendor:	Xcellerex	
Operation:	Batch	
	<u>Input</u>	Quantity (kg/batch)
	Amino Acids	0.21283
	Biomass	0.51536
	Dead Biomass	0.06714
	Glucose	0.62452
Materials Handled:	Inorganic Salts	2.79223
	Mab	0.00588
	Other Media	0.04059
	Vitamins	0.01236
	WFI	493.182
	Total	497.45291
	Model:	Custom XDR 2500
	Vessel Type:	Disposable bag
Characteristics:	Total Volume:	3500 L
	Suggested Working Volume:	500-2500 L
	Additional Features:	disposable
	Temp:	37°C
	Pressure:	1 bar
<b>Operating</b> Conditions:	Agitation:	Bottom-mount impeller
	Dissolved O <sub>2:</sub>	30-40%
	Duration:	9 days
	рН	7.0

Purchase Cost:

\$610,000 \$1500 per bag

Function:	To transfer culture between 300 mL shake flask and Wave bioreactor 1	
Vendor:	Cole-Palmer	
Operation:	Batch	
	Input	Quantity (kg/ml)
	Amino Acids	0.01081
	Biomass	0.01031
	Dead Biomass	0.0013
	Glucose	0.03174
Materials Handled:	Inorganic Salts	0.1419
	Mab	0.00012
	Other Media	0.00206
	Vitamins	0.00063
	WFI	9.74336
	Total	9.94223
	Model:	I/P Modular Digital Dispensing
	Duran Trans	Pump Peristaltic
Characteristics	Pump Type: Flow Rate:	604 L/h
Characteristics:	Power:	.15 kW
	Sterilization:	SIP/CIP
	Temp:	25°C
	Power:	.041 kW
Operating Conditions:	Pressure Change	25 psi
Purchase Cost:	Pump: Masterflex I/P 82 tubing (25 ft. roll)	\$2,874 ): \$196

Function:	To transfer culture between Wave bioreactors 1 and 2	
Vendor:	Cole-Palmer	
Operation:	Batch	
	<u>Input</u>	Quantity (kg/ml)
	Amino Acids	0.03763
	Biomass	0.772
	Dead Biomass	0.00988
	Glucose	0.11042
Materials Handled:	Inorganic Salts	0.49368
	Mab	0.00088
	Other Media	0.00717
	Vitamins	0.00218
	WFI	73.8729
	Total	75.30674
	Model:	I/P Modular Digital Dispensing Pump
	Pump Type:	Peristaltic
Characteristics:	Flow Rate:	604 L/h
Characteristics.	Power:	.15 kW
	Sterilization:	SIP/CIP
	Stermzation.	Sir/Cir
	Temp:	25°C
	Power:	.041 kW
Operating Conditions:	Pressure Change	25 psi
Durchase Cost	Duran	¢2 974
Purchase Cost:	Pump:	\$2,874
	Masterflex I/P 82 tubing (25 ft. roll	): \$196

Function:	To transfer culture between Wave bioreactors 2 and 3	
Vendor:	Cole-Palmer	
Operation:	Batch	
	Input	Quantity (kg/ml)
	Amino Acids	0.21283
	Biomass	0.51536
	Dead Biomass	0.06714
	Glucose	0.62452
	Inorganic Salts	2.79223
Materials Handled:	Mab	0.00588
	Other Media	0.04059
	Vitamins	0.01236
	WFI	493.182
	Total	497.45291
	Model:	I/P Modular Digital Dispensing Pump
	Pump Type:	Peristaltic
Characteristics:	Flow Rate:	604 L/h
	Power:	.15 kW
	Sterilization:	SIP/CIP
	Temp:	25°C
	Power:	.041 kW
Operating Conditions:	Pressure Change	25 psi
Durahasa Cost:	Duran	\$2.97 <i>4</i>
Purchase Cost:	Pump: Mastarflay I/D 82 tubing (25 ft. ro	\$2,874
	Masterflex I/P 82 tubing (25 ft. ro	ll): \$196

#### Media Prep Tank (P-9/V-101)

Function:	Stainless steel media preparation	n tank
Vendor:	Sharpsville Container	
Operation:	Batch	
Materials Handled:	Input Amino Acids Biomass Glucose Inorganic Salts	<u>Quantity (kg/batch)</u> 0.00002 0.00003 0.00007 0.0003
	WFI Total	0.0195 0.01992
	Material of Construction: Height	Stainless Steel 316 3 m
Characteristics:	Diameter Total Volume: Sterilization	1 m 3000 L CIP/SIP
Operating Conditions:	Temp: Pressure:	25°C 1 bar

Purchase Cost: \$120,000

Function:	To transfer media from the 3000 L tank	
Vendor:	Cole-Palmer	
Operation:	Batch	
	Input	Quantity (kg/ml)
	Amino Acids	1.31546
	Glucose	3.86015
Materials Handled:	Inorganic Salts	17.25867
	Other Media	0.2509
	Vitamins	0.07634
	WFI	2702.2834
	Total	2725.04492
	Model:	I/P Modular Digital Dispensing Pump
	Pump Type:	Peristaltic
Characteristics:	Flow Rate:	604 L/h
	Power:	.15 kW
	Sterilization:	SIP/CIP
	Temp:	25°C
	Power:	.041 kW
<b>Operating Conditions:</b>	Pressure Change	25 psi
	Dunna	¢0.974
Purchase Cost:	Pump: Masterflav I/D 82 tubing (25 ft. roll)	\$2,874
	Masterflex I/P 82 tubing (25 ft. roll)	: \$196

#### Sterile Filter (P-10/DE-101)

Function:	To remove bacteria and other co	ntaminants from the media stream
Vendor:	Sartorius Stedim	
Operation:	Batch	
	Input	Quantity (kg/ml)
	Amino Acids	1.31546
	Glucose	3.86015
Materials Handled:	Inorganic Salts	17.25867
	Other Media	0.2509
	Vitamins	0.07634
	WFI	2702.2834
	Total	2725.04492
	Model:	Sartopure GF Plus MaxiCaps
	Filter Type:	Depth Filter
	Cartridge Size:	30"
Characteristics:	Filter Size:	1.2 μm
	Filtration Area:	$1.8 \text{ m}^2$
	Membrane Material:	glass fiber
	Max. Differential Pressure:	4 bar at 20°C
	Other:	Disposable
Operating Conditions:	Temp:	25°C
Purchase Cost:	Sartopure GF Plus MaxiCaps:	\$617

#### 8.3 Downstream Process

Function:	Cells and biomass solids are r	removed from the bioreactor harvest.
Vendor:	Alfa-Laval	
Operation:	Continuous	
Materials Handled:	Input Amino Acids Glucose Inorganic Salts Vitamins Other media components WFI Total	<u>Quantity (kg/ml)</u> 0.614 1.8 8.057 0.12 0.036 1000
Characteristics:	Model: Centrifuge type: Material of Construction: Finish: Maximum bowl speed: Power: Sterilization:	Culturefuge 100 Hermetic 316 stainless steel electro-polish 9,650 rpm 7.5 W SIP/CIP
Operating Conditions:	Temp: Throughput:	25°C 625 L/h

## Disc-Stack Centrifuge (P-12/Disc Stack Cent)

Purchase Cost:

\$750,000

# Pump (P-13/PUMP-1)

Function:	To transfer fluid from the centrifugation unit (P-12/Disc Stack Cent) to the sterile filter (P-14/DE-102)	
Vendor:	Cole-Palmer	
Operation:	Batch	
	<u>Input</u>	<u>Quantity (kg/ml)</u>
	Amino Acids	0.07458
	Biomass	0.08511
Materials Handled:	Dead Biomass	0.2057
	Glucose	0.22135
	Inorganic Salts	0.98644
	Mab	4.90428
	Other media	0.01444
	Vitamins	0.00481
	WFI	2385.74029
	Total	2392.237
	Model:	I/P Modular Digital Dispensing Pump
	Pump Type:	Peristaltic
Characteristics:	Flow Rate:	604 L/h
	Power:	.15 kW
	Sterilization:	SIP/CIP
	Temp:	25°C
	Power:	.041 kW
Operating Conditions:	Pressure Change	25 psi
Purchase Cost:	Pump:	\$2,874
	Masterflex I/P 82 tubing (25 ft.	roll): \$196

# Depth Pre-Filter (P-14/DE-102)

Function:	To remove bacteria and other co and protect the downstream mer	ontaminants from the product stream nbranes
Vendor:	Sartorius Stedim	
Operation:	Batch	
Materials Handled:	<u>Input</u> Amino Acids Glucose Inorganic Salts Vitamins Other media components WFI Total	<u>Quantity (kg/ml)</u> 0.614 1.8 8.057 0.12 0.036 1000
Characteristics:	Model: Filter Type: Cartridge Size: Filter Size: Filtration Area: Membrane Material: Max. Differential Pressure: Other:	Sartopure GF Plus MaxiCaps Depth Filter 30" 1.2 µm 1.8 m <sup>2</sup> glass fiber 4 bar at 20°C Disposable
Operating Conditions:	Temp:	25°C
Purchase Cost:	Sartopure GF Plus MaxiCaps:	\$617

## Storage Tank (P-15/V-104)

Function:	_	To hold the product stream from sterile filtration in preparation for protein A chromatography	
Vendor:	DCI inc.		
Operation:	Batch		
	<u>Input</u>	Quantity (kg/ml)	
	Amino Acids	0.07457	
	Biomass	0.00001	
	Dead Biomass	0.00002	
	Glucose	0.22131	
Materials Handled:	Inorganic Salts	0.98628	
	Mab	4.80619	
	Other media	0.01443	
	Vitamins	0.00481	
	WFI	2385.35652	
	Total	2391.46414	
	Material of Construction:	stainless steel 316L	
Characteristics:	Total Volume:	3,500 L	
	Sterilization:	SIP/CIP	
Operating Conditions:	Temp:	25°C	
	Pressure:	1 bar	

Purchase Cost:

\$48,000

## Pump (P-13/PUMP-2)

Function:	To transfer fluid from the storage tank (P-15/V-104) to the protein A chromatography column (P-17/Protein A Chrom)	
Vendor:	Cole-Palmer	
Operation:	Batch	
	Input	Quantity (kg/ml)
	Amino Acids	0.07457
	Biomass	0.00001
Materials Handled:	Dead Biomass	0.00002
	Glucose	0.22131
	Inorganic Salts	0.98628
	Mab	4.80619
	Other media	0.01443
	Vitamins	0.00481
	WFI	2385.35652
	Total	2391.46414
	Model:	I/P Modular Digital Dispensing Pump
Characteristics:	Pump Type:	Peristaltic
	Flow Rate:	606 L/h
	Power:	.15 kW
	Sterilization:	SIP/CIP
	Temp:	25°C
<b>Operating Conditions:</b>	Power:	.041 kW
	Pressure Change	25 psi
Purchase Cost:	Pump:	\$2,874
	Masterflex I/P 82 tubing (25 ft. rol	ll): \$196

Function:	To purify the monoclonal antibody from the mainstream fluid		
Vendor:	GE Life Sciences	GE Life Sciences	
Operation:	Batch		
Materials Handled:	Input Amino Acids Biomass Citric Acid Dead Biomass Ethyl Alcohol Glucose Inorganic Salts Mab Other Media Tris Base Tris HCL Vitamins WFI Total	<u>Quantity (kg/ml)</u> 0.07457 0.00001 2.87478 0.00002 1307.37793 0.22131 0.98628 4.80619 0.01443 0.76658 2.3026 0.00481 8854.63 10174.05951	
Characteristics:	Column Model: Material of Construction: Inner Diameter: Tube Height: Max. Bed Volume: Max. Pressure: Column Media: Binding Capacity: Working Flow Velocity:	Chromaflow Column: 1000/100-300 acrylic .35 m .25 m 235.5 L 3 bar nProtein A Sepharose 4 Fast Flow 50 g/L 300 cm/h	
Operating Conditions:	Temp: Pressure:	25°C 1 bar	
Purchase Cost:	Chromaflow Column: 1000/100 nProtein A Sepharose 4 Fast Flo		

## Protein A Chromatography Column (P-17/Protein A Chrom)

## Storage Tank (P-19/V-105)

Function:	To hold the waste stream from protein A chromatography to capture product in case the column malfunction	
Vendor:	DCI inc.	
Operation:	Batch	
<u>Materials Handled:</u>	<u>Input</u> Amino Acids Biomass Dead Biomass Glucose Inorganic Salts Mab Other media Vitamins WFI Total	Quantity (kg/ml) 0.07457 0.00001 0.00002 0.22131 0.98628 4.80619 0.01443 0.00481 2385.35652 2391.46414
Characteristics:	Material of Construction: Total Volume: Sterilization:	stainless steel 316L 15000 L SIP/CIP
Operating Conditions:	Temp: Pressure:	25°C 1 bar

Purchase Cost:

\$90,000

#### Pump (P-18/PUMP-3)

Function:	To transfer fluid from the storage tank (P-19/V-105) to the diafiltration unit (P-21/Diafilter 1)	
Vendor:	Cole-Palmer	
Operation:	Batch	
Materials Handled:	<u>Input</u> Citric Acid MAb Tris HCL WFI Total	<u>Quantity (kg/ml)</u> 1.14991 4.32557 0.00115 190.50077 195.9774
Characteristics:	Model: Pump Type: Flow Rate: Power: Sterilization:	I/P Modular Digital Dispensing Pump Peristaltic 49.15 L/h .15 kW SIP/CIP
Operating Conditions:	Temp: Power: Pressure Change	25°C .003 kW 25 psi
Purchase Cost:	Pump: Masterflex I/P 82 tubing (25 ft. roll):	\$2,874 \$196

#### Sterile Filter (P-20/DE-103)

Function:	To remove bacteria and other contaminants from the product stream	
Vendor:	Sartorius Stedim	
Operation:	Batch	
Materials Handled:	<u>Input</u> Citric Acid MAb Tris HCL WFI Total	<u>Quantity (kg/ml)</u> 1.14991 4.32557 0.00115 190.50077 195.9774
Characteristics:	Model: Filter Type: Cartridge Size: Filter Size: Filtration Area: Membrane Material: Max. Differential Pressure: Other:	Sartopore 2 MaxiCaps Depth Filter 10" .2 µm .6 m <sup>2</sup> polyethersulfone (PES) 4 bar at 20°C Disposable
Operating Conditions:	Temp:	25°C
Purchase Cost:	Sartopore 2 MaxiCaps:	\$452

Function:	To concentrate the monoclonal antibody in the product stream by a factor of 5	
Vendor:	Sartorius Stedim	
Operation:	Batch	
Materials Handled:	<u>Input</u> Citric Acid MAb Tris HCL WFI Total	<u>Quantity (kg/ml)</u> 1.14991 4.32557 0.00115 190.50077 195.9774
Characteristics:	Automated System: Material of Construction: Cassette Model: Membrane: Filtration Area per Cassette: Filter MWCO Maximum Feed Pressure: Sterilization:	SartoFlow 20 Automated Crossflow 316 stainless steel electro-polished Sartocube UF Cassettes Sartocon UF Cassettes Hydrostart (cellulose based) 3 m <sup>2</sup> (sartocube) and .6 m <sup>2</sup> (sartocon) 30 kDa 4 bar SIP/CIP, cassette disinfected in 1M NaOH at 40°C for 30 min
Operating Conditions:	number of units: Feed Pressure: Total Filter Area: Temperature	1 Sartocube, 2 Sartocon cassettes 2.74 bar 4.2 m2 25°C
Purchase Cost:	SartoFlow 20 Automated Crossflow Sartocube UF Cassettes: Sartocon UF Cassettes: Cassette Housing:	7: \$25,965 \$8,768 2406 \$10,000

## Diafiltration Unit (P-21/Diafilter 1)

	Storage Tank (P-22/V-106)	
Function:	To mix the product stream from diafiltration (P-21/Diafilter 1) with polysorbate 80 to inactivate any virus particles.	
Vendor:	DCI inc.	
Operation:	Batch	
Materials Handled: Characteristics:	Input Citric Acid MAb Polysorbate 80 WFI Total Material of Construction: Total Volume: Sterilization:	Quantity (kg/ml) 0.00331 4.32557 0.00861 81.73368 86.07117 stainless steel 316L 200 L SIP/CIP
Operating Conditions:	Temp: Pressure:	25°C 1 bar
Purchase Cost:	\$33,000	

#### Pump (P-23/PUMP-4)

Function:	To transfer fluid from the storage tank (P-22/V-106) to the sterile filtration unit (P-24/DE-104)	
Vendor:	Cole-Palmer	
Operation:	Batch	
	Input	Quantity (kg/ml)
	Citric Acid	0.00331
	MAb	4.32557
Materials Handled:	Polysorbate 80	0.00861
	WFI	81.73368
	Total	86.07117
	Model:	I/P Modular Digital Dispensing Pump
Characteristics:	Pump Type:	Peristaltic
	Flow Rate:	21.64 L/h
	Power:	.15 kW
	Sterilization:	SIP/CIP
	Temp:	25°C
<b>Operating Conditions:</b>	Power:	.001 kW
_ <b>.</b>	Pressure Change	25 psi
Purchase Cost:	Purchase Cost:Pump:\$2,874Masterflex I/P 26 tubing (25 ft. roll):\$149	

#### Sterile Filter (P-24/DE-104)

Function:	To remove bacteria and other contaminants from the product stream	
Vendor:	Sartorius Stedim	
Operation:	Batch	
Materials Handled:	Input Citric Acid MAb Polysorbate 80 WFI Total	<u>Quantity (kg/ml)</u> 0.00331 4.32557 0.00861 81.73368 86.07117
Characteristics:	Model: Filter Type: Cartridge Size: Filter Size: Filtration Area: Membrane Material: Max. Differential Pressure: Other:	Sartopore 2 MaxiCaps Depth Filter 10" .2 µm .6 m <sup>2</sup> polyethersulfone (PES) 4 bar at 20°C Disposable
Operating Conditions:	Temp:	25°C
Purchase Cost:	Sartopore 2 MaxiCaps:	\$452

	Storage Tank (P-25/V-107)		
Function:	To hold the product stream from sterile filtration (P-24/DE-104) until it is ready to be loaded onto the cation exchange chromatography column.		
Vendor:	DCI inc.	DCI inc.	
Operation:	Batch		
Materials Handled:	<u>Input</u> Citric Acid MAb Polysorbate 80 WFI Total	<u>Quantity (kg/ml)</u> 0.00331 4.32557 0.00861 81.73368 86.07117	
Characteristics:	Material of Construction: Total Volume: Sterilization:	stainless steel 316L 200 L SIP/CIP	
Operating Conditions:	Temp: Pressure:	25°C 1 bar	

Purchase Cost:

\$28,000

## Pump (P-26/PUMP-5)

Function:	To transfer fluid from the storage tank (P-25/V-107) to the Cation Exchange Column (P-27/CatEX Chrom)	
Vendor:	Cole-Palmer	
Operation:	Batch	
	Input	Quantity (kg/ml)
	Citric Acid	0.00331
	MAb	4.32557
Materials Handled:	Polysorbate 80	0.00861
	WFI	81.73368
	Total	86.07117
	Model:	I/P Modular Digital Dispensing Pump
Characteristics:	Pump Type:	Peristaltic
	Flow Rate:	5.77 L/h
	Power:	.15 kW
	Sterilization:	SIP/CIP
	Temp:	25°C
Operating Conditions:	Power:	.000 kW
operating conditions.	Pressure Change	25 psi
Purchase Cost:	Pump: Masterflex I/P 26 tubing (25 ft. roll)	\$2,874 : \$196

Function:	To separate the monoclonal antibody from the impurities in the mainstream fluid	
Vendor:	GE Life Sciences	
Operation:	Batch	
Materials Handled:	<u>Input</u> Citric Acid Mab Phosphoric Acid Polysorbate 80 Sodium Phosphate WFI Total	Quantity (kg/ml) 0.00327 4.32552 533.439 0.00861 1127.1085 1644.59 3309.4749
<u>Characteristics:</u>	Column Model: Material of Construction: Inner Diameter: Tube Height: Max. Bed Volume: Max. Pressure: Column Media: Binding Capacity: Working Flow Velocity:	Chromaflow Column: 1000/100-300 acrylic .5 m .25 m 235.5 L 3 bar SP Fast Flow Sepharose Resin 30 g/L 300 cm/h
Operating Conditions:	Temp: Pressure:	25°C 1 bar
Purchase Cost:	Chromaflow Column: 1000/100 SP Fast Flow Sepharose Resin	-300 \$4,288.00 (5 liters)

## Cation Exchange Chromatography Column (P-27/CatEX Chrom)

# Storage Tank (P-28/V-108)

Function:	-	To mix the product stream from cation exchange chromatography with buffer solutions in preparation for anion exchange chromatography	
Vendor:	DCI inc.		
Operation:	Batch		
	<u>Input</u>	Quantity (kg/ml)	
	Mab	4.10924	
	Phosphoric Acid	28.69976	
Materials Handled:	Sodium Chloride	4.46327	
	Tris Base	0.4225	
	WFI	368.735	
	Total	406.42977	
	Material of Construction:	stainless steel 316L	
Characteristics:	Total Volume:	1000 L	
	Sterilization:	SIP/CIP	
Operating Conditions:	Temp:	25°C	
	Pressure:	1 bar	

Purchase Cost:

\$50,000

#### Pump (P-29/PUMP-6)

Function:	To transfer fluid from the storage tank (P-28/V-108) to the anion exchange chromatography (P-30/AnIEX Chrom)	
Vendor:	Cole-Palmer	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.10924 28.69976 4.46327 0.4225 368.735 406.42977
Characteristics:	Model: Pump Type: Flow Rate: Power: Sterilization:	I/P Modular Digital Dispensing Pump Peristaltic 604 L/h .15 kW SIP/CIP
Operating Conditions:	Temp: Power: Pressure Change	25°C .002 kW 25 psi
Purchase Cost:	Pump: Masterflex I/P 82 tubing (25 ft. roll)	\$2,874 : \$196

Function:	To separate the monoclonal antibody from the impurities in the mainstream fluid	
Vendor:	GE Life Sciences	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.10924 28.69976 7.85509 1.69983 660.703 703.06692
Characteristics:	Column Model: Material of Construction: Inner Diameter: Tube Height: Max. Bed Volume: Max. Pressure: Column Media: Binding Capacity: Working Flow Velocity:	Chromaflow Column: 400/100-300 acrylic .15 m .25 m 37.8 L 3 bar Q Fast Flow Sepharose Resin 25 g/L 300 cm/h
Operating Conditions:	Temp: Pressure:	25°C 1 bar
Purchase Cost:	Chromaflow Column: 400/100 Q Fast Flow Sepharose Resin	-300 \$8,565.00 (10 liters)

## Anion Exchange Chromatography Column (P-30/AnIEX Chrom)

	Storage Tank (P-31/V-109)		
Function:	*	To hold the product stream from anion exchange before it is transferred to sterile filtration (P-33/DE-105) DCI inc.	
Vendor:	DCI inc.		
Operation:	Batch		
	Input	Quantity (kg/ml)	
	Mab	4.08869	
	Phosphoric Acid	28.69976	
Materials Handled:	Sodium Chloride	4.54527	
	Tris Base	0.56114	
	WFI	401.32875	
	Total	439.22361	
	Material of Construction:	stainless steel 316L	
Characteristics:	Total Volume:	1000 L	
	Sterilization:	SIP/CIP	
Operating Conditions:	Temp:	25°C	
	Pressure:	1 bar	
Purchase Cost:	\$40,000		

## Pump (P-32/PUMP-7)

Function:

To transfer fluid from the storage tank (P-31/V-109) to the sterile filtration

	unit (P-33/DE-105)	
Vendor:	Cole-Palmer	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 28.69976 4.54527 0.56114 401.32875 439.22361
Characteristics:	Model: Pump Type: Flow Rate: Power: Sterilization:	I/P Modular Digital Dispensing Pump Peristaltic 49.15 L/h .15 kW SIP/CIP
Operating Conditions:	Temp: Power: Pressure Change	25°C .047 kW 25 psi
Purchase Cost:	Pump: Masterflex I/P 82 tubing (25 ft.	\$2,874 roll): \$196

#### Sterile Filter (P-33/DE-105)

Function:	To remove bacteria and other contaminants from the product stream	
Vendor:	Sartorius Stedim	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 28.69976 4.54527 0.56114 401.32875 439.22361
<u>Characteristics:</u>	Model: Filter Type: Cartridge Size: Filter Size: Filtration Area: Membrane Material: Max. Differential Pressure: Other:	Sartopore 2 MaxiCaps Depth Filter 30" .2 µm 1.8 m <sup>2</sup> polyethersulfone (PES) 4 bar at 20°C Disposable
Operating Conditions:	Temp:	25°C
Purchase Cost:	Sartopore 2 MaxiCaps:	\$1,357

	Storage Tank (P-34/V-1	Storage Tank (P-34/V-110)	
Function:	To hold the product stream from sterile filtration (P-33/DE-105) until it is transferred to Diafiltration (P-36/Diafilter 2)		
Vendor:	DCI inc.		
Operation:	Batch		
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 28.69976 4.54527 0.56114 401.32875 439.22361	
Characteristics:	Material of Construction: Total Volume: Sterilization:	stainless steel 316L 1000 L SIP/CIP	
Operating Conditions:	Temp: Pressure:	25°C 1 bar	
Purchase Cost:	\$40,000		

#### Pump (P-35/PUMP-8)

Function:	To transfer fluid from the storage tank (P-34/V-110) to the diafiltration unit (P-36/Diafilter 2)	
Vendor:	Cole-Palmer	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 28.69976 4.54527 0.56114 401.32875 439.22361
Characteristics:	Model: Pump Type: Flow Rate: Power: Sterilization:	I/P Modular Digital Dispensing Pump Peristaltic 49.15 L/h .15 kW SIP/CIP
Operating Conditions:	Temp: Power: Pressure Change	25°C .047 kW 25 psi
Purchase Cost:	Pump: Masterflex I/P 82 tubing (25 ft. roll	\$2,874 ): \$196

Function:	To concentrate the monoclonal antibody in the product stream by a factor of 5	
Vendor:	Sartorius Stedim	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	Quantity (kg/ml) 4.08869 28.69976 4.54527 0.56114 401.32875 439.22361
Characteristics:	Automated System: Material of Construction: Cassette Model: Membrane: Filtration Area per Cassette: Filter MWCO Maximum Feed Pressure: Sterilization:	SartoFlow 20 Automated Crossflow 316 stainless steel electro-polished Sartocube UF Cassettes Hydrostart (cellulose based) 3 m <sup>2</sup> 30 kDa 4 bar SIP/CIP, cassette disinfected in 1M NaOH at 40°C for 30 min
Operating Conditions:	number of units: Feed Pressure: Total Filter Area: Temperature	3 1.686 bar 9.0 m2 25°C
Purchase Cost:	SartoFlow 20 Automated Crossflow: Sartocube UF Cassettes: Cassette Housing:	\$25,965 \$8,768 \$10,000

#### Diafiltration Unit (P-36/Diafilter 2)

	Storage Tank (P-37/V-111)	
Function:	To hold the product stream from Diafiltration (P-36/Diafilter 2) until it is transferred to retrovirus filtration (P-39/DE-106)	
Vendor:	DCI inc.	
Operation:	Batch	
Materials Handled:	Input Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 0.00549 0.00087 0.00011 62.87351 66.96867
Characteristics:	Model: Volume: Bag Material: Tubing: Other:	Flexel 3D Bag for Drum 150 L Multiple layer film Thermoweldable TPE tubing gamma irradiated
Operating Conditions:	Temp: Pressure:	25°C 1 bar

Purchase Cost:

\$24,000

## Pump (P-38/PUMP-9)

Function:	To transfer fluid from the storage tank (P-37/V-111) to the retrovirus filtration unit (P-39/DE-106)	
Vendor:	Cole-Palmer	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 0.00549 0.00087 0.00011 62.87351 66.96867
Characteristics:	Model: Pump Type: Flow Rate: Power: Sterilization:	I/P Modular Digital Dispensing Pump Peristaltic 49.15 L/h .15 kW SIP/CIP
Operating Conditions:	Temp: Power: Pressure Change	25°C .021 kW 25 psi
Purchase Cost:	Pump: Masterflex I/P 82 tubing (25 ft. roll)	\$2,874 : \$196

## Retrovirus Filter (P-39/DE-106)

Function:	To remove retrovirus from the product stream	
Vendor:	Millipore	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 0.00549 0.00087 0.00011 62.87351 66.96867
Characteristics:	Model: Filter Material: Filter Size: Filtration Area: Membrane Material: Max. Differential Pressure: Other:	Viresolve Opticap XL 10 polyethersulfone (PES) 78 nm .42 m <sup>2</sup> polyethersulfone (PES) 5.5 bar at 25°C Disposable
Operating Conditions:	Temp:	25°C
Purchase Cost:	Viresolve Opticap XL 10	\$1,686

## Parvovirus Filter (P-40/DE-107)

Function:	To remove parvovirus from the p	product stream
Vendor:	Millipore	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	Quantity (kg/ml) 4.08869 0.00549 0.00087 0.00011 62.87351 66.96867
Characteristics:	Model: Filter Type: Cartridge Size: Filter Size Cutoff: Filtration Area: Membrane Material: Max. Differential Pressure:	Viresolve NFP Cartridge Filter Depth Filter 10" 28 nm .42 m <sup>2</sup> PVDF 5.5 bar at 25°C
Operating Conditions:	Temp:	25°C
Purchase Cost:	Viresolve NFP Cartridge Filter Cartridge Housing	\$4,201 \$1,423

## Pump (P-41/PUMP-10)

Function:	To transfer fluid from the parvovirus desposable storage container (P-42/I	
Vendor:	Cole-Palmer	
Operation:	Batch	
Materials Handled:	Input Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 0.00549 0.00087 0.00011 62.87351 66.96867
Characteristics:	Model: Pump Type: Flow Rate: Power: Sterilization:	I/P Modular Digital Dispensing Pump Peristaltic 49.15 L/h .15 kW SIP/CIP
Operating Conditions:	Temp: Power: Pressure Change	25°C .002 kW 25 psi
Purchase Cost:	Pump: Masterflex I/P 82 tubing (25 ft. roll)	\$2,874 : \$196

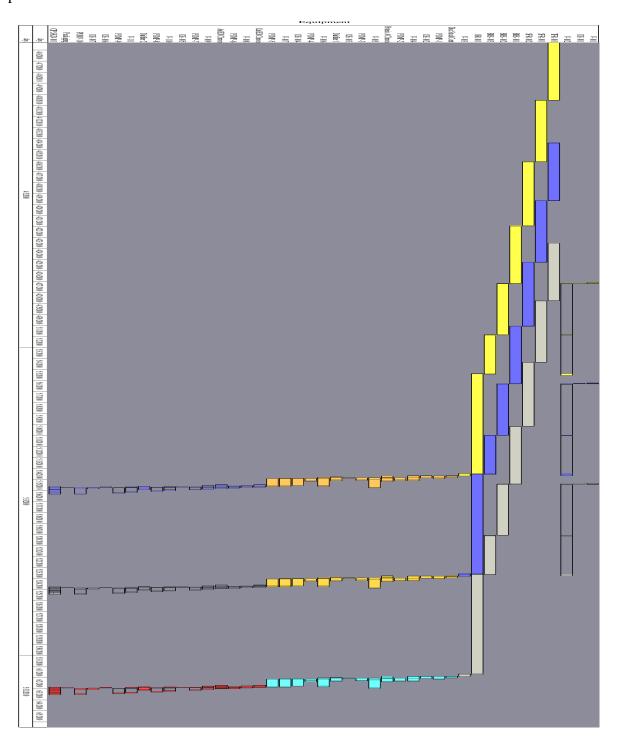
	sposuole container (1 12/1 a	ekaging)
Function:	To store the purified monoclon purification step	al antibody after the final
Vendor:	Sartorius Stedim	
Operation:	Batch	
Materials Handled:	<u>Input</u> Mab Phosphoric Acid Sodium Chloride Tris Base WFI Total	<u>Quantity (kg/ml)</u> 4.08869 0.00549 0.00087 0.00011 62.87351 66.96867
Characteristics:	Material of Construction: Total Volume: Sterilization:	stainless steel 316L 10 ml SIP/CIP
Operating Conditions:	Temp: Pressure:	37°C 1 bar
Purchase Cost:	\$1,731.96 case of 5	

## Disposable Container (P-42/Packaging)

## 9.0 Important Considerations

## 9.1 Scheduling

The Following diagram shows 3 entire batches, with the longest sections being the upstream process:



The total batch time for the process is 41 days. The upstream cell culture takes approximately 39 days, and the downstream purification takes approximately 2 days. The bottleneck in the process is the production bioreactor, which takes approximately 9 days. All of the reactors are disposable, eliminating the need for CIP and SIP, which would add time. This also allows for reactors to be reused with little to no downtime between batches. If the plant runs for 350 days per year at 75% capacity, 29 batches can be completed each year.

#### 9.2 Environmental Concerns

In the manufacturing facility, there are two main environmental concerns: biological and non-biological waste. Biological waste, or waste that contains living cells and viruses, must be sent to be treated in order to inactivate the biohazard before it is disposed. Since disposable bioreactors were used during production and CIP protocols were not needed, the majority of the liquid biohazardous waste comes from the cell selection lab is relatively small volumes. Therefore, liquid biohazardous waste will be chemically decontaminated with sodium hypochlorite. This includes cell culture and the slurry waste removed from the centrifugation unit.

Disposable equipment that comes into contact with living cells, such as the disposable bioreactors, filters, flasks, and serological pipettes, must be thermally decontaminated in an autoclave prior to disposal. After being sterilized, the biohazardous waste containers are collected for disposal by SH Bio-Waste Ltd. for \$38.50 per box. Due to the large size of many of these equipments, the environmental concern is aggravated, especially since there is no recycling system available as of yet.

During production non-hazardous liquid waste streams must be neutralized to a pH of 7.0 before being released into the sewage system. The non-hazardous liquid waste streams are collected into a holding tank and fed into a continuous neutralization system.

Other than the two environmental concerns aforementioned, the plant does not raise other concerns, especially since it does not produce hazardous gases, and there is no carbon dioxide emission at significant quantities.

#### **9.3 Current Good Manufacturing Practices**

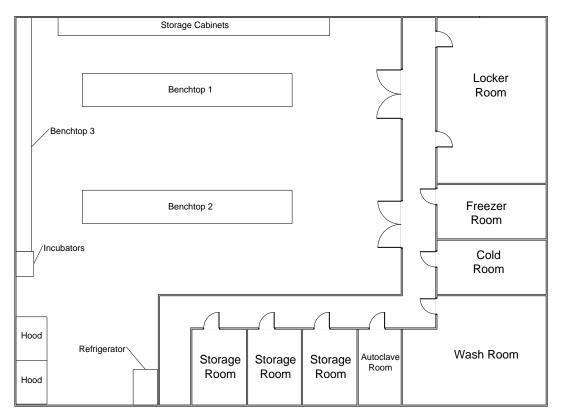
Good Manufacturing Practices for the facility and production are required by the Food and Drug Administration in order to guarantee that the product is safe for consumption and that has the identity, quality, purity and strength that it purports.

The protocol requires written procedures for production and process control and requires that these procedures shall be followed in the execution. The written documentation includes a validation protocol for each batch to ensure that all batches are producing the same product. The guidelines require that only quality material be used in the production, a proper design of the process and production, a layout that is conductive to sterile production, monitoring and control by operators at all times, and a routine for proper testing of the drug throughout since endproduct testing alone may have limited sensitivity. The testing for quality assurance that is performed throughout are done based on small samples of the streams flowing out of all equipment, ensuring not only the quality of the product, but also its uniformity in the batch.

Finally, sterility of the equipments and facility is crucial in avoiding contamination of the product. SIP and CIP procedures are followed for all non-disposable equipments before and after its use, while disposable equipments are already validated and help maintain the sterility required in the production.

#### 9.4 Laboratory and Production Facility

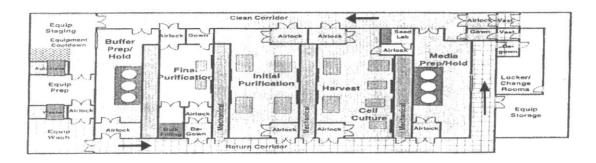
The figure below shows the layout for the cell selection and development lab. The plan leaves room for expansion as demand increases and new equipment is purchased. The cell selection lab has dedicated freezer and cold rooms for material storage. Equipment is sterilized in the autoclave room.



Plant production facility design is the role of architects within the company and is out of the scope of this report. The process is designed for a three-story plant. The figure below is an FDA representation of a typical production floor for a biopharmaceutical plant. The plant features unidirectional flow, meaning that personnel and material enter the individual rooms through a clean corridor and leave the facility through a return corridor.

There are several different areas within the plant. Buffer and media preparation are separated from cell culture and purification. The reason for this is that each area has differing requirements for sterility. All personnel must put on sterile clothing in the locker rooms before they are permitted to enter the facility. Some areas, such as purification, require yet another layer of protection, and there will likely be an additional changing room upon entering or exiting the purification rooms. (Minko)

Material will also need to be kept in sterile conditions. Any material entering or the plant must be analyzed by the quality assurance department. Material leaving the plant must be tested by quality control. Often, the facility has separate personnel and material airlocks.



Prototype Biotechnology Production Facility



#### **10.0 Market Analysis**

The market for MAbs has an extremely wide range of price variations ranging from \$4,400 per month for Genentech's Avastin to over \$45,000 per cycle for Genzyme's Clolar on a per patient basis (Cowen 2006). Based on products listed in the *Cowen Therapeutic Categories Outlook* an appropriate benchmark was estimated. Bristol-Myers Squibb's Erbitux, a MAb used in the treatment of metastatic colorectal cancer, which costs \$10,000 per month was chosen as the benchmark for market analysis. Given that Erbitux treatments are given on a weekly basis, which gives a price of approximately \$2500 per dose. Given that doses are given in either 100 mg or 200 mg doses and dose sizes will vary based on the severity of the patient's condition, an average of 150 mg doses was used as a benchmark dose size. Also a typical course of treatment lasts approximately 18 weeks, which gives a price of \$45,000 per treatment cycle per patient. This also means that each patient requires approximately 2.7 grams of the MAb per treatment cycle.

However, this price is for a well established product within the market and the proposed plant is limited to the production of MAbs being used for clinical trials. As result, finding projected earnings for companies within the same area of production was a difficult task. Considering biopharmaceutical companies would need a large profit margin to cover research costs and the costs of failed products, it was expected that a company primarily producing MAbs for clinical trials would be unable to charge near commercial prices. Using a conservative estimate of 9% given that the company is a startup trying to enter an already competitive market and all factors previously stated, \$225 per dose was used as the benchmark for profitability analysis.

Given by Dr. Tiffany Rau that typical phase I and phase II clinical trials will require the production of 20,000 doses, a total of \$4,500,000 per 4 kg or \$1,125,000/kg MAb can be expected. The estimated total number of batches produced by the plant per year is 39, producing 4.326 kg MAb/batch. As a result, approximately 168.71 kg MAb are produced yearly yielding sales of \$189,798,750/yr.

However, expecting to run at maximum capacity would be unreasonable as there are many factors that can potentially have negative effects on production capacity. Downtime for maintenance or lack of business, variation in MAb production rates as well as a company's cell density specifications can and undoubtedly will adversely affect production capacity. Also, some clients might ask for smaller batches in phase I as proof of concept, which would also lead to lower production amounts. Conversely, the variable working capacity of the facilities due to the use of disposable bioreactors as well as the expectation for expansion have the opposite effect. Although the flexible working capacity of the facilities will invariable lead to smaller production sizes at times, it will also allow for the plant to capture a greater market share. As a result, it was estimated that the plant would be working at 70% of its maximum capacity on average. However, it is realized that during the first year of operation, 70% of the maximum production capacity is still a very high number. As a result, 5% was used as the starting capacity since much of the work received will remain within the development labs while manufacturing will be extremely limited.

#### **10.1 Profitability Analysis**

In order to analyze the profitability of the investment in the startup plant, a proper methodology was necessary. Methods for calculating the net present value (NPV) and internal rate of return (IRR) detailed in *Product and Process Design Principles* were used. The profitability analysis model worksheet created by Holger Nickish (2003) was used as an aid.

#### **10.2 Facility Life**

The life of a facility is highly dependent on its capabilities to stay within the market. The plant's niche in the market is defined by the products it produces, MAbs for clinical testing, and its scale, up to 2500L. As explained in Appendix B, the market for monoclonal antibodies has been expanding rapidly. This upward trend in developing MAb products has lent itself to introduce an exponential need for an increase in production capacity of MAbs at the clinical testing level. As a result, it can be expected that as the market expands it will allow for a lower entry barrier for startups and for an increased longevity of such plants. At the same time, the current plant layout has purposely been designed for expansion in the mammalian suite as well as an expansion into a microbial suite which would allow for an eventual increase in its overall biopharmaceutical market share therefore increasing the overall life of the plant. Although this increases the longevity of the plant, it also decreases pressure to cut costs, lowering profit margins, which is reflected in the pricing estimations. The average life of a biopharmaceutical

plant is approximately five years due to the ever changing technology in the industry. However, as the technology for MAb production becomes more stable due to the fact that the industry has been around for more than 15 years in conjunction with the flexibility and longevity of the technology of the plant due to the use of disposable bioreactors and the rapid growth of the market, Mr. Edward Steve suggested that 10 to 15 years would be a safe assumption. To be conservative, the estimation for facility life used for profitability analysis was 10 years.

#### **10.3 Equipment and Materials Costs**

Equipment and materials costs were found by first researching the industry standards and then various vendors were contacted for catalogues. After finding the proper equipment and materials, the vendors were then contacted for specific equipment and installation costs. As a result, bare module factors were not necessarily needed for certain equipment since it has slowly become an industry standard to have equipment assembled at an offsite workshop. These costs as well as the installation costs were included for such units. However, bare module factors for equipment from vendors who did not provide such information were found in Chapter 22 of *Product and Process Control Principles*. It was realized that these factors might be off due to differences in industry standards. However, it was advised that the bare module factors would in fact be less since most equipment for the biopharmaceutical industry would reflect aforementioned assembly costs. It was reasoned that using a larger bare module factor would only decrease the NPV and IRR and so the real NPV and IRR would indeed reflect a more profitable investment.

#### **10.4 Total Permanent Investment**

The total permanent investment of a project includes onetime costs assuming there is no need for reconstruction. These costs include site preparations, service facilities, contingencies and contractor fees, cost of land and the plant startup itself. *Product and Process Design Principles* provided information pertaining to the percentages to be used for investment allocations and profitability analysis within the Nickish profitability analysis spreadsheet. Also, it was given that all of these costs were to be included within the first year after the design year due to the scope of the project.

#### **10.5 Working Capital**

Working capital is a measurement of both a company's efficiency and its short-term financial health and can be defined as the company's current assets less its current liabilities. As it can be seen, it is a reflection of a company's short-term ability to pay off liabilities or accounts payable with current assets, which include cash reserves, inventory, and accounts receivable. For profitability analysis, accounts receivable, cash reserves, and accounts payable were measured on a 30 day basis while inventory included 7 days of costly raw materials and 7 days of product ready to be shipped.

#### **10.6 Utilities**

Utilities for the facility cost \$54,565.70 per year for electricity and water. By evaluating the needs for each of the upstream and downstream processes using SuperPro Design and receiving yearly utilities usage for development lab equipment, it was found that 17,626 kWh/batch and 18511.5 L/batch of water were necessary to run the plant. The rate used for electricity was \$0.07113, the rate given by National Grid for commercial consumption. For water, Aquarion had the best price at \$2.074/1000 gal or \$0.007851/L. These numbers were then used to calculate the total utilities costs for the facility.

#### **10.7 Fixed Costs**

Fixed costs include costs of operations, maintenance and operative overhead. Simply put they are regular, annual costs. Much of this portion of the profitability analysis is based on the salaries and wages of the company employees. The total number of employees at the facility numbered 18 in total. This number includes 13 employees working on a salary basis, five engineers and five scientists who were to be placed throughout the facility for each of the cell selection, seed train, and product purification processes and three management positions needed for engineering, financial and human resources related issues. Two custodians and three waste management, CIP, and other workers were to work on hourly wages. Based on figures supplied by the Bureau of Labor Statistics, a weight average for hourly wages was calculated and found to be \$36.47 per hour. Also included within this portion are employee benefits. Benefits offered to employees include medicare, which was found to be 1.45% of salaries to be paid for by the employer, as well as employee health insurance, which would cost the employer \$300 per month per employee. These figures were also found through the Bureau of Labor Statistics. Overhead, the expenses on an income statement except for direct labor and materials, includes general plant overhead, mechanical department services, employee relations, business services, property taxes and insurance, and depreciation. Percentages used for allocation for each of these costs were found in the Nickish profitability analysis spreadsheet provided by *Product and Process Design Principles*.

#### **10.8 Other Variable Costs**

Variable costs not included within the rest of the analysis include selling and transferring expenses, direct research, allocated research, and administrative expenses. Although management incentives are usually included within this section, it was decided to remove these incentives as a percentage of total sales. Due to the size of the facility in conjunction with nature of the source of revenue, monoclonal antibodies entering clinical trials, the total and margin of profit will be relatively small compared to the production of retail MAbs as explained in section providing market analysis. As a result, stock options were decided to be a better option for management incentives since it would be in the best interest of management to perform in order to make the startup more successful. Realizing this would give management more incentive to work towards increasing the net worth of the company by running on a lean budget but still keeping the company in a safe financial situation. This would also alleviate strain on the startup's initial debt repayment.

#### **10.9 Depreciation**

Total depreciable capital in the case of this proposition includes all costs of contingencies and contractor fees. Based on regulations found through the IRS, the General Depreciation System of the MACRS for a 5 year recovery period was used. Employed on the first year of production, the percentages for depreciation start at 20% for year one and go on to 32%, 19.20%, 11.52%, 11.52%, and 5.76% for each consecutive year.

#### **11.0 Conclusions and Recommendations**

This proposal has explored in depth the feasibility of starting up a flexible facility to produce monoclonal antibodies using CHO cells and the processes that go along with it. The CDO aims to take advantage of small biotechnology firms' need for CDOs and the increasing demand for increases in total production capacity as the number of MAbs entering the clinic continues to expand. By employing the latest technology in conjunction with proper scientific and engineering techniques, the equipment in the facility will allow for flexibility that will in turn permit the production of myriad types of MAbs that are in or may enter clinical trials. At the same time, the segment within the market that the proposed CDO will fall under is highly specific to the production of MAbs entering clinical trials, which requires extremely pure and stable products ready for human consumption and within a small scale.

With such specificity and reasonable pricing, the CDO aims to acquire a portion of the market share. By analyzing the market and pricing the MAbs produced at \$1,125,000/kg MAb and running at full capacity for 350 days of the year, the facility will produce 168.71 kg MAb and generate \$189,798,750 on a yearly basis. By assuming a 5% production capacity in the first year and increasing to 70% in two years, the NPV of the ten year project is \$111,907,800 with an IRR of 52.96% and a ROI of 115.83%. Taking all of these profitability metrics into consideration with the expanding MAb market, it is urged that this facility be built in order to take advantage of the demand for an increase in production capacity for MAbs entering clinical trials.

#### **12.0** Acknowledgments

The project would not have been completed without the help of many individuals. We would like to thank our industrial consultant Dr. Tiffany Rau for all of her help throughout the semester, despite her busy traveling schedule. Dr. Rau took the time to meet with us in the design meetings as well as outside during many weekends, to teleconference with us numerous times, and to email us giving advice and answering our many questions in a timely fashion. Dr. Rau also provided extremely useful references used in the project. Dr. Rau went above and beyond what was expected of her as our consultant and we are truly appreciative of her help throughout.

We would also like Mr. Edward Steve for his help as he joined many of our design meetings and provided his expertise in the field given his experience in previous MAb production facilities. Mr. Steve provided us with extremely helpful guidelines in layout and costs as well as equipment details and requirements in the production and purification process. Mr. Steve also opened the doors of CDI Corporation, met with us to answer many of our questions and provided help with the scheduling of our process. We would also like to thank Ms. Kangsan Kim from CDI Corporation who allowed us to use her versions of SuperPro Designer and SchedulePro at her office. Finally, we would also like to thank Mr. George Minko, also from CDI Corporation, for providing his expertise in the requirements of a design for a MAb production facility, explaining the details of air flow, waste disposable, sanitation requirements and more.

Next, we would like to thank Dr. Matthew Lazzara for meeting us at all design meetings and providing advice throughout. Dr. Lazzara helped us with understanding of the biological aspect of the process from the cell line screening to the details of the purification process. Dr. Lazzara also clarified different questions and raised interesting points throughout in order to ensure that we fully understood the different aspects of the process.

We would also like to thank Professor Leonard Fabiano for meeting with us at many design meetings and outside the meeting times as well. Prof. Fabiano also provided his expertise throughout, especially in SuperPro Designer. Prof. Fabiano also guided us to get in touch with Mr. Edward Steve, who was an extremely helpful source as aforementioned.

Finally, we would like to thank all of the industrial consultants that met with us at our weekly design meetings for offering their insight given their industrial experience. We would

also like to thank all of the Professors in the CBE department of the University of Pennsylvania for teaching all the different concepts and skills required to complete this project.

## **Appendix A – Calculations**

#### **Growth Rate**

The doubling time of a cell culture,  $\tau_D$ , is given by the following equation;

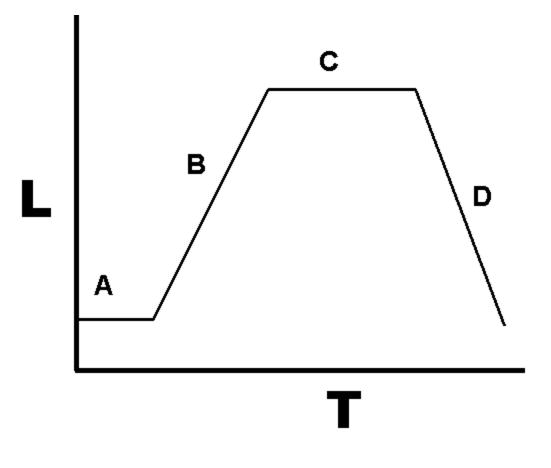
$$\tau_D = \frac{ln2}{\mu}$$

Where  $\mu$  is the specific growth rate of the cells. Specific growth rate is defined as increase in cell mass per unit cell mass per time.

For our calculations, we used a doubling time of 30 hours. This is a conservative estimate for CHO cells. This leads to a  $\mu$  of 0.023 hr<sup>-1</sup>.

### **Growth Curve**

The following curve is a typical growth curve for CHO cells. Time is plotted on the x-axis, and the y-axis shows the  $log_{10}$ (number of live cells):



Section A is a lag phase, where the cells are first adjusting to the conditions in the vessel. When designing a process, one goal is to minimize the length of this phase because it increases the overall process time without significant growth of cells.

Section B is the exponential growth phase. Section C is a stationary phase, where cells are beginning to die. Most biopharmaceutical products are made during the growth and stationary phases.

Section D is the death phase. Cells in this phase are dying faster than the culture is growing. Scale-up reactors are typically passaged before the culture reaches this phase, but a production reactor culture usually reaches the death phase.

#### **MAb Production**

Production of MAb by a CHO cell culture can vary depending on the cell line, nature of the product, and how well optimized the process is. Typically, MAb is produced at a rate of 15-45 pg/cell-day. For our calculations, we used the lower limit of the range to design for a worst-case scenario. In reality, once the process is optimized, the production can be expected to increase.

#### **Appendix B – Economic Analysis**

#### **Profitability Analysis Methods**

There are three methods used for profitability analysis in this report, net present value (NPV), return on investment (ROI), and internal rate of return (IRR). All of these methods have their pros and cons, though, and so for the sake of completion we will consider all three. The easiest method of measuring profitability is return on investment which can be described as the annual interest rate made by the profits on the original investment (Seider 2009). However, its simplicity is due to the fact that there are many assumptions made such as assuming unchanging earnings and so it does not consider the shortcomings of the years shortly following the opening of the plant. At the same time, it does not consider the magnitude of the effects of the venture as a larger company would not choose to invest in a project that would have minimal effects on its overall value. The ROI of this project was 115.83%.

To help combat the downsides of the ROI method, the NPV method is employed which is a sum of the discounted cash flows of the investment or as the name implies, it is the net present value of cash flow of a project. The rule of thumb when using the NPV approach is to accept projects with values exceeding zero. The NPV calculated was \$111,907,800 for a 10 year period after the initial investment, which reflects a gain of that amount in present dollars given a constant discount rate of 15%. The upside to using this method is that it recognizes the time value of money and the risk associated with future cash flows as a result. However, its simplicity is also a weakness since it does not allow for an analysis of when a positive NPV is achieved. It also assumes that there is no capital rationing being considered. In other words it does not take into consideration the affordability of the initial investment.

The shortcomings of the NPV method, specifically its lack of consideration for capital rationing, can be supplemented by using the IRR approach. This method quantifies the rate of return provided by the initial investment and is evaluated by comparing the IRR to the opportunity cost of capital. Essentially, the IRR is calculated by setting the NPV of a project to zero and solving for the discount rate. In the case of our project, the IRR was found to be 52.96%. Although this method also takes into account the time value of money and is a widely accepted way of predicting the value of a project, it is also flawed in that it assumes the discount

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rate remains unchanged year by year. As a result, it would be impossible to make a comparison if this parameter did change since the IRR is compared against the market interest rate.

#### **Sensitivity Analysis**

As it can be seen by the complexity of the profitability analysis spreadsheet and the myriad factors contributing to it, there are many things that can greatly affect the return on investment for this project. However, the factors that have the greatest effects on the overall profitability are those that can be easily changed while contributing large fluctuations. In particular, the benchmark selling price, facility life, and items that have high costs but have a chance for fluctuation such as the chromatography resin have the greatest effects. The choice to remove monetary management incentives with stock options will also be explored.

#### **Benchmark Selling Price**

To see the effects of changing the benchmark selling price is straight forward. By keeping all other variables constant and changing only the selling price of the MAbs produce and recording data points for the NPV and IRR, it can be observed how each of these profitability metrics changes. It can be observed that the ROI changes drastically as the product price is changed only slight and when compared to the change in the IRR. However, changing the product price can create very large swings in the returns as made evident in Table B.1, which shows the effects of changing the benchmark selling price for all three metrics.

Product Price(\$MM)	IRR (%)	NPV (15% discount rate)	ROI (%)
0.750	27.75%	\$30,004,500	60.29%
1.000	45.51%	\$84,606,700	98.73%
1.125	52.96%	\$111,907,800	115.83%
1.500	72.05%	\$193,811,200	160.30%
2.000	92.78%	\$303,015,600	207.44%
2.500	110.20%	\$414,220,000	244.68%

Table B.1: Benchmark price sensitivity data.

#### **Facility Life**

By changing the facility life of the project, the NPV and IRR can once again be record to show how the facility life changes the profitability of the project. As it can be seen in the table below, the NPV and IRR increase from \$45,177,300 and 43.40% to \$161,447,100 and 53.87% when the facility life is increased from five to twenty years. It should also be noted that the IRR quickly meets an asymptote as the facility life increases while the ROI remains unchanged. However, as explained earlier, an increase in longevity of the facility also relieves pressure on management to cut costs, decreasing profit margins. Although this effect is not reflected in the model, it is realistic effect that should be considered when analyzing the results seen in Table B.2.

Facility Life (years)	IRR (%)	NPV (15% discount rate)	ROI (%)
5	43.40%	\$45,177,300	115.83%
10	52.96%	\$111,907,800	115.83%
15	53.78%	\$144,996,300	115.83%
20	53.87%	\$161,447,100	115.83%

Table B.2: Facility life sensitivity data.

#### **Chromatography Resin**

The changing the price of the chromatography resin as a whole can drastically change the IRR and NPV of the project since it affects the overall costs greatly considering their prices. Protein A chromatography resin alone costs \$93,014 per 10 L. Reduction of these prices due to technological advancement could result in a much higher profit margin for the project. Table B.3 shows the effects of changing the weighted average resin price by  $\pm$ 50% on the IRR, NPV and ROI while keeping all other variables the same for the same 10 year project. As it can be observed, the IRR, NPV, and ROI all change slightly as the resin cost fluctuates. The IRR varies from 54.83% to 51.23% on the ends of the given spectrum, a 3.6% change overall. However, in terms of NPV, that change is \$113,820,700 to \$109,995,000, a difference of nearly \$4,000,000.

Change in Resin	Weighted Average	IRR (%)	NPV (15%	ROI (%)
Price (%)	Resin Cost (\$/L)		discount rate)	
- 50.0%	\$2377.33	54.83%	\$113,820,700	122.39%

- 25.0%	\$3565.99	53.88%	\$112,864,300	119.03%
- 12.5%	\$4160.32	53.42%	\$112,386,110	117.41%
0	\$4754.65	52.96%	\$111,907,800	115.83%
12.5%	\$5348.98	52.52%	\$111,429,600	114.29%
25%	\$5943.31	52.08%	\$110,951,400	112.79%
50%	\$7131.98	51.23%	\$109,995,000	109.88%

Table B.3: Chromatography resin sensitivity data.

#### **Management Incentives**

As stated earlier, management incentives such as bonuses and daily monetary allowances were eliminated in exchange for stock options, which were justified by the idea that this will create a goal for managers to add value by running lean but sound. However, the straight forward effects of removing these incentives altogether on the IRR, NPV, and ROI should also be explored. Table B.4 shows how small percentage allocations of total sales towards management incentive compensation can greatly affect the profitability metrics. By simply increasing the management incentive compensation to 1% of sales, the IRR decreases by 0.76%, the NPV by \$2,657,300 and the ROI by 1.97%. As a result, using stock options as a replacement for direct monetary management compensation is a worthwhile idea.

Sales Allocated to	IRR (%)	NPV (15% discount rate)	ROI (%)
Management Incentives (%)			
0	52.96%	\$111,907,800	115.83%
1.00%	52.22%	\$109,250,500	113.86%
1.25%	52.03%	\$108,586,200	113.37%
1.50%	51.84%	\$107,921,900	112.88%

Table B.4: Management incentives sensitivity data.

## Appendix C – Profitability Analysis

#### **General Information**

Process Title: Senior Design #4 Product: Monoclonal Antibodies Plant Site Location: US Northeast Site Factor: 1.10 Operating Hours per Year: 8400 Operating Days Per Year: 350 Operating Factor: 0.9589

Product Information

This Process will Yield

0 kg of Monoclonal Antibodies per hour
0 kg of Monoclonal Antibodies per day
169 kg of Monoclonal Antibodies per year

Price

\$1,125,000.00 /kg

onology					
		Distribution of	Production	<b>Depreciation</b>	Product Pric
Year	Action	Permanent Investment	Capacity	5 year MACRS	
2010 De	sign		0.0%		
2011 Co	Instruction	100%	0.0%		
2012 Pro	oduction	0%	3.5%	20.00%	\$1,125,000.
2013 Pro	oduction	0%	36.8%	32.00%	\$1,125,000.
2014 Pro	oduction	0%	70.0%	19.20%	\$1,125,000.
2015 Pro	oduction		70.0%	11.52%	\$1,125,000.
2016 Pro	oduction		70.0%	11.52%	\$1,125,000.
2017 Pro	oduction		70.0%	5.76%	\$1,125,000.
2018 Pro	oduction		70.0%		\$1,125,000.
2019 Pro	oduction		70.0%		\$1,125,000.
2020 Pro	oduction		70.0%		\$1,125,000.
2021 Pro	oduction		70.0%		\$1,125,000.

#### Equipment Costs

### Equipment Description

## Bare Module Cost

T-Flasks + Shake Flasks (2153) Disposable Bags (196) Depth Filters (274) Chromatography Colums (3) Diafilter (2) 10 mL Bioreactor (4) 3 L Bioreactor (12) Wave Bioreactors (3) Production Bioreactor Stirred Reactors (2) HVAC	Fabricated Equipment Fabricated Equipment Fabricated Equipment Fabricated Equipment Fabricated Equipment Fabricated Equipment Fabricated Equipment Fabricated Equipment Fabricated Equipment Fabricated Equipment	\$779,573 \$156,382 \$908,767 \$710,325 \$120,478 \$400,400 \$325,716 \$680,562 \$2,537,600 \$345,280 \$960,000
Centrifuge (2)	Process Machinery	\$20,944
Media Prep Tank	Process Machinery	\$499,200
Pumps (14)	Process Machinery	\$141,834
Virus Filter (Retro and Parvo)	Process Machinery	\$313,599
CIP Skid (3)	Process Machinery	\$432,200
WFI System	Process Machinery	\$1,400,000
USP Treatment Package	Process Machinery	\$52,844
Pure Steam Generator	Process Machinery	\$250,000
Blood Gas Analyzer	Spares	\$25,487
ViCell	Spares	\$53,350
Neutralization Waste System	Spares	\$77,000
Biowaste Inactivation System	Spares	\$145,600
Filter Integrity Test Unit	Spares	\$25,000
Laminar Fume Hood	Spares	\$47,249
Refrigerators/Freezers	Storage	\$104,597
Storage Tanks (5)	Storage	\$1,181,440
Incubated Orbital Shaker	Storage	\$33,575
Additional Equipment		\$3,851,850

<u>Total</u>

<u>\$16,580,853</u>

#### **Raw Materials**

ateriais			
Raw Material:	<u>Unit:</u>	Required Ratio:	Cost of Raw Material:
1 Serum Free CH	) Media kg	22.96 kg per kg of Monoclonal Antibodie	\$21.900 per kg
2 Protein A Buffers	s kg	1.188 kg per kg of Monoclonal Antibodie	\$89.66 per kg
3 H3PO4	kg	1139.5 kg per kg of Monoclonal Antibodie	\$0.14 per kg
4 NaOH (0.1M & 0	.5M) kg	854.92 kg per kg of Monoclonal Antibodie	\$0.26 per kg
5 Cation Buffers	kg	515.5421 kg per kg of Monoclonal Antibodie	\$53.10 per kg
6 Anion Buffers	kg	1.177 kg per kg of Monoclonal Antibodie	\$69.26 per kg
7 Ethanol	kg	1.035 kg per kg of Monoclonal Antibodie	\$56.25 per kg
8 Citric & Phospho	ric Acid kg	1140.052 kg per kg of Monoclonal Antibodie	\$25.30 per kg
9 Polysorbate 80	L	0.003625 L per kg of Monoclonal Antibodies	\$82.00 per L
10 WFI	L	3625.528 L per kg of Monoclonal Antibodies	\$0.15 per L

<u>Utility:</u>	Unit:	Required Ratio		U	tility Cost
1 Electricity	kWh	4152.4 kWh p	er kg of Monoclo		\$0.071 per kWł
2 Process Water	L	3702.3 L per l	kg of Monoclonal	Antibodies	\$7.851E-03 per L
ariable Costs					
General Expenses:					
	Selling / Trans	fer Expenses:	3.00% of S	Sales	
	Dire	ect Research:	0.00% of S	Sales	
	Allocat	ted Research:	0.00% of S	Sales	
	Administra	tive Expense:	2.00% of S	Sales	
Man	nagement Incentive C	ompensation:	0.00% of S	Sales	
orking Capital					
orking Capital Accounts Receivable		₽	30	Days	
	ding Raw Materials)	ት ት	30 30	Days Days	
Accounts Receivable	ding Raw Materials)	-		-	
Accounts Receivable Cash Reserves (exclue	- ,	⇒	30	Days	
Cash Reserves (exclue Accounts Payable	- ,		30 30	Days Days	
Accounts Receivable Cash Reserves (exclue Accounts Payable Monoclonal Antibodies	- ,	ት ት ት	30 30 7	Days Days Days	
Accounts Receivable Cash Reserves (exclue Accounts Payable Monoclonal Antibodies	- ,	ት ት ት	30 30 7	Days Days Days	
Accounts Receivable Cash Reserves (exclue Accounts Payable Monoclonal Antibodies Raw Materials	s Inventory	ት ት ት	30 30 7 7 7	Days Days Days	odule Costs

Allocated Costs for utility plants and related facilities: Cost of Contingencies and Contractor Fees: Cost of Land:

Cost of Royalties: Cost of Plant Start-Up:

oust of Flam Otart-op.

5.00% of Total Bare Module Costs \$0

- 18.00% of Direct Permanent Investment 2.00% of Total Depreciable Capital
  - \$0
- 10.00% of Total Depreciable Capital

# Fixed Costs

<u>Operations</u>	
Operators per Shift:	18 (assuming 18 shifts)
Direct Wages and Benefits:	\$36 /operator hour
Direct Salaries and Benefits:	15% of Direct Wages and Benefits
Operating Supplies and Services:	6% of Direct Wages and Benefits
Technical Assistance to Manufacturing:	\$0.00 per year, for each Operator per Shift
Control Laboratory:	\$0.00 per year, for each Operator per Shift
<u>Maintenance</u>	
Wages and Benefits:	4.50% of Total Depreciable Capital
Salaries and Benefits:	25% of Maintenance Wages and Benefits
Materials and Services:	100% of Maintenance Wages and Benefits
Materials and Services. Maintenance Overhead:	-
Maintenance Overnead:	5% of Maintenance Wages and Benefits
Operating Overhead	
General Plant Overhead:	7.10% of Maintenance and Operations Wages and Benefits
Mechanical Department Services:	2.40% of Maintenance and Operations Wages and Benefits
Employee Relations Department:	5.90% of Maintenance and Operations Wages and Benefits
Business Services:	7.40% of Maintenance and Operations Wages and Benefits
Dusiness Services.	1.40% of Maintenance and Operations wages and Benefits
Property Taxes and Insurance	
Property Taxes and Insurance:	2% of Total Depreciable Capital
Straight Line Depreciation	
Direct Plant: 8.00% of Total Dep	reciable Capital, less 1.18 times the Allocated Costs for Utility Plants and Related Facilities
Allocated Plant: 6.00% of 1.18 times	the Allocated Costs for Utility Plants and Related Facilities
Other Annual Expenses	
Rental Fees (Office and Laboratory Space):	\$0
Licensing Fees:	\$0
Miscellaneous:	\$0 \$0
Miscellaneous.	<b>\$</b> 0
Depletion Allowance	
Annual Depletion Allowance:	\$0

### Variable Cost Summary

	Variable	Costs	at 1	00%	Ca	pacity:	
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#### **General Expenses**

Direct Rese Allocated F Administrat		\$ \$ \$ \$	5,693,963 - - 3,795,975 -
Total General Expenses	3	\$	9,489,938
Raw Materials	\$57,893.698922 per kg of Monoclonal Anti	bo	\$9,767,246
<b>Byproducts</b>	\$0.000000 per kg of Monoclonal Anti	bo	\$0
<u>Utilities</u>	\$324.426762 per kg of Monoclonal Anti	bo	\$54,734
Total Variable Costs		\$	19,311,917

#### **Operations**

Total Fixed	Costs	\$	38,982,794
	Total Other Annual Expenses	\$	<u> </u>
	Miscellaneous:	\$	-
	Licensing Fees:	\$ \$ \$	-
	Rental Fees (Office and Laboratory Space):	\$	-
Other Annu	al Expenses		
	Property Taxes and Insurance:	\$	410,675
Property Ta	xes and Insurance		
	Total Operating Overhead	\$	6,707,661
	Business Services:	\$	2,177,048
	Employee Relations Department:	\$ \$	1,735,754
	Mechanical Department Services:	\$	706,070
	General Plant Overhead:	\$	2,088,789
Operating C	Iverhead		
	Total Maintenance	\$	2,125,245
	Maintenance Overhead	Φ	46,201
	Materials and Services	\$ \$	924,019
	Salaries and Benefits	\$ \$	231,005
<u>Maintenanc</u>	Wages and Benefits	\$	924,019
	Total Operations	\$	29,739,214
		r	00 700 044
	Control Laboratory	\$	-
	Operating Supplies and Services Technical Assistance to Manufacturing	φ ¢	1,474,672
	Direct Salaries and Benefits	\$ \$ \$	3,686,679
	Direct Wages and Benefits	\$	24,577,862

## **Investment Summary**

Bare Modul	e Costs				
	Fabricated Equipment	\$	9,304,514		
	Process Machinery	\$	3,110,621		
	Spares	\$ \$ \$ \$ \$ \$	373,686		
	Storage	\$	558,300		
	Other Equipment	\$	2,472,420		
	Catalysts	\$	-		
	Computers, Software, Etc.	\$	-		
	Total Bare Module Costs:			\$	15,819,540
Direct Perm	anent Investment				
	Cost of Site Preparations:	\$	790,977		
	Cost of Service Facilities:		790,977		
	Allocated Costs for utility plants and related facilities:	\$ \$	-		
	Direct Permanent Investment			\$	17,401,494
<u>Total Depre</u>	ciable Capital				
	Cost of Contingencies & Contractor Fees	\$	3,132,269		
	Total Depreciable Capital			\$	20,533,763
Total Perma	nent Investment				
	Cost of Land:	\$	410,675		
	Cost of Royalties:	\$	-		
	Cost of Plant Start-Up:	\$	2,053,376		
	Total Permanent Investment - Unadjusted			\$	22,997,815
	Site Factor			Ψ	1.10
	Total Permanent Investment			\$	25,297,597
				<u>*</u>	

# Working Capital

	<u>2011</u>	<u>2012</u>	<u>2013</u>
Accounts Receivable	\$ 545,996	\$ 5,186,966	\$ 5,186,966
Cash Reserves	\$ 112,300	\$ 1,066,848	\$ 1,066,848
Accounts Payable	\$ (28,255)	\$ (268,423)	\$ (268,423)
Monoclonal Antibodies Inventory	\$ 127,399	\$ 1,210,292	\$ 1,210,292
Raw Materials	\$ 6,556	\$ 62,283	\$ 62,283
Total	\$ 763,996	\$ 7,257,966	\$ 7,257,966
Present Value at 15%	\$ 664,345	\$ 5,488,065	\$ 4,772,230
Total Capital Investment		\$ 36,222,236	

# Cash Flow Summary

	Percentage of	Product Unit												Cumulative Net
Year	Design Capacity	Price	<u>Sales</u>	Capital Costs	Working Capital	Working Capital	Var Costs	Fixed Costs	Depreciation	Taxible Income	Taxes	Net Earnings	Cash Flow	Present Value at 15%
2010	0%			-		•					-		-	-
2011	0%			(25,297,600)	(763,996)	(764,000)					-		(26,061,600)	(22,662,300)
2012	4%	\$1,125,000.00	6,643,000		(7,257,966)	(7,258,000)	(675,900)	(38,982,800)	(4,106,800)	(37,122,500)	14,849,000	(22,273,500)	(25,424,700)	(41,887,000)
2013	37%	\$1,125,000.00	69,751,000		(7,257,966)	(7,258,000)	(7,097,100)	(38,982,800)	(6,570,800)	17,100,300	(6,840,100)	10,260,200	9,573,000	(35,592,600)
2014	70%	\$1,125,000.00	132,859,100		-	-	(13,518,300)	(38,982,800)	(3,942,500)	76,415,500	(30,566,200)	45,849,300	49,791,800	(7,124,000)
2015	70%	\$1,125,000.00	132,859,100	-			(13,518,300)	(38,982,800)	(2,365,500)	77,992,500	(31,197,000)	46,795,500	49,161,000	17,317,700
2016	70%	\$1,125,000.00	132,859,100				(13,518,300)	(38,982,800)	(2,365,500)	77,992,500	(31,197,000)	46,795,500	49,161,000	38,571,400
2017	70%	\$1,125,000.00	132,859,100				(13,518,300)	(38,982,800)	(1,182,700)	79,175,200	(31,670,100)	47,505,100	48,687,900	56,875,000
2018	70%	\$1,125,000.00	132,859,100	-			(13,518,300)	(38,982,800)	-	80,358,000	(32,143,200)	48,214,800	48,214,800	72,636,500
2019	70%	\$1,125,000.00	132,859,100				(13,518,300)	(38,982,800)		80,358,000	(32,143,200)	48,214,800	48,214,800	86,342,100
2020	70%	\$1,125,000.00	132,859,100				(13,518,300)	(38,982,800)		80,358,000	(32,143,200)	48,214,800	48,214,800	98,260,100
2021	70%	\$1,125,000.00	132,859,100	-	15,279,928	15,279,900	(13,518,300)	(38,982,800)	-	80,358,000	(32,143,200)	48,214,800	63,494,700	111,907,800

# Profitability Measures

The Internal Rate of Return (IRR) for this project is	52.96%
The Net Present Value (NPV) of this project in 2010 is	\$ 111,907,800

**ROI Analysis (Third Production Year)** 

Annual Sales	132,859,125
Annual Costs	(52,501,137)
Depreciation	(2,023,808)
Income Tax	(31,333,672)
Net Earnings	47,000,508
Total Capital Investment	40,577,524
ROI	115.83%

#### **Appendix D – CIP and SIP Procedure**

CIP and SIP are automated cleaning tools commonly used in the chemical production industry, especially due to their repeatability, ease of use and lower cost than other methods and operations. These methods are especially important in pharmaceuticals as it makes FDA validation easier since validation for cleaning is required for all equipments used in every batch.

The following procedure is the standard CIP procedure used for all mixing tanks and pipes throughout:

- 1. Pre-Rinse: the vessel is washed with WFI with an amount equal to half the volume of the vessel for 10 minutes. The goal of this step is to remove as much "loose" soil as possible.
- 2. Alkaline wash: half the vessel's volume of 0.5M NaOH (cleaning solution) is sprayed into the tank for 30 minutes.
- Post Rinse: half a vessel's volume of WFI is used to rinse off the cleaning solution for 10 minutes.
- 4. Acid Rinse: half the vessel's volume of  $H_3PO_4$  5% w/w is sprayed into the tank for 30 minutes. The acid neutralizes the alkaline cleaner and also removes mineral deposits.
- Wash: half the vessel's volume of WFI is used to wash off the acid solution for 10 minutes
- 6. Final Rinse: half the vessel's volume of WFI is used for a final wash for 10 minutes. Diafiltration and Ultrafiltratilon units use a different procedure for CIP as recommended by their manufacturers: WFI is flushed through the system at 50°C, followed by a wash of

NaOCl solution with pH of 10 or 11 for one hour, and finalized by a wash of WFI through the system, again at  $50^{\circ}$ C.

The instruments that require steam in place before usage of the equipment, water steam at 152°C is sprayed into the equipment with a volumetric flow rate of 3lb/hr per feet squared for approximately 30 minutes. Once the procedure is finished, the equipment usage is otherwise the same, still ending with the appropriate CIP procedure as listed above.

Chromatography columns do not require this SIP procedure and a lighter CIP procedure is used instead, especially given all the washing steps that the column goes through as it runs. Thus, the CIP consists of half the bed volume of 0.1M NaOH rinse for 1 hour followed by a 15 minute wash using the equivalent of its entire volume of WFI. (Stewart 2006)

## Appendix E – Superpro Stream Reports

Upstream Process				
Stream Name	Media-1	From vial	S-101	Media-2
Source	INPUT	INPUT	P-1	INPUT
Destination	P-1	P-1	P-2	P-2
Stream Properties			12	. 2
	0.00	0.00	0.00	0.00
Activity (U/ml) Temperature (°C)	25.00	25.00	37.00	0.00 25.00
Pressure (bar)	1.01	1.01	1.76	25.00
Density (g/L)	995.22	994.70	990.65	995.22
Component Flowrates (kg/batch)	99 <b>0.</b> 22	334.70	990.00	333.22
Amino acids	0.00	0.00	0.00	0.00
Biomass	0.00	0.00	0.00	0.00 0.00
Dead Biomass	0.00	0.00	0.00	0.00
Glucose	0.00	0.00	0.00	0.00
Inorganic Salts	0.00	0.00	0.00	0.00
MAb	0.00	0.00	0.00	0.00
Other media com	0.00	0.00	0.00	0.00
Vitamins	0.00	0.00	0.00	0.00
WFI	0.02	0.00	0.02	0.00
TOTAL (kg/batch)	0.02	0.00	0.02	0.13
TOTAL (L/batch)	0.02	0.00	0.02	0.13
	0.02	0.00	0.02	0.10
Stream Name	S-102	Media-3	S-103	Media-4
Source	P-2	INPUT	P-3	INPUT
Destination	P-3	P-3	P-4	P-4
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	37.00	25.00	37.00	25.00
Pressure (bar)	2.65	1.01	2.65	1.01
Density (g/L)	990.60	995.22	990.59	995.22
Component Flowrates (kg/batch)				
Amino acids	0.00	0.00	0.00	0.01
Biomass	0.00	0.00	0.01	0.00
Dead Biomass	0.00	0.00	0.00	0.00
Glucose	0.00	0.00	0.00	0.03
Inorganic Salts	0.00	0.02	0.01	0.13
MAb	0.00	0.00	0.00	0.00
Other media com	0.00	0.00	0.00	0.00
Vitamins	0.00	0.00	0.00	0.00
WFI	0.15	1.02	1.17	8.57

TOTAL (kg/batch)	0.15	1.05	1.19	8.75
TOTAL (L/batch)	0.15	1.05	1.21	8.79
Stream Name	S-104	WFI	Media Powder	S-107
Source	P-4	INPUT	INPUT	P-9
Destination	P-5	P-9	P-9	P-10
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	37.00	25.00	25.00	25.00
Pressure (bar)	1.32	1.01	1.01	10.13
Density (g/L)	990.61	994.70	1025.05	994.92
Component Flowrates (kg/batch)				
Amino acids	0.01	0.00	1.32	1.32
Biomass	0.08	0.00	0.00	0.00
Dead Biomass	0.01	0.00	0.00	0.00
Glucose	0.02	0.00	3.86	3.86
Inorganic Salts	0.08	0.00	17.26	17.26
MAb	0.00	0.00	0.00	0.00
Other media com	0.00	0.00	0.25	0.25
Vitamins	0.00	0.00	0.08	0.08
WFI	9.74	2702.28	0.00	2702.28
TOTAL (kg/batch)	9.94	2702.28	22.76	2725.05
TOTAL (L/batch)	10.04	2716.67	22.21	2738.96
Stream Name	S-109	Media-5	Media-6	Media-7
Source	P-10	P-11	P-11	P-11
Destination	P-11	P-5	P-6	P-7
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.00	25.00	25.00	25.00
Pressure (bar)	10.13	10.13	8.35	3.88
Density (g/L)	994.92	994.92	994.92	994.92
Component Flowrates (kg/batch)				
Amino acids	1.32	0.03	0.20	0.96
Glucose	3.86	0.09	0.60	2.82
Inorganic Salts	17.26	0.41	2.68	12.60
Other media com	0.25	0.01	0.04	0.18
Vitamins	0.08	0.00	0.01	0.06
WFI	2702.28	64.13	419.31	1973.22
TOTAL (kg/batch)	2725.05	64.67	422.84	1989.84
TOTAL (L/batch)	2738.96	65.00	425.00	2000.00
Stream Name	S-105	S-106	S-110	To Purification
	3-103	3-100	3-110	
				133

Source	P-5	P-6	P-7	P-8
Destination	P-6	P-7	P-8	OUTPUT
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	37.00	37.00	37.00	37.00
Pressure (bar)	1.69	1.41	2.11	10.54
Density (g/L)	990.38	990.40	990.34	990.35
Component Flowrates (kg/batch)				
Amino acids	0.01	0.08	0.08	0.08
Biomass	0.52	2.58	4.26	4.26
Dead Biomass	0.07	0.35	10.28	10.28
Glucose	0.03	0.22	0.23	0.23
Inorganic Salts	0.11	1.00	1.02	1.02
MAb	0.01	0.03	5.01	5.01
Other media com	0.00	0.01	0.02	0.02
Vitamins	0.00	0.00	0.01	0.01
WFI	73.87	493.18	2466.40	2466.40
TOTAL (kg/batch)	74.61	497.45	2487.29	2487.29
TOTAL (L/batch)	75.34	502.28	2511.54	2511.54

## **Downstream Process Part 1**

Stream Name	From Seed Train	S-111	Waste-2	PA-Equil
Source	INPUT	P-12	P-12	INPUT
Destination	P-12	P-13	OUTPUT	P-17
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	37.00	38.84	38.84	25.00
Pressure (bar)	1.01	1.01	1.01	1.01
Density (g/L)	990.43	989.66	992.16	996.86
Component Flowrates (kg/batch)				
Amino Acids	0.08	0.07	0.00	0.00
Biomass	4.26	0.09	4.17	0.00
				4.25

dead biomass	10.28	0.21	10.08	0.00
Glucose	0.23	0.22	0.01	0.00
Inorganic Salts	1.02	0.99	0.03	0.00
MAB	5.00	4.90	0.10	0.00
Other Media Com	0.01	0.01	0.00	0.00
TRIS Base	0.00	0.00	0.00	0.29
TRIS HCI	0.00	0.00	0.00	0.86
Vitamins	0.00	0.00	0.00	0.00
WFI	2466.37	2385.74	80.63	286.32
TOTAL (kg/batch)	2487.26	2392.24	95.02	287.47
TOTAL (L/batch)	2511.30	2417.22	95.77	288.37
Stream Name	PA-Wash	PA-Elute	PA-Reg	S-115
Source	INPUT	INPUT	INPUT	P-16
Destination	P-17	P-17	P-17	P-17
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.00	25.00	25.00	38.85
Pressure (bar)	1.01	1.01	1.01	12.33
Density (g/L)	996.86	996.90	944.51	989.65
Component Flowrates (kg/batch)				
Amino Acids	0.00	0.00	0.00	0.07
Biomass	0.00	0.00	0.00	0.00
Citric Acid	0.00	2.87	0.00	0.00
dead biomass	0.00	0.00	0.00	0.00
Ethyl Alcohol	0.00	0.00	1307.38	0.00
Glucose	0.00	0.00	0.00	0.22
Inorganic Salts	0.00	0.00	0.00	0.99
MAB	0.00	0.00	0.00	4.81
Other Media Com	0.00	0.00	0.00	0.01
TRIS Base	0.48	0.00	0.00	0.00
TRIS HCI	1.44	0.00	0.00	0.00
Vitamins	0.00	0.00	0.00	0.00
WFI	477.19	476.25	5229.51	2385.36
TOTAL (kg/batch)	479.11	479.13	6536.89	2391.46
TOTAL (L/batch)	480.62	480.62	6920.92	2416.46
Stream Name	S-116	S-117	S-112	S-113
Source	P-17	P-17	P-13	P-14
Destination	P-18	P-19	P-14	P-15
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
	0.00	0.00	0.00	0.00

Temperature (°C)	25.31	28.31	38.85	38.85
Pressure (bar)	1.01	1.01	2.74	2.74
Density (g/L)	996.74	959.89	989.66	989.65
Component Flowrates (kg/batch)				
Amino Acids	0.00	0.07	0.07	0.07
Biomass	0.00	0.00	0.09	0.00
Citric Acid	1.15	1.72	0.00	0.00
dead biomass	0.00	0.00	0.21	0.00
Ethyl Alcohol	0.00	1307.38	0.00	0.00
Glucose	0.00	0.22	0.22	0.22
Inorganic Salts	0.00	0.99	0.99	0.99
MAB	4.33	0.48	4.90	4.81
Other Media Com	0.00	0.01	0.01	0.01
TRIS Base	0.00	0.77	0.00	0.00
TRIS HCI	0.00	2.30	0.00	0.00
Vitamins	0.00	0.00	0.00	0.00
WFI	190.50	8664.13	2385.74	2385.36
TOTAL (kg/batch)	195.98	9978.08	2392.24	2391.46
TOTAL (L/batch)	196.62	10395.00	2417.24	2416.46
Stream Name	Waste-3	S-114	S-120	S-105
Course	<b>-</b> 44	D 45		D 00
Source	P-14	P-15	INPUT	P-20
Destination	P-14 OUTPUT	P-15 P-16	P-21	P-20 P-21
				-
Destination				-
<b>Destination</b> Stream Properties	OUTPUT	P-16	P-21	P-21
Destination Stream Properties Activity (U/ml)	<b>OUTPUT</b> 0.00	<b>P-16</b> 0.00	<b>P-21</b>	<b>P-21</b>
Destination Stream Properties Activity (U/ml) Temperature (°C)	OUTPUT 0.00 38.85	<b>P-16</b> 0.00 38.84	<b>P-21</b> 0.00 25.00	<b>P-21</b> 0.00 25.32
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar)	OUTPUT 0.00 38.85 2.74	<b>P-16</b> 0.00 38.84 10.60	<b>P-21</b> 0.00 25.00 1.01	<b>P-21</b> 0.00 25.32 2.74
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L)	OUTPUT 0.00 38.85 2.74	<b>P-16</b> 0.00 38.84 10.60	<b>P-21</b> 0.00 25.00 1.01	<b>P-21</b> 0.00 25.32 2.74
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch)	0.00 38.85 2.74 995.96	<b>P-16</b> 0.00 38.84 10.60 989.66	<b>P-21</b> 0.00 25.00 1.01 994.70	<b>P-21</b> 0.00 25.32 2.74 996.73
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids	OUTPUT 0.00 38.85 2.74 995.96 0.00	P-16 0.00 38.84 10.60 989.66 0.07	<b>P-21</b> 0.00 25.00 1.01 994.70 0.00	<b>P-21</b> 0.00 25.32 2.74 996.73 0.00
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09	P-16 0.00 38.84 10.60 989.66 0.07 0.00	P-21 0.00 25.00 1.01 994.70 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00	P-21 0.00 25.00 1.01 994.70 0.00 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid dead biomass	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00 0.21	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00 0.00	P-21 0.00 25.00 1.01 994.70 0.00 0.00 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15 0.00
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid dead biomass Glucose	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00 0.21 0.00	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00 0.00 0.00 0.22	P-21 0.00 25.00 1.01 994.70 0.00 0.00 0.00 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15 0.00 0.00
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid dead biomass Glucose Inorganic Salts	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00 0.21 0.00 0.21 0.00 0.00	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00 0.00 0.00 0.22 0.99	P-21 0.00 25.00 1.01 994.70 0.00 0.00 0.00 0.00 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15 0.00 0.00 0.00 0.00
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid dead biomass Glucose Inorganic Salts MAB	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.21	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00 0.00 0.00 0.22 0.99 4.81	P-21 0.00 25.00 1.01 994.70 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15 0.00 0.00 0.00 4.33
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid dead biomass Glucose Inorganic Salts MAB Other Media Com	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.00 0.00 0.00	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00 0.00 0.00 0.22 0.99 4.81 0.01	P-21 0.00 25.00 1.01 994.70 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15 0.00 0.00 0.00 4.33 0.00
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid dead biomass Glucose Inorganic Salts MAB Other Media Com TRIS HCI	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.10 0.00 0.10 0.00	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00 0.00 0.22 0.99 4.81 0.01 0.00	P-21 0.00 25.00 1.01 994.70 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00 0.00	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15 0.00 0.00 0.00 4.33 0.00 0.00
Destination Stream Properties Activity (U/ml) Temperature (°C) Pressure (bar) Density (g/L) Component Flowrates (kg/batch) Amino Acids Biomass Citric Acid dead biomass Glucose Inorganic Salts MAB Other Media Com TRIS HCl Vitamins	OUTPUT 0.00 38.85 2.74 995.96 0.00 0.09 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.21 0.00 0.21 0.000 0.00 0.00 0.0000 0.0000 0.0000 0.0000 0.0000 0.0000 0.0000 0.0000 0.0000 0.00000 0.00000 0.00000 0.00000000	P-16 0.00 38.84 10.60 989.66 0.07 0.00 0.00 0.00 0.00 0.22 0.99 4.81 0.01 0.00 0.00 0.00	P-21 0.00 25.00 1.01 994.70 0.0	P-21 0.00 25.32 2.74 996.73 0.00 0.00 1.15 0.00 0.00 0.00 4.33 0.00 0.00 0.00 0.00

Stream Name	S-119	S-122	S-121	Waste-6
Source	INPUT	P-21	P-21	P-21
Destination	P-21	P-22	OUTPUT	OUTPUT
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.00	25.85	25.00	25.85
Pressure (bar)	1.01	1.01	1.01	1.01
Density (g/L)	994.70	994.41	994.70	995.17
Component Flowrates (kg/batch)				
Citric Acid	0.00	0.00	0.00	1.15
МАВ	0.00	4.33	0.00	0.00
TRIS HCI	0.00	0.00	0.00	0.00
WFI	497.35	81.73	497.35	539.04
TOTAL (kg/batch)	497.35	86.05	497.35	540.19
TOTAL (L/batch)	500.00	86.54	500.00	542.81
Stream Name	Polysorbate 80	S-123	S-124	Waste-4
Source	INPUT	P-22	P-22	P-19
Destination	P-22	OUTPUT	P-23	OUTPUT
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.00	25.85	25.85	28.31
Pressure (bar)	1.01	1.01	1.01	10.24
Density (g/L)	994.70	1.18	994.41	959.89
Component Flowrates (kg/batch)				
Amino Acids	0.00	0.00	0.00	0.07
Biomass	0.00	0.00	0.00	0.00
Citric Acid	0.00	0.00	0.00	1.72
dead biomass	0.00	0.00	0.00	0.00
Ethyl Alcohol	0.00	0.00	0.00	1307.38
Glucose	0.00	0.00	0.00	0.22
Inorganic Salts	0.00	0.00	0.00	0.99
MAB	0.00	0.00	4.33	0.48
Nitrogen	0.00	0.08	0.00	0.00
Other Media Com	0.00	0.00	0.00	0.01
Oxygen	0.00	0.02	0.00	0.00
polysorbate 80	0.01	0.00	0.01	0.00
TRIS Base	0.00	0.00	0.00	0.77
TRIS HCI	0.00	0.00	0.00	2.30
Vitamins	0.00	0.00	0.00	0.00
WFI	0.01	0.00	81.73	8664.13
TOTAL (kg/batch)	0.02	0.10	86.07	9978.08

TOTAL (L/batch)	0.02	86.83	
Stream Name	S-118	S-126	
Source	P-18	P-24	
Destination	P-20	P-25	
Stream Properties			
Activity (U/ml)	0.00	0.00	
Temperature (°C)	25.32	25.87	
Pressure (bar)	2.74	2.74	
Density (g/L)	996.73	994.40	
Component Flowrates (kg/ba	tch)		
Citric Acid	1.15	0.00	
MAB	4.33	4.33	
olysorbate 80	0.00	0.01	
RIS HCI	0.00	0.00	
/FI	190.50	81.73	
OTAL (kg/batch)	195.98	86.07	
)TAL (L/batch)	196.62	86.56	
ream Name	To Purification II		
ource	P-26		
stination	OUTPUT		
	OUTPUT		
eam Properties	<b>OUTPUT</b> 0.00		
eam Properties vity (U/ml)			
ream Properties tivity (U/ml) mperature (°C)	0.00		
ream Properties tivity (U/ml) mperature (°C) essure (bar)	0.00 25.88		
ream Properties tivity (U/ml) mperature (°C) essure (bar) ensity (g/L)	0.00 25.88 11.89 994.40		
rream Properties ctivity (U/ml) emperature (°C) essure (bar) ensity (g/L) omponent Flowrates (kg/ba	0.00 25.88 11.89 994.40		
tream Properties ctivity (U/ml) emperature (°C) ressure (bar) ensity (g/L) omponent Flowrates (kg/ba tric Acid	0.00 25.88 11.89 994.40 tch)		
tream Properties ctivity (U/ml) emperature (°C) ressure (bar) ensity (g/L) omponent Flowrates (kg/ba tric Acid AB	0.00 25.88 11.89 994.40 tch) 0.00		
tream Properties ctivity (U/ml) emperature (°C) ressure (bar) ensity (g/L) omponent Flowrates (kg/ba itric Acid AB olysorbate 80	0.00 25.88 11.89 994.40 tch) 0.00 4.33		
tream Properties ctivity (U/ml) emperature (°C) ressure (bar) ensity (g/L) omponent Flowrates (kg/ba itric Acid AB olysorbate 80 RIS HCI	0.00 25.88 11.89 994.40 tch) 0.00 4.33 0.01		
tream Properties ctivity (U/ml) emperature (°C) ressure (bar) ensity (g/L) component Flowrates (kg/ba itric Acid IAB olysorbate 80 RIS HCI /FI	0.00 25.88 11.89 994.40 tch) 0.00 4.33 0.01 0.00		
Destination Stream Properties Activity (U/ml) Semperature (°C) Pressure (bar) Pensity (g/L) Component Flowrates (kg/ba Stric Acid MAB olysorbate 80 RIS HCI VFI OTAL (kg/batch) OTAL (L/batch)	0.00 25.88 11.89 994.40 tch) 0.00 4.33 0.01 0.00 81.73		

## **Downstream Process Part 2**

Stream Name	IEX-Equi	IEX wash	IEX-WFI	IEX EI
Source	INPUT	INPUT	INPUT	INPUT
Destination	P-27	P-27	P-27	P-27
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.00	25.00	25.00	25.00
Pressure (bar)	1.01	1.01	1.01	1.01
Density (g/L)	1944.91	1665.61	994.70	1798.56
Component Flowrates (kg/batch)				
Phosphoric Acid	0.00	461.69	0.00	71.75
Sodium Chloride	0.00	550.64	0.00	10.53
Sodium Phosphat	1127.11	0.00	0.00	0.00
WFI	275.01	188.44	669.21	4.30
TOTAL (kg/batch)	1402.12	1200.77	669.21	86.59
TOTAL (L/batch)	720.92	720.92	672.78	48.14
Churchen Norme		From	6 400	
Stream Name	IEX strip	Purification I	S-128	IEX-waste
Source	INPUT	INPUT	P-27	P-27
Destination	P-27	P-27	P-28	OUTPUT
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.00	25.88	25.01	25.02
Pressure (bar)	1.01	2.74	1.01	1.01
Density (g/L)	1004.27	994.40	1047.62	1495.27
Component Flowrates (kg/batch)				
Citric Acid	0.00	0.00	0.00	0.00
MAb	0.00	4.33	4.11	0.22
Phosphoric Acid	0.00	0.00	28.70	504.74
polysorbate 80	0.00	0.01	0.00	0.01
Sodium Chloride	8.51	0.00	4.21	565.47
Sodium Phosphat	0.00	0.00	0.00	1127.11
WFI	425.88	81.73	269.41	1375.18
TOTAL (kg/batch)	434.40	86.07	306.43	3572.73
TOTAL (L/batch)	432.55	86.55	292.50	2389.35
Stream Name	AEX- Equil	AEX-Wash	AEX-Elute	AEX-Strip
Source	INPUT	INPUT	INPUT	INPUT
Destination	P-30	P-30	P-30	P-30
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
				140

Temperature (°C)	25.00	25.00	25.00	25.00
Pressure (bar)	1.01	1.01	1.01	1.01
Density (g/L)	998.20	998.20	998.20	1024.67
Component Flowrates (kg/batch)				
Sodium Chloride	0.21	0.21	0.21	2.78
TRIS Base	0.35	0.35	0.35	0.24
WFI	81.48	81.48	81.48	47.51
TOTAL (kg/batch)	82.04	82.04	82.04	50.53
TOTAL (L/batch)	82.18	82.18	82.18	49.31
Stream Name	S-130	S-131	AEX- waste	AEX-load
Source	P-29	P-30	P-30	INPUT
Destination	P-30	P-31	OUTPUT	P-28
Stream Properties	1 50	1 01	001101	1 20
	0.00	0.00	0.00	0.00
Activity (U/ml)	0.00	0.00 25.02	0.00	0.00
Temperature (°C)	25.03	25.02	25.00 1.01	25.00
Pressure (bar)	11.86 1035.01			1.01
Density (g/L)	1035.01	1032.16	1003.16	998.20
Component Flowrates (kg/batch)		4.00	0.00	0.00
MAb	4.11	4.09	0.02	0.00
Phosphoric Acid	28.70	28.70	0.00	0.00
Sodium Chloride	4.46	4.55	3.31	0.25
TRIS Base	0.42	0.56	1.14	0.42
	368.73 406.43	401.33	259.37	99.33
TOTAL (kg/batch)	392.68	439.22 425.54	263.84 263.01	100.00 100.18
TOTAL (L/batch)	392.00	425.54	203.01	100.18
Stream Name	S-129	S-132	S-137	S-136
Source	P-28	P-31	INPUT	P-35
Destination	P-29	P-32	P-36	P-36
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.01	25.02	25.00	25.06
Pressure (bar)	10.13	10.13	1.01	11.86
Density (g/L)	1035.01	1032.16	994.70	1032.15
Component Flowrates (kg/batch)				
MAb	4.11	4.09	0.00	4.09
Phosphoric Acid	28.70	28.70	0.00	28.70
Sodium Chloride	4.46	4.55	0.00	4.55
TRIS Base	0.42	0.56	0.00	0.56
WFI	368.73	401.33	624.19	401.33
TOTAL (kg/batch)	406.43	439.22	624.19	439.22

TOTAL (L/batch)	392.68	425.54	627.51	425.54
Stream Name	S-138	S-140	S-139	Waste-9
Source	INPUT	P-36	P-36	P-36
Destination	P-36	P-37	OUTPUT	OUTPUT
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.00	25.84	25.00	25.84
Pressure (bar)	1.01	1.01	1.01	1.01
Density (g/L)	994.70	994.44	994.70	1010.57
Component Flowrates (kg/batch)				
MAb	0.00	4.09	0.00	0.00
Phosphoric Acid	0.00	0.01	0.00	28.69
Sodium Chloride	0.00	0.00	0.00	4.54
TRIS Base	0.00	0.00	0.00	0.56
WFI	497.35	62.87	497.35	962.64
TOTAL (kg/batch)	497.35	66.97	497.35	996.44
TOTAL (L/batch)	500.00	67.34	500.00	986.02
Stream Name	S-134	S-135	S-133	S-141
Source	P-33	P-34	P-32	P-37
Destination	P-34	P-35	P-33	P-38
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.04	25.04	25.04	25.84
Pressure (bar)	11.86	10.13	11.86	10.16
Density (g/L)	1032.16	1032.16	1032.16	994.44
Component Flowrates (kg/batch)				
MAb	4.09	4.09	4.09	4.09
Phosphoric Acid	28.70	28.70	28.70	0.01
Sodium Chloride	4.55	4.55	4.55	0.00
TRIS Base	0.56	0.56	0.56	0.00
WFI	401.33	401.33	401.33	62.87
TOTAL (kg/batch)	439.22	439.22	439.22	66.97
TOTAL (L/batch)	425.54	425.54	425.54	67.34
Stream Name	S-142	S-143	S-145	Final Product
Source	P-38	P-39	P-41	P-42
Destination	P-39	P-40	P-42	OUTPUT
Stream Properties				
Activity (U/ml)	0.00	0.00	0.00	0.00
Temperature (°C)	25.86	25.86	25.88	25.87
	20.00	20.00	20.00	20.01

Pressure (bar)	11.88	11.88	13.61	3.11
Density (g/L)	994.44	994.44	994.43	994.43
Component Flowrates (kg/batch)				
MAb	4.09	4.09	4.09	4.09
Phosphoric Acid	0.01	0.01	0.01	0.01
Sodium Chloride	0.00	0.00	0.00	0.00
TRIS Base	0.00	0.00	0.00	0.00
WFI	62.87	62.87	62.87	62.87
TOTAL (kg/batch)	66.97	66.97	66.97	66.97
TOTAL (L/batch)	67.34	67.34	67.34	67.34
Stream Name	S-144			
Source	P-40			
Destination	P-41			
Stream Properties				
Activity (U/ml)	0.00			
Temperature (°C)	25.86			
Pressure (bar)	11.88			
Density (g/L)	994.44			
Component Flowrates (kg/batch)				
MAb	4.09			
Phosphoric Acid	0.01			
Sodium Chloride	0.00			
TRIS Base	0.00			
WFI	62.87			
TOTAL (kg/batch)	66.97			
TOTAL (L/batch)	67.34			

Appendix F – MSDS and Vendor Spec Sheets





Health	2
Fire	1
Reactivity	0
Personal Protection	Ε

# Material Safety Data Sheet Citric acid MSDS

Section 1: Chemical Product and Company Identification		
Product Name: Citric acid	Contact Information:	
Catalog Codes: SLC5449, SLC2665, SLC4453, SLC1660, SLC3451	<b>Sciencelab.com, Inc.</b> 14025 Smith Rd. Houston, Texas 77396	
<b>CAS#:</b> 77-92-9	US Sales: <b>1-800-901-7247</b>	
RTECS: GE7350000	International Sales: 1-281-441-4400	
<b>TSCA:</b> TSCA 8(b) inventory: Citric acid	Order Online: ScienceLab.com	
Cl#: Not available.	CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300	
Synonym: 2-Hydroxy-1,2,3-propanetricarboxylic acid	International CHEMTREC, call: 1-703-527-3887	
Chemical Name: Citric Acid	For non-emergency assistance, call: 1-281-441-4400	
Chemical Formula: C6H8O7		

# Section 2: Composition and Information on Ingredients Composition: CAS # % by Weight Citric acid 77-92-9 100

Toxicological Data on Ingredients: Citric acid: ORAL (LD50): Acute: 5040 mg/kg [Mouse]. 3000 mg/kg [Rat].

## **Section 3: Hazards Identification**

#### **Potential Acute Health Effects:**

Hazardous in case of eye contact (irritant), of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion. The amount of tissue damage depends on length of contact. Eye contact can result in corneal damage or blindness. Skin contact can produce inflammation and blistering. Severe over-exposure can produce lung damage, choking, unconsciousness or death.

#### **Potential Chronic Health Effects:**

Slightly hazardous in case of skin contact (sensitizer). CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. The substance may be toxic to teeth. Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure of the eyes to a low level of dust can produce eye irritation. Repeated skin exposure can produce local skin destruction, or dermatitis. Repeated inhalation of dust can produce varying degree of respiratory irritation or lung damage.

## **Section 4: First Aid Measures**

#### Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

#### Skin Contact:

In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

#### Serious Skin Contact:

Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

## **Section 5: Fire and Explosion Data**

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: 1010°C (1850°F)

Flash Points: Not available.

Flammable Limits: LOWER: 0.28 Kg/M3 (Dust) UPPER: 2.29 Kg/M3 (Dust)

Products of Combustion: These products are carbon oxides (CO, CO2).

## Fire Hazards in Presence of Various Substances:

Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.

Explosion Hazards in Presence of Various Substances:

Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.

#### Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: As with most organic solids, fire is possible at elevated temperatures

#### Special Remarks on Explosion Hazards:

Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

## Section 6: Accidental Release Measures

#### Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

#### Large Spill:

Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Eliminate all ignition sources. Call for assistance on disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

## **Section 7: Handling and Storage**

#### **Precautions:**

Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, reducing agents, metals, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

## Section 8: Exposure Controls/Personal Protection

#### **Engineering Controls:**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

#### **Personal Protection:**

Safety glasses. Lab coat. Gloves (impervious). Dust respirator. Be sure to use an approved/certified respirator or equivalent. The dust respirator should be used for conditions where exposure has exceeded recommended exposure limits, dust is apparent, and engineering controls(adequate ventilation) are not feasible.

#### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

#### **Exposure Limits:**

No exposure guidelines have been established.

ACGIH, NIOSH and OSHA have not developed exposure limits for this product. The exposure limits given below are for particulates not otherwise classified: ACGIH: 10 mg/m3 TWA (Total Inhalable fraction); 3 mg/m3 TWA (Respirable fraction) OSHA: 15 mg/m3 TWA (Total dust); 5 mg/m3 TWA (Respirable Fraction)

## Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (Crystalline powde)

Odor: Odorless.

Taste: Acid. (Strong.)

Molecular Weight: 192.13 g/mole

Color: Not available.

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 153°C (307.4°F)

Critical Temperature: Not available.

**Specific Gravity:** 1.665 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: The product is more soluble in water; log(oil/water) = -1.7

lonicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility:

Soluble in cold water, hot water, diethyl ether. Insoluble in benzene.

## Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, reducing agents, metals, alkalis.

#### **Corrosivity:**

Corrosive in presence of aluminum, of zinc, of copper. Non-corrosive in presence of glass.

#### Special Remarks on Reactivity:

Incompatible with oxidizing agents, potassium tartrate, alkali, alkaline earth carbonates and bicarbonates, acetates, and sulfides, metal nitrates

Special Remarks on Corrosivity: Will corrode copper, zinc, aluminum and their alloys.

Polymerization: Will not occur.

## **Section 11: Toxicological Information**

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 3000 mg/kg [Rat].

Chronic Effects on Humans: May cause damage to the following organs: teeth.

Other Toxic Effects on Humans:

Hazardous in case of inhalation (lung irritant). Slightly hazardous in case of skin contact (irritant, sensitizer), of ingestion.

Special Remarks on Toxicity to Animals: LDL[Rabbit] - Route: oral; Dose: 7000mg/kg

Special Remarks on Chronic Effects on Humans: Not available.

#### Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects:

Skin: Causes mild to moderate skin irritation. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material.

Eyes: Causes moderate to severe eye irritation and possible injury.

Ingestion: May cause gastrointestinal (digestive) tract irritation with nausea, vomiting, diarrhea. Excessive intake may cause erosion of teeth and hypocalcemia (calcium deficiency in blood). May affect behavior/central nervous system (tremor, convulsions, muscle contraction or spasticity).

Inhalation: Causes moderate respiratory tract and mucous membrane irritation.

Chronic Potential Health Effects:

Frequent intake of citrated beverages may cause erosion of dental enamel and irritation of mucous membranes.

## **Section 12: Ecological Information**

Ecotoxicity: Not available.

BOD5 and COD: Not available.

**Products of Biodegradation:** 

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

## **Section 13: Disposal Considerations**

#### Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

## Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

## Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Citric acid

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): CLASS E: Corrosive solid.

DSCL (EEC):

R36/37/38- Irritating to eyes, respiratory system and skin. S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39- Wear suitable gloves and eye/face protection.

#### HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 1

Reactivity: 0

Personal Protection: e

#### National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 1

Reactivity: 0

Specific hazard:

#### **Protective Equipment:**

Gloves (impervious). Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Safety glasses.

## **Section 16: Other Information**

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 04:56 PM

## Last Updated: 11/06/2008 12:00 PM

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Health	2
Fire	3
Reactivity	0
Personal Protection	н

# Material Safety Data Sheet Ethyl Alcohol 190 Proof MSDS

Section 1: Chemical Product and Company Identification		
Product Name: Ethyl Alcohol 190 Proof	Contact Information:	
Catalog Codes: SLE1036, SLE1609, SLE1288	<b>Sciencelab.com, Inc.</b> 14025 Smith Rd.	
CAS#: Mixture.	Houston, Texas 77396	
RTECS: Not applicable.	US Sales: <b>1-800-901-7247</b> International Sales: <b>1-281-441-4400</b>	
TSCA: TSCA 8(b) inventory: Water; Ethyl alcohol 200 Proof	Order Online: ScienceLab.com	
CI#: Not applicable.	<b>CHEMTREC (24HR Emergency Telephone), call:</b> 1-800-424-9300	
Synonym: Ethyl Alcohol 190 Proof		
Chemical Formula: Not applicable.	International CHEMTREC, call: 1-703-527-3887	
	For non-emergency assistance, call: 1-281-441-4400	

## Section 2: Composition and Information on Ingredients

#### **Composition:**

Name	CAS #	% by Weight
Water	7732-18-5	5
Ethyl alcohol 200 Proof	64-17-5	95

**Toxicological Data on Ingredients:** Ethyl alcohol 200 Proof: ORAL (LD50): Acute: 7060 mg/kg [Rat]. 3450 mg/kg [Mouse]. VAPOR (LC50): Acute: 20000 ppm 8 hours [Rat]. 39000 mg/m 4 hours [Mouse].

## Section 3: Hazards Identification

#### **Potential Acute Health Effects:**

Hazardous in case of skin contact (irritant), of eye contact (irritant), . Slightly hazardous in case of skin contact (permeator), of ingestion. Non-corrosive for skin. Non-corrosive to the eyes. Non-corrosive for lungs.

#### **Potential Chronic Health Effects:**

Slightly hazardous in case of skin contact (sensitizer)

CARCINOGENIC EFFECTS: Classified PROVEN by State of California Proposition 65 [Ethyl alcohol 200 Proof].

Classified A4 (Not classifiable for human or animal.) by ACGIH [Ethyl alcohol 200 Proof].

MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. [Ethyl alcohol 200 Proof]. Mutagenic for bacteria and/or yeast. [Ethyl alcohol 200 Proof].

TERATOGENIC EFFECTS: Classified PROVEN for human [Ethyl alcohol 200 Proof].

DEVELOPMENTAL TOXICITY: Classified Development toxin [PROVEN] [Ethyl alcohol 200 Proof]. Classified Reproductive system/toxin/male [POSSIBLE] [Ethyl alcohol 200 Proof].

The substance is toxic to blood, the reproductive system, liver, upper respiratory tract, skin, central nervous

## **Section 4: First Aid Measures**

#### Eye Contact:

Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Cold water may be used. Get medical attention.

#### Skin Contact:

In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

#### Serious Skin Contact:

Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

#### Serious Inhalation:

Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek medical attention.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

#### Serious Ingestion: Not available.

## Section 5: Fire and Explosion Data

Flammability of the Product: Flammable.

Auto-Ignition Temperature: The lowest known value is 363°C (685.4°F) (Ethyl alcohol 200 Proof).

Flash Points: CLOSED CUP: 18.5°C (65.3°F).(estimated)

Flammable Limits: The greatest known range is LOWER: 3.3% UPPER: 19% (Ethyl alcohol 200 Proof)

Products of Combustion: These products are carbon oxides (CO, CO2).

#### Fire Hazards in Presence of Various Substances:

Highly flammable in presence of open flames and sparks, of heat. Slightly flammable to flammable in presence of oxidizing materials. Non-flammable in presence of shocks, of reducing materials, of combustible materials, of organic materials, of metals, of acids, of alkalis.

#### **Explosion Hazards in Presence of Various Substances:**

Slightly explosive in presence of open flames and sparks, of heat, of oxidizing materials, of acids. Non-explosive in presence of shocks.

#### Fire Fighting Media and Instructions:

Flammable liquid, soluble or dispersed in water. SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use alcohol foam, water spray or fog.

#### Special Remarks on Fire Hazards:

Containers should be grounded. CAUTION: MAY BURN WITH NEAR INVISIBLE FLAME Vapor may travel considerable distance to source of ignition and flash back. May form explosive mixtures with air. Contact with Bromine pentafluoride is likely to cause fire or explosion. Ethanol ignites on contact with chromyl chloride. Ethanol ignites on contact with iodine heptafluoride gas. It ignites than explodes upon contact with nitrosyl perchlorate. Additon of platinum black catalyst caused ignition. (Ethyl alcohol 200 Proof) Special Remarks on Explosion Hazards: Ethanol has an explosive reaction with the oxidized coating around potassium metal. Ethanol ignites and then explodes on contact with acetic anhydride + sodium hydrosulfate (ignites and may explode), disulfuric acid + nitric acid, phosphorous(III) oxide platinum, potassium-tert-butoxide+ acids. Ethanol forms explosive products in reaction with the following compound : ammonia + silver nitrate (forms silver nitride and silver fulminate), iodine + phosphorus (forms ethane iodide), magnesium perchlorate (forms ethyl perchlorate), mercuric nitrate, nitric acid + silver (forms silver fulminate) silver nitrate (forms ethyl nitrate) silver(I) oxide + ammonia or hydrazine (forms silver nitride and silver fulminate), sodium (evolves hydrogen gas). Sodium Hydrazide + alcohol can produce an explosion. Alcohols should not be mixed with mercuric nitrate, as explosive mercuric fulminate may be formed. May form explosive mixture with manganese perchlorate + 2.2-dimethoxypropane. Addition of alcohols to highly concentrate hydrogen peroxide forms powerful explosives. Explodes on contact with calcium hypochlorite Vapor may explode if ignited in an enclosed area. Containers may explode when heated or involved in a fire. (Ethyl alcohol 200 Proof)

## Section 6: Accidental Release Measures

#### Small Spill:

Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container.

#### Large Spill:

Flammable liquid.

Keep away from heat. Keep away from sources of ignition. Stop leak if without risk. Absorb with DRY earth, sand or other non-combustible material. Do not touch spilled material. Prevent entry into sewers, basements or confined areas; dike if needed. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

## Section 7: Handling and Storage

#### Precautions:

Keep locked up.. Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe gas/fumes/ vapor/spray. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, acids, alkalis, moisture.

#### Storage:

Store in a segregated and approved area. Keep container in a cool, well-ventilated area. Keep container tightly closed and sealed until ready for use. Avoid all possible sources of ignition (spark or flame). Do not store above 23°C (73.4°F).

## Section 8: Exposure Controls/Personal Protection

Engineering Controls:

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

#### **Personal Protection:**

Splash goggles. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

#### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Vapor respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

#### **Exposure Limits:**

Ethyl alcohol 200 Proof TWA: 1900 (mg/m3) from OSHA (PEL) [United States] TWA: 1000 (ppm) from OSHA (PEL) [United States] TWA: 1900 (mg/m3) from NIOSH [United States] TWA: 1000 (ppm) from NIOSH [United States] TWA: 1000 (ppm) [United Kingdom (UK)] TWA: 1920 (mg/m3) [United Kingdom (UK)] TWA: 1000 STEL: 1250 (ppm) [Canada] Consult local authorities for acceptable exposure limits.

## Section 9: Physical and Chemical Properties

#### Physical state and appearance: Liquid.

#### Odor:

Alcohol like. Mild to strong. Like wine or whiskey; Ethereal, vinous. Pleasant.

Taste: Burning. Pungent.

Molecular Weight: Not applicable.

Color: Clear Colorless.

pH (1% soln/water): Neutral.

Boiling Point: The lowest known value is 78.5°C (173.3°F) (Ethyl alcohol 200 Proof). Weighted average: 79.58°C (175.2°F)

Melting Point: May start to solidify at -114.1°C (-173.4°F) based on data for: Ethyl alcohol 200 Proof.

Critical Temperature: The lowest known value is 243°C (469.4°F) (Ethyl alcohol 200 Proof).

**Specific Gravity:** Weighted average: 0.8 (Water = 1)

Vapor Pressure: The highest known value is 5.7 kPa (@ 20°C) (Ethyl alcohol 200 Proof). Weighted average: 5.53 kPa (@ 20°C) (20°C)

Vapor Density: The highest known value is 1.59 (Air = 1) (Ethyl alcohol 200 Proof). Weighted average: 1.54 (Air = 1)

Volatility: Not available.

Odor Threshold: 100 ppm

Water/Oil Dist. Coeff.: Not available.

lonicity (in Water): Not available.

Dispersion Properties: See solubility in water, methanol, diethyl ether, acetone.

Solubility:

Easily soluble in cold water, hot water, methanol, diethyl ether. Soluble in acetone.

## Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials, heat, sources of ignition.

Incompatibility with various substances: Reactive with oxidizing agents, acids, alkalis.

Corrosivity: Non-corrosive in presence of glass.

#### Special Remarks on Reactivity:

Ethanol rapidly absorbs moisture from the air.

Can react vigorously with oxiders.

The following oxidants have been demonstrated to undergo vigorous/explosive reaction with ethanol: barium perchlorate, bromine pentafluoride, calcium hypochlorite, chloryl perchlorate, chromium trioxide, chromyl chloride, dioxygen difluoride, disulfuryl difluoride, fluorine nitrate, hydrogen peroxide, iodine heptafluoride, nitric acid nitrosyl perchlorate, perchlorate, perchloric acid permanganic acid, peroxodisulfuric acid, potassium dioxide, potassium perchlorate, potassium perchlorate, uranyl perchlorate.

Ethanol reacts violently/expodes with the following compounds: acetyl bromide (evolves hydrogen bromide) acetyl chloride, aluminum, sesquibromide ethylate, ammonium hydroxide & silver oxide, chlorate, chromic anhydride, cyanuric acid + water, dichloromethane + sulfuric acid + nitrate (or) nitrite, hydrogen peroxide + sulfuric acid, iodine + methanol + mercuric oxide, manganese perchlorate + 2,2-dimethoxy propane, perchlorates, permanganates + sulfuric acid, potassium superoxide, potassium tert-butoxide, silver & nitric acid, silver perchlorate, sodium hydrazide, sulfuric acid + sodium dichromate, tetrachlorisilane + water. Ethanol is also incompatible with platinium, and sodium.

No really safe conditions exist under which ethyl alcohol and chlorine oxides can be handled. Reacts vigorously with acetyl chloride (Ethyl alcohol 200 Proof)

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

**Section 11: Toxicological Information** 

Routes of Entry: Absorbed through skin. Eye contact. Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 3632 mg/kg (Mouse) (Calculated value for the mixture).

#### **Chronic Effects on Humans:**

CARCINOGENIC EFFECTS: Classified PROVEN by State of California Proposition 65 [Ethyl alcohol 200 Proof]. Classified A4 (Not classifiable for human or animal.) by ACGIH [Ethyl alcohol 200 Proof]. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. [Ethyl alcohol 200 Proof]. Mutagenic for bacteria and/or yeast. [Ethyl alcohol 200 Proof].

TERATOGENIC EFFECTS: Classified PROVEN for human [Ethyl alcohol 200 Proof].

DEVELOPMENTAL TOXICITY: Classified Development toxin [PROVEN] [Ethyl alcohol 200 Proof]. Classified Reproductive system/toxin/male [POSSIBLE] [Ethyl alcohol 200 Proof].

#### Other Toxic Effects on Humans:

Hazardous in case of skin contact (irritant), of inhalation. Slightly hazardous in case of skin contact (permeator), of ingestion.

## Special Remarks on Toxicity to Animals:

Lowest Published Dose/Conc: LDL[Human] - Route: Oral; Dose: 1400 mg/kg LDL[Human child] - Route: Oral; Dose: 2000 mg/kg LDL[Rabbit] - Route: Skin; Dose: 20000 mg/kg (Ethyl alcohol 200 Proof)

#### Special Remarks on Chronic Effects on Humans:

May affect genetic material (mutagenic) Causes adverse reproductive effects and birth defects (teratogenic), based on moderate to heavy consumption. May cause cancer based on animal data.

## Human: passes through the placenta, excreted in maternal milk. (Ethyl alcohol 200 Proof)

#### Special Remarks on other Toxic Effects on Humans:

Acute potential health effects:

Skin: causes skin irritation

Eyes: causes eye irritation

Ingestion: May cause gastrointestinal tract irritation with nausea, vomiting, diarrhea, and alterations in gastric secretions. May affect behavior/central nervous system (central nervous system depression - amnesia, headache, muscular incoordination, excitation, mild euphoria, slurred speech, drowsiness, staggaring gait, fatigue, changes in mood/personality, excessive talking, dizziness, ataxia, somnolence, coma/narcosis, hallucinations, distorted perceptions, general anesthetic), peripherial nervous system (spastic paralysis)vision (diplopia). Moderately toxic and narcotic in high concentrations. May also affect metabolism, blood, liver, respiration (dyspnea), and endocrine system. May affect respiratory tract, cardiovascular(cardiac arrhythmias, hypotension), and urinary systems. Inhalation: May cause irritation of the respiratory tract and affect behavior/central nervous system with symptoms similar to ingestion. Chronic Potential Health Effects:

Skin: Prolonged or repeated skin contact may casue dermatitis, an allergic reaction.

Ingestion: Prolonged or repeated ingestion will have similiar effects as acute ingestion. It may also affect the brain. (Ethyl alcohol 200 Proof)

## **Section 12: Ecological Information**

Ecotoxicity: Not available.

BOD5 and COD: Not available.

#### Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

## **Section 13: Disposal Considerations**

#### Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

## Section 14: Transport Information

**DOT Classification:** CLASS 3: Flammable liquid.

Identification: : Ethanol (Ethyl alcohol 200 Proof) UNNA: 1170 PG: II

Special Provisions for Transport: Not available.

## **Section 15: Other Regulatory Information**

#### Federal and State Regulations:

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Ethyl alcohol 200 Proof (in alcoholic beverage) California prop. 65: This product contains the following ingredients for which the State of California has found to cause birth defects which would require a warning under the statute: Ethyl alcohol 200 Proof (in alcoholic beverage) Connecticut hazardous material survey .: Ethyl alcohol 200 Proof Illinois toxic substances disclosure to employee act: Ethyl alcohol 200 Proof Rhode Island RTK hazardous substances: Ethyl alcohol 200 Proof Pennsylvania RTK: Ethyl alcohol 200 Proof Florida: Ethyl alcohol 200 Proof Minnesota: Ethyl alcohol 200 Proof Massachusetts RTK: Ethyl alcohol 200 Proof Massachusetts spill list: Ethyl alcohol 200 Proof New Jersey: Ethyl alcohol 200 Proof TSCA 8(b) inventory: Water; Ethyl alcohol 200 Proof

Other Regulations: OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

#### Other Classifications:

#### WHMIS (Canada):

CLASS B-2: Flammable liquid with a flash point lower than 37.8°C (100°F). CLASS D-2B: Material causing other toxic effects (TOXIC).

#### DSCL (EEC):

R11- Highly flammable. S7- Keep container tightly closed. S16- Keep away from sources of ignition - No smoking.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 3

Reactivity: 0

Personal Protection: h

#### National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 3

Reactivity: 0

Specific hazard:

#### **Protective Equipment:**

Gloves. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.

## **Section 16: Other Information**

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 05:28 PM

Last Updated: 11/06/2008 12:00 PM

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# Material Safety Data Sheet Phosphoric acid, 85% MSDS

Section 1: Chemical Product and Company Identification		
Product Name: Phosphoric acid, 85%	Contact Information:	
Catalog Codes: SLP5569, SLP4555, SLP1732	<b>Sciencelab.com, Inc.</b> 14025 Smith Rd.	
CAS#: Mixture.	Houston, Texas 77396	
RTECS: Not applicable.	US Sales: <b>1-800-901-7247</b> International Sales: <b>1-281-441-4400</b>	
TSCA: TSCA 8(b) inventory: Phosphoric Acid; Water	Order Online: ScienceLab.com	
Cl#: Not available.	CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300	
<b>Synonym:</b> Phosphoric Acid 85%; Phosphoric Acid; Orthophosphoric acid	International CHEMTREC, call: 1-703-527-3887	
Chemical Name: Not applicable.	For non-emergency assistance, call: 1-281-441-4400	

Chemical Formula: Not applicable.

## Section 2: Composition and Information on Ingredients

Composition:		
Name	CAS #	% by Weight
Phosphoric Acid	7664-38-2	85-88
Water	7732-18-5	12-15

**Toxicological Data on Ingredients:** Phosphoric Acid: ORAL (LD50): Acute: 1530 mg/kg [Rat]. DERMAL (LD50): Acute: 2740 mg/kg [Rabbit]. DUST (LC50): Acute: >850 mg/m 1 hours [Rat].

## **Section 3: Hazards Identification**

## **Potential Acute Health Effects:**

Very hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, . Hazardous in case of skin contact (corrosive, permeator), of eye contact (corrosive). Slightly hazardous in case of inhalation (lung sensitizer). Liquid or spray mist may produce tissue damage particularly on mucous membranes of eyes, mouth and respiratory tract. Skin contact may produce burns. Inhalation of the spray mist may produce severe irritation of respiratory tract, characterized by coughing, choking, or shortness of breath. Severe over-exposure can result in death. Inflammation of the eye is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, or, occasionally, blistering.

## Potential Chronic Health Effects:

CARCINOGENIC EFFECTS: Not available.

MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available.

DEVELOPMENTAL TOXICITY: Not available.

The substance may be toxic to blood, liver, skin, eyes, bone marrow.

Repeated or prolonged exposure to the substance can produce target organs damage. Repeated or prolonged contact with spray mist may produce chronic eye irritation and severe skin irritation. Repeated or prolonged exposure to spray mist may produce respiratory tract irritation leading to frequent attacks of bronchial infection. Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

## **Section 4: First Aid Measures**

#### Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.

#### Skin Contact:

In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Cover the irritated skin with an emollient. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.

#### Serious Skin Contact:

Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek immediate medical attention.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

#### Serious Inhalation:

Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. WARNING: It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled material is toxic, infectious or corrosive. Seek immediate medical attention.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

## Section 5: Fire and Explosion Data

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: of metals

Explosion Hazards in Presence of Various Substances: Non-explosive in presence of open flames and sparks, of shocks.

Fire Fighting Media and Instructions: Not applicable.

#### Special Remarks on Fire Hazards:

Reacts with metals to liberate flammable hydrogen gas.

Formation of flammable gases with aldehydes, cyanides, mercaptins, and sulfides.

#### Special Remarks on Explosion Hazards: Mixtures with nitromethane are explosive. (Phosphoric Acid)

## **Section 6: Accidental Release Measures**

#### Small Spill:

Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. If necessary: Neutralize the residue with a dilute solution of sodium carbonate.

#### Large Spill:

Corrosive liquid. Poisonous liquid.

Stop leak if without risk. Absorb with DRY earth, sand or other non-combustible material. Do not get water inside container. Do not touch spilled material. Use water spray curtain to divert vapor drift. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Call for assistance on disposal. Neutralize the residue with a dilute solution of sodium carbonate. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

## **Section 7: Handling and Storage**

#### **Precautions:**

Do not ingest. Do not breathe gas/fumes/ vapor/spray. Never add water to this product. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, combustible materials, metals, alkalis.

May corrode metallic surfaces. Store in a metallic or coated fiberboard drum using a strong polyethylene inner package.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

## **Section 8: Exposure Controls/Personal Protection**

#### **Engineering Controls:**

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

#### **Personal Protection:**

Face shield. Full suit. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves. Boots.

#### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Vapor respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Phosphoric Acid TWA: 1 STEL: 3 (mg/m3) from ACGIH (TLV) [United States] TWA: 1 STEL: 3 (mg/m3) from OSHA (PEL) [United States] TWA: 1 STEL: 3 (mg/m3) from NIOSH TWA: 1 STEL: 3 (mg/m3) [Mexico]Consult local authorities for acceptable exposure limits.

## **Section 9: Physical and Chemical Properties**

## Physical state and appearance: Liquid. (Syrupy liquid Viscous liquid.)

Odor: Odorless.

Taste: Acid.

Molecular Weight: Not applicable.

Color: Clear Colorless.

pH (1% soln/water): Acidic.

Boiling Point: 158°C (316.4°F)

Melting Point: 21°C (69.8°F)

Critical Temperature: Not available.

**Specific Gravity:** 1.685 @ 25 C (Water = 1)

Vapor Pressure: 0.3 kPa (@ 20°C)

Vapor Density: 3.4 (Air = 1)

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

lonicity (in Water): Not available.

Dispersion Properties: See solubility in water.

**Solubility:** Easily soluble in hot water. Soluble in cold water.

## Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents, combustible materials, metals, alkalis.

#### Corrosivity:

Extremely corrosive in presence of copper, of stainless steel(304), of stainless steel(316). Highly corrosive in presence of aluminum. Non-corrosive in presence of glass.

#### Special Remarks on Reactivity:

Reacts with metals to liberate flammable hydrogen gas. Incompatible with sodium tetrahydroborate producing a violent exothermic reaction. Heat generated with: alcohols, glycols, aldehydes, amides, amines, azo-compounds, carbamates, caustics, esters, ketones, phenols and cresols, organophosphates, epoxides, combustible materials, unsaturated halides, organic peroxides.

Formation of flammable gases, with aldehydes, cyanides, mercaptins, and sulfides.

Formation of toxic fumes with cyanides, fluorides, halogenated organics, sulfides, and organic peroxides. Do not mix with solutions containing bleach or ammonia. Incompatible with nitromethane, chlorides + staiinless steel. (Phosphoric Acid)

#### Special Remarks on Corrosivity:

Minor corrosive effect on bronze. Severe corrosive effect on brass. Corrosive to ferrous metals and allovs.

Polymerization: Will not occur.

## **Section 11: Toxicological Information**

Routes of Entry: Absorbed through skin. Dermal contact. Eye contact. Inhalation. Ingestion.

#### **Toxicity to Animals:**

Acute oral toxicity (LD50): 1530 mg/kg [Rat]. Acute dermal toxicity (LD50): 2740 mg/kg [Rabbit].

Chronic Effects on Humans: May cause damage to the following organs: blood, liver, skin, eyes, bone marrow.

#### **Other Toxic Effects on Humans:**

Extremely hazardous in case of inhalation (lung corrosive). Very hazardous in case of skin contact (irritant), of ingestion, . Hazardous in case of skin contact (corrosive, permeator), of eye contact (corrosive).

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

#### Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects:

Skin: Corrosive and causes severe skin irritation and can cause severe skin burns. May affect behavior (somnolence or excitement) if absorbed through skin.

Eyes: Corrosive. Liquid or vapor causes severe eye irritation and can cause severe eye burns leading to permanent corneal damage or chemical conjunctivitis.

Ingestion: May be harmful if swallowed. Causes irritation and burns of the gastrointestinal (digestive) tract. Causes severe pain, nausea, vomiting, diarrhea hematemesis, gastrointestinal hemmorrhaging, and shock. May cause corrosion and permanent tissue destruction of the esophagus and digestive tract. May affect behavior and urinary system, liver (hepatocellular damage, hepatic enzymes increased), blood (blood dyscrasia). May also

## Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

#### Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.

#### Special Remarks on the Products of Biodegradation: Not available.

## Section 13: Disposal Considerations

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

## Section 14: Transport Information

**DOT Classification:** Class 8: Corrosive material

Identification: : Phosphoric acid (Phosphoric Acid) UNNA: 1805 PG: III

Special Provisions for Transport: Not available.

## **Section 15: Other Regulatory Information**

#### Federal and State Regulations:

Connecticut hazardous material survey .: Phosphoric Acid Illinois toxic substances disclosure to employee act: Phosphoric acid Illinois chemical safety act: Phosphoric acid New York release reporting list: Phosphoric acid Rhode Island RTK hazardous substances: Phosphoric acid Pennsylvania RTK: Phosphoric acid Minnesota: Phosphoric acid Massachusetts RTK: Phosphoric acid Massachusetts spill list: Phosphoric acid New Jersey: Phosphoric acid New Jersey spill list: Phosphoric acid Louisiana spill reporting: Phosphoric acid California Director's list of hazardous substances: Phosphoric acid TSCA 8(b) inventory: Phosphoric Acid; Water SARA 313 toxic chemical notification and release reporting: Phosphoric acid CERCLA: Hazardous substances.: Phosphoric acid: 5000 lbs. (2268 kg)

Other Regulations: OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200).

#### **Other Classifications:**

WHMIS (Canada): CLASS E: Corrosive liquid.

#### DSCL (EEC):

R34- Causes burns. S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

HMIS (U.S.A.):

Health Hazard: 3

Fire Hazard: 0

Reactivity: 0

**Personal Protection:** 

#### National Fire Protection Association (U.S.A.):

Health: 3

#### Flammability: 0

Reactivity: 0

Specific hazard:

## **Protective Equipment:**

Gloves. Full suit. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Face shield.

## **Section 16: Other Information**

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 08:47 PM

Last Updated: 11/06/2008 12:00 PM

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Health	1
Fire	1
Reactivity	0
Personal Protection	Α

# Material Safety Data Sheet POLYSORBATE 80 MSDS

## Section 1: Chemical Product and Company Identification

Product Name: POLYSORBATE 80

Catalog Codes: SLP4093

CAS#: 9005-65-6

RTECS: WG2935000

TSCA: TSCA 8(b) inventory: POLYSORBATE 80

Cl#: Not available.

**Synonym:** TWEEN 80; Polyoxyethylene 20 sorbitan monooleate; Polyethylene oxide sorbitan mono-oleate; Polyoxyethylene sorbitan monooleate; Polyoxyethylene sorbitan oleate; Sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivatives; Sorethytan (20) monooleate

**Chemical Name:** Sorbitan, monooleate polyoxyethylene deriv.

Chemical Formula: Not available.

#### Contact Information:

Sciencelab.com, Inc. 14025 Smith Rd. Houston, Texas 77396

US Sales: 1-800-901-7247 International Sales: 1-281-441-4400

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: 0	Composition and Info	ormation on Ingredients
--------------	----------------------	-------------------------

**Composition:** 

Name

POLYSORBATE 80

 CAS #
 % by Weight

 9005-65-6
 100

Toxicological Data on Ingredients: Not applicable.

## Section 3: Hazards Identification

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects: CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

## **Section 4: First Aid Measures**

#### Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

#### Skin Contact:

Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

#### Serious Skin Contact: Not available.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

#### Serious Inhalation: Not available.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

#### Serious Ingestion: Not available.

## **Section 5: Fire and Explosion Data**

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: CLOSED CUP: >148.89°C (300°F).

Flammable Limits: Not available.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: Slightly flammable to flammable in presence of heat.

#### **Explosion Hazards in Presence of Various Substances:**

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

#### Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

## Section 6: Accidental Release Measures

Small Spill:

Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

#### Large Spill:

Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by

spreading water on the contaminated surface and allow to evacuate through the sanitary system.

## Section 7: Handling and Storage

#### **Precautions:**

Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe gas/fumes/ vapor/spray. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.

#### Storage:

Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 32.2°C (90°F). Preferably store at temperatures between 50 deg F to 90 deg. F.

## Section 8: Exposure Controls/Personal Protection

#### Engineering Controls:

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal Protection: Safety glasses. Lab coat.

#### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

## Section 9: Physical and Chemical Properties

Physical state and appearance: Liquid. (Oily liquid.)

Odor: fatty (Slight.)

Taste: Not available.

Molecular Weight: Not available.

Color: Clear Amber. Yellow.

pH (1% soln/water): 7 [Neutral.]

Boiling Point: >100°C (212°F)

Melting Point: -20.556°C (-5°F)

Critical Temperature: Not available.

Specific Gravity: 1.06 - 1.10 (Water = 1)

Vapor Pressure: <0.1 kPa (@ 20°C)

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, methanol.

**Solubility:** Easily soluble in cold water, hot water. Soluble in methanol. Soluble in Toluene, alcohol, cottonseed oil, corn oil, Ethyl Acetate. Insoluble in mineral oil.

## Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents.

Corrosivity: Non-corrosive in presence of glass, of stainless steel(304), of stainless steel(316).

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

## **Section 11: Toxicological Information**

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 25000 mg/kg [Mouse].

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

#### Special Remarks on Toxicity to Animals:

Lethal Dose/Conc 50% Kill: LD50 [Rat] - Route: Oral; Dose: 34500 ul/kg

#### Special Remarks on Chronic Effects on Humans:

May cause adverse reproductive effects based on animal test data. No human data found. May cause cancer based on animal test data. No human data found. May affect genetic material (mutagenic)

#### Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: No irritation is expected, but it may cause mild/slight irritation in more sensitive individuals. It will probably not be absorbed through the skin. Eyes: It may cause eye irritation. Inhalation: No expected to be a health hazard. No irritation is expected to be associated with the inhalation of this material. No toxic effects are known to be associated with the inhalation of this material. Ingestion: This material is not likely to cause irritation upon ingestion. It is classified as "relatively harmless" by ingestion and considered to be a low ingestion hazard. Ingestion of very large doses may cause abdominal

spasms and diarrhea. Animal studies have shown it to cause cardiac changes, changes in behavior (altered sleep

time) and weight loss (upon repeated or prolonged ingestion). However, no similar human data has been reported.

# **Section 12: Ecological Information**

Ecotoxicity: Not available.

BOD5 and COD: Not available.

#### **Products of Biodegradation:**

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: Not available.

Special Remarks on the Products of Biodegradation: Not available.

# **Section 13: Disposal Considerations**

#### Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

# Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

# Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: POLYSORBATE 80

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

**Other Classifications:** 

WHMIS (Canada): Not controlled under WHMIS (Canada).

**DSCL (EEC):** This product is not classified according to the EU regulations. Not applicable.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: a

National Fire Protection Association (U.S.A.):

#### Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

#### **Protective Equipment:**

Not applicable. Lab coat. Not applicable. Safety glasses.

# **Section 16: Other Information**

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 11:35 AM

Last Updated: 11/06/2008 12:00 PM

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Health	1
Fire	0
Reactivity	0
Personal Protection	Ε

# Material Safety Data Sheet Sodium chloride MSDS

Section 1: Chemical Product and Company Identification		
Product Name: Sodium chloride	Contact Information:	
Catalog Codes: SLS3262, SLS1045, SLS3889, SLS1669, SLS3091	<b>Sciencelab.com, Inc.</b> 14025 Smith Rd. Houston, Texas 77396	
<b>CAS#</b> : 7647-14-5	US Sales: <b>1-800-901-7247</b>	
RTECS: VZ4725000	International Sales: 1-281-441-4400	
TSCA: TSCA 8(b) inventory: Sodium chloride	Order Online: ScienceLab.com	
Cl#: Not applicable. Synonym:	CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300	
Salt; Sea Salt Chemical Name:	International CHEMTREC, call: 1-703-527-3887	
Sodium chloride Chemical	For non-emergency assistance, call: 1-281-441-4400	
Formula: NaCl		

# Section 2: Composition and Information on Ingredients

Com	position:
00111	poontion.

Name	CAS #	% by Weight
Sodium chloride	7647-14-5	100

**Toxicological Data on Ingredients:** Sodium chloride: ORAL (LD50): Acute: 3000 mg/kg [Rat.]. 4000 mg/kg [Mouse]. DERMAL (LD50): Acute: >10000 mg/kg [Rabbit]. DUST (LC50): Acute: >42000 mg/m 1 hours [Rat].

# **Section 3: Hazards Identification**

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects: CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

# **Section 4: First Aid Measures**

# Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

#### Skin Contact:

Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Serious Inhalation: Not available.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

# **Section 5: Fire and Explosion Data**

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: Not applicable.

#### Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions: Not applicable.

Special Remarks on Fire Hazards: When heated to decomposition it emits toxic fumes.

#### Special Remarks on Explosion Hazards:

Electrolysis of sodium chloride in presence of nitrogenous compounds to produce chlorine may lead to formation of explosive nitrogen trichloride.

Potentially explosive reaction with dichloromaleic anhydride + urea.

# Section 6: Accidental Release Measures

Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water

# Section 7: Handling and Storage

#### Precautions:

Keep locked up.. Do not ingest. Do not breathe dust. Avoid contact with eyes. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents, acids.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Hygroscopic

# **Section 8: Exposure Controls/Personal Protection**

#### **Engineering Controls:**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

#### **Personal Protection:**

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

#### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

# **Section 9: Physical and Chemical Properties**

Physical state and appearance: Solid. (Solid crystalline powder.)

Odor: Slight.

Taste: Saline.

Molecular Weight: 58.44 g/mole

Color: White.

pH (1% soln/water): 7 [Neutral.]

Boiling Point: 1413°C (2575.4°F)

Melting Point: 801°C (1473.8°F)

Critical Temperature: Not available.

Specific Gravity: 2.165 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

## Solubility:

Easily soluble in cold water, hot water. Soluble in glycerol, and ammonia. Very slightly soluble in alcohol. Insoluble in Hydrochloric Acid.

# Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials, high temperatures.

Incompatibility with various substances: Reactive with oxidizing agents, metals, acids.

Corrosivity: Not considered to be corrosive for metals and glass.

## Special Remarks on Reactivity:

Hygroscopic.

Reacts with most nonnoble metals such as iron or steel, building materials (such as cement) Sodium chloride is rapidly attacked by bromine trifluoride. Violent reaction with lithium.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

# **Section 11: Toxicological Information**

Routes of Entry: Inhalation. Ingestion.

#### **Toxicity to Animals:**

WARNING: THE LC50 VALUES HEREUNDER ARE ESTIMATED ON THE BASIS OF A 4-HOUR EXPOSURE. Acute oral toxicity (LD50): 3000 mg/kg [Rat.]. Acute dermal toxicity (LD50): >10000 mg/kg [Rabbit]. Acute toxicity of the dust (LC50): >42000 mg/m3 1 hours [Rat].

**Chronic Effects on Humans:** MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Lowest Published Lethal Dose (LDL) [Man] - Route: Oral; Dose: 1000 mg/kg

# Special Remarks on Chronic Effects on Humans:

Causes adverse reproductive effects in humans (fetotoxicity, abortion, ) by intraplacental route. High intake of sodium chloride, whether from occupational exposure or in the diet, may increase risk of TOXEMIA OF PREGNANCY in susceptible women (Bishop, 1978). Hypertonic sodium chloride solutions have been used to induce abortion in late pregnancy by direct infusion into the uterus (Brown et al, 1972), but this route of administration is not relevant to occupational exposures.

May cause adverse reproductive effects and birth defects in animals, particularly rats and mice (fetotoxicity, abortion, musculoskeletal abnormalities, and maternal effects (effects on ovaries, fallopian tubes) by oral,

intraperitoneal, intraplacental, intrauterine, parenteral, and subcutaneous routes. While sodium chloride has been used as a negative control n some reproductive studies, it has also been used as an example that almost any chemical can cause birth defects in experimental animals if studied under the right conditions (Nishimura & Miyamoto, 1969). In experimental animals, sodium chloride has caused delayed effects on newborns, has been fetotoxic, and has caused birth defects and abortions in rats and mice (RTECS, 1997). May affect genetic material (mutagenic)

#### Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects: Skin: May cause skin irritation. Eyes: Causes eye irritation. Ingestion: Ingestion of large quantities can irritate the stomach (as in overuse of salt tablets) with nausea and vomiting. May affect behavior (muscle spasicity/contraction somnolence) sense organs metabolism and

vomiting. May affect behavior (muscle spasicity/contraction, somnolence), sense organs, metabolism, and cardiovascular system. Continued exposure may produce dehydration, internal organ congestion, and coma. Inhalation: Material is irritating to mucous membranes and upper respiratory tract.

# Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

#### Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

# Section 13: Disposal Considerations

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

# Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

# Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Sodium chloride

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): R40- Possible risks of irreversible effects. S24/25- Avoid contact with skin and eyes.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 0

Reactivity: 0

**Personal Protection: E** 

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 0

Reactivity: 0

Specific hazard:

**Protective Equipment:** 

Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Splash goggles.

# **Section 16: Other Information**

**References:** 

-Hawley, G.G.. The Condensed Chemical Dictionary, 11e ed., New York N.Y., Van Nostrand Reinold, 1987. -SAX, N.I. Dangerous Properties of Indutrial Materials. Toronto, Van Nostrand Reinold, 6e ed. 1984. -The Sigma-Aldrich Library of Chemical Safety Data, Edition II.

Other Special Considerations: Not available.

Created: 10/11/2005 12:33 PM

Last Updated: 11/06/2008 12:00 PM

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Health	3
Fire	0
Reactivity	2
Personal Protection	J

# Material Safety Data Sheet Sodium hydroxide MSDS

Section 1: Chemical Product and Company Identification		
Product Name: Sodium hydroxide	Contact Information:	
Catalog Codes: SLS3298, SLS1081, SLS2503, SLS3925, SLS1705	<b>Sciencelab.com, Inc.</b> 14025 Smith Rd. Houston, Texas 77396	
CAS#: 1310-73-2	US Sales: <b>1-800-901-7247</b>	
RTECS: WB4900000	International Sales: 1-281-441-4400	
TSCA: TSCA 8(b) inventory: Sodium hydroxide	Order Online: ScienceLab.com	
CI#: Not available.	CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300	
Synonym: Caustic Soda	International CHEMTREC, call: 1-703-527-3887	
Chemical Name: Sodium Hydroxide	For non-emergency assistance, call: 1-281-441-4400	
Chemical Formula: NaOH		

# Section 2: Composition and Information on Ingredients

Composition:		
Name	CAS #	% by Weight
Sodium hydroxide	1310-73-2	100

Toxicological Data on Ingredients: Sodium hydroxide LD50: Not available. LC50: Not available.

# Section 3: Hazards Identification

#### **Potential Acute Health Effects:**

Very hazardous in case of skin contact (corrosive, irritant, permeator), of eye contact (irritant, corrosive), of ingestion, of inhalation. The amount of tissue damage depends on length of contact. Eye contact can result in corneal damage or blindness. Skin contact can produce inflammation and blistering. Inhalation of dust will produce irritation to gastro-intestinal or respiratory tract, characterized by burning, sneezing and coughing. Severe over-exposure can produce lung damage, choking, unconsciousness or death. Inflammation of the eye is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, scaling, reddening, or, occasionally, blistering.

#### **Potential Chronic Health Effects:**

CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. The substance may be toxic to mucous membranes, upper respiratory tract, skin, eyes. Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure of the eyes to a low level of dust can produce eye irritation. Repeated skin exposure can produce local skin destruction, or dermatitis. Repeated inhalation of dust can produce varying degree of respiratory irritation or lung damage.

# **Section 4: First Aid Measures**

#### Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.

#### Skin Contact:

In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Cover the irritated skin with an emollient. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.

#### Serious Skin Contact:

Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

#### Serious Inhalation:

Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. WARNING: It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled material is toxic, infectious or corrosive. Seek immediate medical attention.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

# **Section 5: Fire and Explosion Data**

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: metals

**Explosion Hazards in Presence of Various Substances:** Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available. Slightly explosive in presence of heat.

Fire Fighting Media and Instructions: Not available

**Special Remarks on Fire Hazards:** sodium hydroxide + zinc metal dust causes ignition of the latter.

Under proper conditions of temperature, pressure and state of division, it can ignite or react violently with acetaldehyde, ally alcohol, allyl chloride, benzene-1,4-diol, chlorine trifluoride, 1,2 dichlorethylene, nitroethane, nitromethane, nitroparaffins, nitropropane, cinnamaldehyde, 2,2-dichloro-3,3-dimethylbutane. Sodium hydroxide in contact with water may generate enough heat to ignite adjacent combustible materials. Phosphorous boiled with NaOH yields mixed phosphines which may ignite spontanously in air. sodium hydroxide and cinnamaldehyde + heat may cause ignition. Reaction with certain metals releases flammable and explosive hydrogen gas.

#### Special Remarks on Explosion Hazards:

Sodium hydroxide reacts to form explosive products with ammonia + silver nitrate. Benzene extract of allyl benzenesulfonate prepared from allyl alcohol, and benzene sulfonyl chloride in presence of aquesous sodium hydroxide, under vacuum distillation, residue darkened and exploded. Sodium Hydroxde + impure tetrahydrofuran, which can contain peroxides, can cause serious explosions. Dry mixtures of sodium hydroxide and sodium tetrahydroborate liberate hydrogen explosively at 230-270 deg. C. Sodium Hydroxide reacts with sodium salt of trichlorophenol + methyl alcohol + trichlorobenzene + heat to cause an explosion.

# Section 6: Accidental Release Measures

#### Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. If necessary: Neutralize the residue with a dilute solution of acetic acid.

#### Large Spill:

Corrosive solid.

Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Call for assistance on disposal. Neutralize the residue with a dilute solution of acetic acid. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

# Section 7: Handling and Storage

#### Precautions:

Keep container dry. Do not breathe dust. Never add water to this product. In case of insufficient ventilation, wear suitable respiratory equipment. If you feel unwell, seek medical attention and show the label when possible. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, reducing agents, metals, acids, alkalis, moisture.

**Storage:** Keep container tightly closed. Keep container in a cool, well-ventilated area. Hygroscopic. Deliquescent.

# **Section 8: Exposure Controls/Personal Protection**

#### Engineering Controls:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

#### **Personal Protection:**

Splash goggles. Synthetic apron. Vapor and dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

#### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Vapor and dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

#### **Exposure Limits:**

STEL: 2 (mg/m3) from ACGIH (TLV) [United States]

Section 9: Physical and Chemical Prope	erties
Physical state and appearance: Solid. (Deliquescent solid.)	
Odor: Odorless. Taste: Not	
available. Molecular Weight:	
40 g/mole <b>Color:</b> White.	
<b>pH (1% soln/water):</b> 13.5 [Basic.]	
Boiling Point: 1388°C (2530.4°F)	
Melting Point: 323°C (613.4°F)	
Critical Temperature: Not available.	
Specific Gravity: 2.13 (Water = 1)	
Vapor Pressure: Not applicable.	
Vapor Density: Not available.	
Volatility: Not available.	
Odor Threshold: Not available.	
Water/Oil Dist. Coeff.: Not available.	
Ionicity (in Water): Not available.	
Dispersion Properties: See solubility in water.	
Solubility: Easily soluble in cold water.	

# Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials, moisture, moist air

#### Incompatibility with various substances:

Highly reactive with metals. Reactive with oxidizing agents, reducing agents, acids, alkalis, moisture.

Corrosivity: Not available.

#### Special Remarks on Reactivity:

Hygroscopic. Much heat is evolved when solid material is dissolved in water. Therefore cold water and caution must be used for this process. Sodium hydroxide solution and octanol + diborane during a work-up of a reaction mixture of oxime and diborane in tetrahyrofuran is very exothermic, a mild explosion being noted on one occassion. Reactive with water, acids (mineral, non-oxidizing, e.g. hydrochloric, hydrofluoric acid, muriatic acid, phosphoric), acids (mineral, oxidizing e.g. chromic acid, hypochlorous acid, nitric acid, sulfuric acid), acids (organic e.g. acetic acid, benzoic acid, formic acid, methanoic acid, oxalic acid), aldehydes (e.g. acetaldehyde, acrolein, chloral hydrate, foraldehyde), carbamates (e.g. carbanolate, carbofuran), esters (e.g. butyl acetate, ethyl acetate, propyl formate), halogenated organics (dibromoethane, hexachlorobenzene, methyl chloride, trichloroethylene), isocyanates (e.g. methyl isocyanate), ketones (acetone, acetophenone, MEK, MIBK), acid chlorides, strong bases, strong oxidizing agents, strong reducing agents, flammable liquids, powdered metals and metals (i.e aluminum, tin, zinc, hafnium, raney nickel), metals (alkali and alkaline e.g. cesium, potassium, sodium), metal compounds (toxic e.g. berylium, lead acetate, nickel carbonyl, tetraethyl lead), mitrides (e.g. nitrobenzene, nitrobenzene, nitrobenzene, nitrobenzene, nitrobenzene, nitrobenzene, acetoi (organic e.g. nitrobenzene, nitrobenzene, nitrobenzene, nitrobenzene, nitrobenzene, nitrobenzene, sodium nitride), nitriles (e.g. acetonitrile, methyl cyanide), nitro compounds (organic e.g. nitrobenzene, nitrobenzene, nitrobenzene, acylonitrile, phorosous pentoxide, chloroethanol, chloroform-methanol, tetrahydroborate, cyanogen azide, 1,2,4,5 tetrachlorobenzene, cinnamaldehyde. Reacts with formaldehyde hydroxide to yield formic acid, and hydrogen.

Special Remarks on Corrosivity: Very caustic to aluminum and other metals in presence of moisture.

Polymerization: Will not occur.

# Section 11: Toxicological Information

Routes of Entry: Absorbed through skin. Dermal contact. Eye contact. Inhalation. Ingestion.

# **Toxicity to Animals:**

LD50: Not available. LC50: Not available.

#### **Chronic Effects on Humans:**

MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. May cause damage to the following organs: mucous membranes, upper respiratory tract, skin, eyes.

#### Other Toxic Effects on Humans:

Extremely hazardous in case of inhalation (lung corrosive). Very hazardous in case of skin contact (corrosive, irritant, permeator), of eye contact (corrosive), of ingestion, .

#### **Special Remarks on Toxicity to Animals:**

Lowest Published Lethal Dose: LDL [Rabbit] - Route: Oral; Dose: 500 mg/kg

Special Remarks on Chronic Effects on Humans: May affect genetic material. Investigation as a mutagen (cytogenetic analysis)

Special Remarks on other Toxic Effects on Humans:

# Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

#### Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

# **Section 13: Disposal Considerations**

Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

## **Section 14: Transport Information**

DOT Classification: Class 8: Corrosive material

Identification: : Sodium hydroxide, solid UNNA: 1823 PG: II

#### Special Provisions for Transport: Not available.

## **Section 15: Other Regulatory Information**

#### Federal and State Regulations:

Illinois toxic substances disclosure to employee act: Sodium hydroxide Illinois chemical safety act: Sodium hydroxide New York release reporting list: Sodium hydroxide Rhode Island RTK hazardous substances: Sodium hydroxide Pennsylvania RTK: Sodium hydroxide Minnesota: Sodium hydroxide Massachusetts RTK: Sodium hydroxide New Jersey: Sodium hydroxide Louisiana spill reporting: Sodium hydroxide California Director's List of Hazardous Substances: Sodium hydroxide TSCA 8(b) inventory: Sodium hydroxide CERCLA: Hazardous substances.: Sodium hydroxide: 1000 lbs. (453.6 kg)

#### **Other Regulations:**

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

#### **Other Classifications:**

WHMIS (Canada): CLASS E: Corrosive solid.

#### DSCL (EEC):

R35- Causes severe burns. S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S37/39- Wear suitable gloves and eye/face protection. S45- In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

HMIS (U.S.A.):

Health Hazard: 3

Fire Hazard: 0

Reactivity: 2

**Personal Protection:** j

National Fire Protection Association (U.S.A.):

#### Health: 3

Flammability: 0

Reactivity: 1

Specific hazard:

#### **Protective Equipment:**

Gloves. Synthetic apron. Vapor and dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.

# **Section 16: Other Information**

References: Not available.

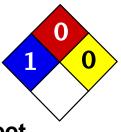
Other Special Considerations: Not available.

Created: 10/09/2005 06:32 PM

Last Updated: 11/06/2008 12:00 PM

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Health1Fire0Reactivity0Personal<br/>ProtectionE

# Material Safety Data Sheet Sodium phosphate monobasic, Anhydrous MSDS

Section 1: Chemical Product and Company Identification		
Product Name: Sodium phosphate monobasic, Anhydrous	Contact Information:	
Catalog Codes: SLS3160, SLS4582	<b>Sciencelab.com, Inc.</b> 14025 Smith Rd.	
CAS#: 7558-80-7	Houston, Texas 77396	
RTECS: WA1900000	US Sales: <b>1-800-901-7247</b> International Sales: <b>1-281-441-4400</b>	
<b>TSCA:</b> TSCA 8(b) inventory: Sodium phosphate monobasic, Anhydrous	Order Online: ScienceLab.com	
Cl#: Not available.	CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300	
<b>Synonym:</b> Sodium phosphate monobasic; sodium dihydrogen phosphate; Monosodium Dihydrogen Phosphate;	International CHEMTREC, call: 1-703-527-3887	
Monosodium Hydrogen Phosphate; Monsodium Orthophosphate, Phosphoric Acid, Monosodium Salt	For non-emergency assistance, call: 1-281-441-4400	
Chemical Name: Sodium Phosphate Monobasic, Anhydrous		

Chemical Formula: NaH2PO4

# Section 2: Composition and Information on Ingredients

CAS #	% by Weight
7558-80-7	100

Toxicological Data on Ingredients: Not applicable.

# **Section 3: Hazards Identification**

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects: CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

# **Section 4: First Aid Measures**

#### Eye Contact:

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

#### Skin Contact:

Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

#### Serious Skin Contact: Not available.

#### Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

#### Serious Inhalation: Not available.

#### Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

#### Serious Ingestion: Not available.

# Section 5: Fire and Explosion Data

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: When heated to decomp ... emits toxic fumes of phosphoxides and sodium oxide.

Fire Hazards in Presence of Various Substances: Not applicable.

Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions: Not applicable.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

# Section 6: Accidental Release Measures

#### Small Spill:

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

#### Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

# Section 7: Handling and Storage

#### **Precautions:**

Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as acids, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area.

## **Section 8: Exposure Controls/Personal Protection**

#### **Engineering Controls:**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Personal Protection:** Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

#### Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

# **Section 9: Physical and Chemical Properties**

Physical state and appearance: Solid. (crystalline powder)

Odor: Odorless.

Taste: Not available.

Molecular Weight: 119.98 g/mole

Color: White.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: Not available.

Critical Temperature: Not available.

Specific Gravity: Not available.

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

lonicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: Easily soluble in cold water, hot water.

# Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials, excess heat, dust generation

Incompatibility with various substances: Reactive with acids, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:

It is a neutralizing agent for acids and caustics. Also incompatible with magnesium and methenamine, and carbonates.

Special Remarks on Corrosivity: When wet, mild steel or brass may be corroded.

Polymerization: Will not occur.

# **Section 11: Toxicological Information**

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 8290 mg/kg [Rat].

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

#### Special Remarks on other Toxic Effects on Humans:

Acute Potential Health Effects:

Skin: May cause skin irritation.

Eye: Dust may cause eye irritation.

Inhalation: It is considered a low hazard for ususal industrial handling. Dust may cause respiratory tract irritation and may affect respiration (mechanically impede respiration).

Ingestion: It is considered a low hazard for usual industrial handling and systemic reactions are unlikely when ingested (because they are slowly and incompletely absorbed in the intestinal tract). The most frequently seen effect is gastrointestinal irritation with abdominal pain and cramping, vomiting, diarrhea. If a significant amount of phosphate is asborbed, the following may occur: mineral imbalance in the body, adversely affecting the osmotic pressure of body fluids resulting in hyperphosphatemia, hypocalcemia, hypomagnesemia. Severe hyperphosphatemia and hypocalcemia may result in tetany, seizures, severe dehydration, metabolic acidosis, hypernaturemia, lethargy, and hyperpyrexia, carpal spasm, and possible. May also affect the cardiovascular system (hypotension, tachycardia, bradycardia, dysrhythmias). The estimated fatal dose is 50 grams. Chronic Potential Health Effects: No information was available.

# Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

#### Products of Biodegradation:

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

# **Section 13: Disposal Considerations**

#### Waste Disposal:

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

#### Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

# **Section 15: Other Regulatory Information**

Federal and State Regulations: TSCA 8(b) inventory: Sodium phosphate monobasic, Anhydrous

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

**DSCL (EEC):** This product is not classified according to the EU regulations. Not applicable.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

#### National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 0

Reactivity: 0

Specific hazard:

**Protective Equipment:** 

Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

# **Section 16: Other Information**

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 06:34 PM

Last Updated: 11/06/2008 12:00 PM

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#### TRIS BASE

#### SECTION 1 - MATERIAL IDENTIFICATION AND INFORMATION

MANUFACTURER'S NAME: ADDRESS:

TELEPHONE NUMBER: US EMERGENCY PHONE: INTERNATIONAL EMERGENCY PHONE:

**CAS NUMBER:** 77-86-1 **RTECS NUMBER:** TY2900000 GENOMIC SOLUTIONS, INC. 4355 VARSITY DR. ANN ARBOR, MI 48108 (734) 975-4800 (800) 535-5053 1(352) 323-3500 (Call Collect)

SUBSTANCE: TRIS BASE

#### **TRADE NAMES/SYNONYMS:**

80-0077, TRIS BASE, 500G; 80-0160, TRIS BASE, 2500G; 2-AMINO-2- (HYDROXYMETHYL) -1,3-PROPANEDIOL; AMINOTRIMETHYLOLMETHANE; AMINOTRIS (HYDROXYMETHYL) METHANE; TRIMETHYLOLAMINOMETHANE; TRIS (BUFFERING AGENT); TRIS BUFFER; TRIS (HYDROXYMETHYL) METHANAMINE; TRIS (HYDROXYMETHYL) METHYLAMINE; TRIS (METHYLOLAMINO) METHANE; TROMETHAMINE; TROMETHANE; TROMETHANE; TROMETHANE; TRIS (HYDROXYMETHYL) AMINOMETHANE; 1,3-PROPANEDIOL, 2-AMINO-2- (HYDROXYMETHYL) -; TRIS (HYDROXYMETHYL) AMINOMETHANE; C4H11NO3.

#### CHEMICAL FAMILY: AMINE, HYDROXYL, ALIPHATIC

<b>CREATION DATE:</b>	6/14/95
<b>REVISED:</b>	2/20/98

#### SECTION 2 - PHYSICAL / CHEMICAL CHARACTERISTICS

COMPONENT: TRIS(HYDROXYMETHYL)AMINOMETHANE CAS NUMBER: 77-86-1 PERCENTAGE: 100 OTHER CONTAMINANTS: NONE

#### PHYSICAL AND CHEMICAL PROPERTIES

DESCRIPTION: Odorless, hygroscopic, crystalline mass or white crystalline powder MOLECULAR WEIGHT: 121.14 MOLECULAR FORMULA: (H-O-C-H2)3-C-N-H2 MELTING POINT: 340-342 F (171-172 C) BOILING POINT: 426-428 F (219-220 C) @ 10 mmHg VAPOR PRESSURE: no data available VAPOR DENSITY: N/A SPECIFIC GRAVITY: not available WATER SOLUBILITY: 55% VOLATILITY: pH: 10.4 @ 1.2% solution ODOR THRESHOLD: no data available EVAPORATION RATE: N/A

#### TRIS BASE

**SOLVENT SOLUBILITY:** Moderately soluble in methanol, ethanol, ethylene glycol, dimethylformamide; slightly soluble in acetone, ether; very slightly soluble in ethyl acetate, cyclohexane, chloroform, carbon tetrachloride.

#### SECTION 3 - FIRE AND EXPLOSION HAZARD DATA

#### **CERCLA RATINGS (SCALE 0-3): HEALTH = 2 FIRE = 1 REACTIVITY = 0 PERSISTENCE = 0 NFPA RATINGS (SCALE 0-4): HEALTH = 2 FIRE = 1 REACTIVITY = 0**

#### **EMERGENCY OVERVIEW:**

Odorless, hygroscopic, crystalline mass or white crystalline powder. Causes respiratory tract, skin and eye irritation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Keep container tightly closed. Wash thoroughly after handling. Use only with adequate ventilation.

#### POTENTIAL HEALTH EFFECTS

#### **INHALATION:**

Short Term Effects: May cause irritation. Additional effects may include coughing, chest pain and difficulty breathing.

Long Term Effects: No information is available.

#### SKIN CONTACT:

Short Term Effects: May cause irritation. Long Term Effects: Same effects as short term exposure.

#### EYE CONTACT:

*Short Term Effects:* May cause irritation. Additional effects may include eye damage. *Long Term Effects:* Same effects as short term exposure.

#### **INGESTION:**

Short Term Effects: May cause gastrointestinal irritation. Additional effects may include burns, digestive disorders and weakness.

Long Term Effects: No information is available.

#### **CARCINOGEN STATUS:**

OSHA: N NTP: N IARC: N

#### FIRE FIGHTING MEASURES

#### FIRE AND EXPLOSION HAZARD:

Slight fire hazard when exposed to heat or flame.

#### **EXTINGUISHING MEDIA:**

Dry chemical, carbon dioxide, water spray or regular foam (1993 Emergency Response Guidebook, RSPA P 5800.6).

For larger fires, use water spray, fog or regular foam (1993 Emergency Response Guidebook, RSPA P 5800.6).

#### FIREFIGHTING:

Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal (1993 Emergency Response Guidebook, RSPA P 5800.6, Guide Page 31).

Use agents suitable for type of surrounding fire. Avoid breathing hazardous vapors, keep upwind.

#### TRIS BASE

FLASH POINT: no data available LOWER FLAMMABLE LIMIT: no data available UPPER FLAMMABLE LIMIT: no data available AUTOIGNITION: no data available

#### HAZARDOUS COMBUSTION PRODUCTS:

Thermal decomposition products may include toxic oxides of carbon and nitrogen.

#### SECTION 4 - REACTIVITY HAZARD DATA

#### STABILITY AND REACTIVITY

#### **REACTIVITY:**

Stable under normal temperatures and pressures.

#### **CONDITIONS TO AVOID:**

May burn but does not ignite readily. Avoid contact with strong oxidizers, excessive heat, sparks, or open flame.

#### **INCOMPATIBILITIES:**

TRIS(HYDROXYMETHYL)AMINOMETHANE: ACIDS: Vigorous reaction ALKALIES (STRONG): Incompatible ALUMINUM: Corrosive BRASS: Corrosive COPPER: Corrosive OXIDIZERS (STRONG): Fire and explosion hazard

#### HAZARDOUS DECOMPOSITION:

Thermal decomposition products may include toxic oxides of carbon and nitrogen.

#### **POLYMERIZATION:**

Hazardous polymerization has not been reported to occur under normal temperatures and pressures.

#### SECTION 5 - HEALTH HAZARD DATA

#### **EMERGENCY FIRST AID**

#### **INHALATION:**

*First Aid* - Remove from exposure area to fresh air immediately. Perform artificial respiration if necessary. Keep person warm and at rest. Treat symptomatically and supportively. Get medical attention immediately.

#### **SKIN CONTACT:**

*First Aid* - Remove contaminated clothing and shoes immediately. Wash with soap or mild detergent and large amounts of water until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

#### EYE CONTACT:

*First Aid* - Wash eyes immediately with large amounts of water or normal saline, occasionally lifting upper and lower lids, until no evidence of chemical remains (at least 15-20 minutes). Get medical attention immediately.

#### TRIS BASE

#### **INGESTION:**

*First Aid* - If vomiting occurs, keep head lower than hips to help prevent aspiration. Treat symptomatically and supportively. Get medical attention if needed.

NOTE TO PHYSICIAN ANTIDOTE: No specific antidote. Treat symptomatically and supportively.

#### **TOXICOLOGY INFORMATION**

TRIS(HYDROXYMETHYL)AMINOMETHANE: **TOXICITY DATA:** 5900 mg/kg oral-rat LD50 1000 mg/kg oral-rabbit LDLo

1800 mg/kg intravenous-rat LD50 1210 mg/kg intravenous-mouse LD50

**CARCINOGEN STATUS:** None **LOCAL EFFECTS:** Irritant- inhalation, skin, eye **ACUTE TOXICITY LEVEL:** Slightly toxic by ingestion **TARGET EFFECTS:** No data available

#### **HEALTH EFFECTS**

#### **INHALATION:**

TRIS(HYDROXYMETHYL)AMINOMETHANE: IRRITANT.

*Acute Exposure:* May cause irritation of the mucous membranes with tightness and pain in the chest, coughing, and difficulty breathing.

Chronic Exposure: No data available.

#### **SKIN CONTACT:**

TRIS(HYDROXYMETHYL)AMINOMETHANE: IRRITANT.

*Acute Exposure:* May cause irritation with redness, pain, and possibly sensitization. *Chronic Exposure:* May cause dermatitis due to irritation or sensitization.

#### **EYE CONTACT:**

TRIS(HYDROXYMETHYL)AMINOMETHANE:

IRRITANT.

*Acute Exposure:* May cause irritation with redness, pain, and possibly corneal damage. *Chronic Exposure:* Prolonged or repeated exposure to irritants may cause conjunctivitis.

#### **INGESTION:**

#### TRIS(HYDROXYMETHYL)AMINOMETHANE:

*Acute Exposure:* May cause gastrointestinal irritation and possibly burns to the mouth and stomach. Large doses to laboratory animals caused weakness, collapse and death. The estimated fatal dose is 50 grams.

Chronic Exposure: No data available.

#### SECTION 6 - CONTROL AND PROTECTIVE MEASURES

#### **EXPOSURE LIMITS:**

No occupational exposure limits established by OSHA, ACGIH, or NIOSH.

#### TRIS BASE

#### **VENTILATION:**

Provide local exhaust ventilation. Ventilation equipment should be explosion-proof if explosive concentrations of dust, vapor or fume are present.

#### **EYE PROTECTION:**

Employee must wear splash-proof or dust-resistant safety goggles to prevent contact with this substance.

#### **EMERGENCY WASH FACILITIES:**

Where there is any possibility that an employee's eyes and/or skin may be exposed to this substance, the employer should provide an eye wash fountain and quick drench shower within the immediate work area for emergency use.

#### **CLOTHING:**

Employee must wear appropriate protective (impervious) clothing and equipment to prevent repeated or prolonged skin contact with this substance.

#### **GLOVES:**

Employee must wear appropriate protective gloves to prevent contact with this substance.

#### **RESPIRATOR:**

The following respirators are recommended based on information found in the physical data, toxicity and health effects sections. They are ranked in order from minimum to maximum respiratory protection. The specific respirator selected must be based on contamination levels found in the work place, must be based on the specific operation, must not exceed the working limits of the respirator and must be jointly approved by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH-MSHA).

Any dust and mist respirator.

Any air-purifying respirator with a high-efficiency particulate filter.

Any powered air-purifying respirator with a dust and mist filter.

Any powered air-purifying respirator with a high-efficiency particulate filter.

Any type 'C' supplied-air respirator operated in the pressure-demand or other positive pressure or continuous-flow mode.

Any self-contained breathing apparatus.

# FOR FIREFIGHTING AND OTHER IMMEDIATELY DANGEROUS TO LIFE OR HEALTH CONDITIONS:

Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

Any supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.

#### SECTION 7 - PRECAUTIONS FOR SAFE HANDLING & USE/LEAK PROCEDURES

#### ACCIDENTAL RELEASE MEASURES

#### **OCCUPATIONAL SPILL:**

#### TRIS BASE

Sweep up and place in suitable clean, dry containers for reclamation or later disposal. Do not flush spilled material into sewer. Keep unnecessary people away.

#### HANDLING AND STORAGE

Observe all federal, state and local regulations when storing this substance. Store away from incompatible substances. Store in a cool, dry place; keep container tightly closed when not in use.

#### **DISPOSAL INFORMATION**

Observe all federal, state and local regulations when disposing of this substance.

#### SECTION 8 - TRANSPORTATION AND REGULATORY INFORMATION

**TRANSPORTATION INFORMATION:** No classification currently assigned

**REGULATORY INFORMATION:** 

 TSCA STATUS:
 Y

 CERCLA SECTION 103 (40CFR302.4):
 N

 SARA SECTION 302 (40CFR355.30):
 N

 SARA SECTION 304 (40CFR355.40):
 N

 SARA SECTION 313 (40CFR372..65):
 N

 OSHA PROCESS SAFETY (29CFR1910.119):
 N

 CALIFORNIA PROPOSITION 65:
 N

SARA HAZARD CATEGORIES, SARA SECTIONS 311/312 (40 CFR 370.21)ACUTE HAZARD:YCHRONIC HAZARD:NFIRE HAZARD:NREACTIVITY HAZARD:NSUDDEN RELEASE HAZARD:N

# TRIS BASE

While the information and recommendations set forth herein are believed to be accurate as of the date hereof, ESA, Inc. makes no warranty with respect thereto and disclaims all liability from reliance thereon.

·---- IDENTIFICATION -----

Stratagene Cloning Systems 11011 N. Torrey Pines Rd. La Jolla, CA 92037 Date of Last Update: 4/16/03 Phone #: 800-894-1304 Fax # : 858-535-0071

Catalog # : 1053-13 CAS # : 1185-53-1 Product Name: Tris-HCl

Chemical Name & Synonyms: Tris Hydrochloride, Molecular Biology Grade Tris-(Hydroxymethyl)-aminomethane hydrochloride, Trizma Hydrochloride Reagent Grade

OSHA PEL Limits: N/A ACGIH TLV: N/A Other Limits Recommended: N/A

KIT 300182 Tris-HCl, Ultrapure molecular biology grade, 1 kilogram

Irritation Data

Irritating to eyes, skin, mucous membranes, and upper respiratory tract.

Toxicity Data No data available.

Reviews, Standards, and Regulations No data available.

Target Organ Data

No data available.

#### ----- Health Hazard Data

Acute/Chronic Effects

May be harmful by inhalation, ingestion, or skin absorption. Causes eye and skin irritation. Material is irritating to mucous membranes and upper respiratory tract.

RTECS #: Data not available. RTECS Name : Data not available.

First	Aid

Skin contact: Wash skin with soap and copious amounts of water for at least 15 minutes. Eve contact: Flush eyes with copious amounts of water for at least 15 minutes. Ingestion: Wash out mouth with water provided person is conscious. Inhalation: Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult give oxygen. In all cases immediately contact a physician. Signs and Symptoms of Exposure: Watery eyes, rough red skin. Medical Conditions Generally Aggravated by Exposure: Respiratory ailments, sensitive skin. Physical Data ———— Molecular Formula  $C_4H_{12}NO_3Cl$ Appearance and Odor Odorless white crystals. Melting point: 149-151 °C. - Fire and Explosion Hazard Data -Extinguishing Media Water spray, carbon dioxide, dry chemical powder, alcohol or polymer foam. **Special Firefighting Procedures** Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Unusual Fire and Explosion Hazards: Emits toxic fumes under fire conditions. Reactivity Data -Incompatibilities Bases, oxidizing agents. Hazardous Combustion or Decomposition Products Thermal decomposition may produce carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride gas. Stability Stable. Avoid extreme heat. Hazardous polymerization Will not occur.

Spill or Leak Procedures

Steps to be taken if Material is Released or Spilled

Ventilate area. Wear respirator, chemical safety goggles, rubber boots, and heavy rubber gloves. Avoid raising dust. Sweep up, place in a sealed container, and hold for waste disposal. Wash spill site after material pickup is complete.

#### Waste Disposal Method (Observe all federal, state, and local environmental regulations.)

The material should be ignited in the presence of sodium carbonate and slaked lime (calcium hydroxide). The substance should be mixed with vermiculite and then with dry caustics, wrapped in paper and burned in a chemical incinerator equipped with an afterburner and scrubber.

#### Precautions to be Taken in Handling and Storage

Label Precautionary Statements No data available.

Exposure Controls/Personal Protection

Wear chemical safety goggles, compatible chemical-resistant gloves, NIOSH/MSHA-approved respirator, and lab apron, or other protective clothing.

An eye wash station and safety shower must be present.

Storage and Handling Precautions

Do not breathe dust. Avoid contact with eyes, skin, and clothing. Avoid repeated or prolonged exposure. Wash thoroughly after handling. Irritant. Hygroscopic. Keep tightly closed. Store in a cool dry place.

#### Ventilation

Mechanical exhaust required.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Stratagene shall not be held liable for any damage resulting from handling or from contact with the above product.



#### Data Sheet

# Mobius<sup>®</sup> CellReady 3L Bioreactor Optimize Your Process With Mobius Single-Use Bioreactor Technology



#### **Mobius CellReady 3L Bioreactor**

- Single-use 3L stirred tank bioreactor
- Pre-assembled and gamma irradiated
- Compatible with your existing controller

The Mobius family of products features single-use bioprocess containers and systems that provide faster turnaround time and reliable performance, right out of the box.

Introducing the Mobius CellReady 3L Bioreactor – a single-use stirred tank bioreactor ideal for bench-scale cell culture. The CellReady bioreactor is pre-assembled and gamma irradiated, significantly reducing turnaround times typically associated with glass bioreactors. The CellReady bioreactor ensures maximum operational flexibility, with pre-fitted weldable tubing and vent filter, two sparging options, and compatibility with most standard bioreactor controller configurations. Designed to replace traditional glass, bench-scale bioreactors, the CellReady bioreactor has additional functionality through integrated side sampling, addition and drain ports. Ready to run right out of the box, allowing for increased flexibility in planning experiments, and freedom from cleaning glassware.



Volume	
Total	3.0 L
Minimum	0.6 L
Working	2.4 L

Dimensions	
Vessel diameter (inner)	5.4" (137.0 mm)
Overall height	9.8" (249.0 mm)
Overall weight	1.5 lb (680.0 g)
Base diameter	9.5" (241.0 mm)
Thermowell diameter	0.3" (7.6 mm)
Impeller diameter (Marine; Scoping)	3.0" (76.2 mm)

Materials	
Vessel, shaft and base	Polycarbonate
Headplate, thermowell and impeller	HDPE
O-rings and seals	Silicone
Ports	
PG 13.5 threaded (2)	Fits standard 12 mm probes (200-235 mm length)

Connection	s					
		C-Flex <sup>®</sup> Clear 082 Tubing ID				
	Loca- tion	1/8″ (3.2mm)	1/4" (6.4mm)	Connec- tor	Filter	One-way Check Valve
Fluid addition 1	Head- plate	yes				
Fluid addition 2	Head- plate	yes	yes	1/8″ Male		
Fluid addition 3	Vessel	yes		Luer with Cap		yes
Fluid addition 4	Vessel	yes				yes
Harvest	Vessel	yes	yes			
Air inlet (overlay)	Head- plate	yes				
Sparge 1 (micro- sparger)	Vessel	yes			yes	yes
Sparge 2 (open pipe)	Vessel	yes				yes
Air outlet (vent)	Head- plate		yes		yes	



# www.millipore.com/cellready

ADVANCING LIFE SCIENCE TOGETHER<sup>™</sup> Research. Development. Production.

Gas Filters			
Overlay and sparge inlets	Millipore Millex® 33 mm 0.22 µm PVDF (hydrophobic)		
Vent outlet	Millipore 50 mm, 0.22 µm nylon (hydrophobic)		
Sampling			
Luer-actuated sampling ports (2)			
Sparging			
Sintered Polyethylene Microsparger (pore size)		15-30 micron	
Open pipe sparger diameter		0.09" (2.3 mm)	
Compatibility			
Motor Drive Adapter required		Integrates with most standard 3L motors	
Heating blankets		Compatible with most standard 3L heating blankets	

Recommended Application: Mammalian cell culture Gamma Irradiated to dose exceeding 25kGy 100% Integrity testing

# ORDERING INFORMATION

Description	Catalog #
Mobius CellReady 3L Bioreactor	CR0003L100
Mobius CellReady 3L motor adapter - Applikon® Style	CR0003L102

In the U.S. and Canada, call toll-free 1-800-MILLIPORE

(1-800-645-5476 1-781.533.6000)

Europe (+31.20.567.2601)

Technical Service (+1.781.533.6000)

Email: orders@millipore.com

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# **Mobius® CellReady 3L platform**

# Single use bioreactor system



# for mammalian cell culture



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#### Introduction

The Mobius<sup>®</sup> CellReady bioreactor is a joint development of Millipore and Applikon Biotechnology. Both partners included their specific knowhow to create a platform of the highest quality. The CellReady platform is fast and easy to set-up and very economical in operation. The CellReady bioreactor is an ideal tool mammalian cell culture development. The system is pre-configured to measure and control pH, temperature, dissolved oxygen (DO) and agitation.

# <u>Features</u>

## Ready to use "out-of-the box"

The 3 liter CellReady bioreactor is ready to use "out-of-the-box". The fully assembled bioreactor is gamma radiated and double-bagged. Connection of sensors, addition bottles and inoculum are the only manipulations required before cultivation begins. The ez-Control system is pre-configured, fully equipped and ready to use."

The total system is completed with tubing, addition bottle and a "starter kit" with spares, even including syringes for sampling. The platform is easy to set-up, requires no special skills or tools, easy to learn and easy to operate.

#### Quality without compromise

Millipore and Applikon take great care in designing bioreactors and control systems. No detail is overlooked, making the system functional, easy to use, reliable and effective. This is the Millipore-Applikon quality advantage, based on their tight collaboration. Some examples:

- A single use bioreactor with exactly the same vessel dynamics as a classical autoclavable bioreactor.
- All tubing on the bioreactor is clear c-Flex suitable for tube welding.
- A very quiet agitation motor is included. This is an important feature in a busy lab work environment.
- The controller is sophisticated yet easy to use by means of the integrated touch screen.
- A USB-stick is included to locally perform software updates. This does not require assistance of an external service engineer.
- Remote viewing and operating of the controller is possible.

#### Ease of use and sophistication in one platform

The CellReady platform provides a unique combination of ease of use and sophistication, reducing the time to start-up a process. The system is equipped with the intelligent and powerful *ez*-Control: easy and intuitive to operate, such that the user-manual might not even be needed.

The *ez-Control* has five control loops (pH, Temperature, Dissolved Oxygen, Level and Stirrer) and can apply a combination of digital and analog outputs. A total of fourteen actuators can be mounted in the cabinet to control the five parameters. Actuators such as rotameters, solenoid valves, MassFlow controllers, pumps and other can be controlled. The operator can set P-I-D values, dead-band for pH control, cascade control strategies, and dose monitors for liquid additions.

#### Compact design

The platform is designed to occupy as small a footprint as possible. All accessories such as pumps and gas flow control valves are conveniently integrated in a compact console. The compact design reduces the need for expensive lab space.



## Materials

The materials in contact with the culture are polycarbonate, high density polyethylene, silicone and nitrile. All of these materials are proven to be non-toxic and chemically inert. All components are carefully selected.

# Safety

Several safety precautions have been taken into account to ensure maximal operator safety and optimal performance. For the platform as described:

- The heating blanket is limited to 80°C to avoid overheating, as stated by the CE guidelines.
- Each actuator can be manually operated to ensure functionality before starting the process.
- A pressure safety switch is built into the control unit to avoid overpressure in the bioreactor.

## Software for data acquisition and supervisory control

The *ez-Control* includes an Ethernet connection port to connect to a PC with software for data acquisition or SCADA such as the Applikon BioXpert packages. BioXpert Lite (data acquisition) is included in this platform. Multiple bioreactors can be connected to one PC for data acquisition.

Optional BioXpert packages are BioXpert 2 and BioXpert XP: SCADA of multiple bioreactors, including cGMP production applications.

## **Cost Saving**

The platform is a pre-packed system. The assembling of the platforms in series provides a cost saving which is for the benefit of the customer.

### Expandable

With only minor additions the control system can be expanded or upgraded. Additional gas lines can be added, mass flow controllers, feed pumps or an IO card including multiple inputs for additional sensors and multiple outputs for controlling pumps or valves.

### Summarising

Overall some of the benefits the CellReady bioreactor platform provides, include:

- dependable and reliable operation = greater productivity and yield
   less downtime, no cleaning or sterilization = greater economy in operation, higher yield to cost ratio
   simple operation = less operator training required, the product can be
  - less operator training required, the product can be put to effective use more quickly



# 1 CellReady 3 L for Cell Culture Application

# 1.1 System description

In the biotechnological and pharmaceutical industry the popularity of the single-use concept is increasing rapidly. Initially, single-use bags were used to store raw materials, intermediates and finished products. Nowadays the single-use technology has migrated towards single-use bioreactor systems, like the CellReady platform. Single-use bioreactor systems offer significant benefits, including lower requirements for cleaning and cleaning validation, lower likelihood of microbial fouling or cross-contamination, and greater opportunities for flexibility and efficiency in both plant design and operations.

The CellReady bioreactor platform comes with 6 bioreactors, which can be used for cell cultures (animal-, insects-, and plant cells). The geometry of the bioreactor is a duplicate of the 3L glass bioreactor, including a top stirrer with marine impeller providing similar mixing times and kLa's.

The bioreactor is equipped with multiple addition-, sample- and harvesting tubing. All tubings are clear cflex, suitable for tube welding. Multiple diameter sizes of tubing are used provided for smaller and larger additions. Each line is also provided with a Luer lock connector. The sample ports are provided with Luer lock connector. Four gas lines are present: gas inlet overlay, open pipe sparger, porous sparger and exhaust gas. All lines are provided with a sterile (vent) filter.

The system is configured to measure and control pH, temperature and dissolved oxygen (DO). Reusable sensors are provided for pH, temperature and dissolved oxygen.

# pH Control

pH is controlled by the *ez*-Control. When pH starts to deviate from setpoint (e.g. below setpoint), the controller activates a peristaltic pump. This pump introduces a liquid base to the culture through one of the addition lines. A non-return valve on the side of the bioreactor prevents medium from mixing with the base in the addition line. A reagent addition bottle is provided for the storage and sterilization of the base. When pH is above setpoint, the controller opens a gas solenoid valve, directing a flow of CO<sub>2</sub> into one of the gas lines of the CellReady bioreactor. A deadband may be set to suspend controller action when the measured pH value is close to the setpoint. The CO<sub>2</sub> gas flow rate can be adjusted using a "direct read" rotameter and needle valve.

### **Dissolved Oxygen Control**

A continuous flow of air can be introduced into the headspace of the bioreactor. A "direct read" rotameter and needle valve can be used to adjust the airflow rate. When the measured process value for DO is below setpoint, the *ez***-Control** automatically opens a solenoid valve directing the flow of oxygen gas to the gas supply line where  $O_2$  is mixed with the air flow, increasing the oxygen concentration in the gas flow to the bioreactor. All these gasses can be entered through an open pipe sparger, porous sparger or via the headspace.

### **Temperature Control**

A heating blanket is used to control temperature. When the measured process value is below setpoint, the *ez*-Control activates the heating blanket to increase the temperature of the culture medium. The heating blanket is wrapped around the bioreactor. Inserts in the heating blanket provide maximum coverage of the working volume of the bioreactor. This actuator provides a simple, proven and effective method for temperature control.



# **Agitation Control**

The bioreactor includes a lipseal stirrer assembly with a scoping type, marine impeller, with the sparger tip located near to the impeller. The agitation system is powered by a reliable and quiet motor. An adapter creates a smooth coupling between the stirrer motor and the CellReady bioreactor.

The CellReady bioreactor and speed controller combination is able to run within a range of 10 - 300 rpm. The encoder feedback loop of the stirrer assembly ensures accurate control; no additional calibration is required.

The motor delivers sufficient torque to maintain accurate agitation even at low agitation rates and when media viscosity may become high due to high cell densities.

## P.I.D.

All process parameters are controlled using P.I.D. (Proportional, Integral, and Derivative) functions. The user independently can define these settings. Also functions such as dead zone for pH control and cascade control can be defined freely. Additionally automatic control of the PID settings, known as adaptive control, can be set simply by just one touch of a button on the screen. During adaptive control, the *ez-Control* will find the optimal PID settings for the process: accurate control and repeatability of experiments are assured.

### **Dose Monitoring**

The *ez*-Control provides dose monitoring capabilities for all liquid and gas additions as performed with the actuators installed. The dose monitor provides a running total of the reagent that has been added to the bioreactor for control purposes (cumulative). Gas addition can be monitored using the optional Mass Flow Controllers. A total of 4 MFC's can be mounted into the *ez*-Control.

### Other

Four gas filters (sterile barrier) are included: for the air outlet line, for the air overlay line and for the two spargers, open pipe and porous. Several addition lines in the side of the bioreactor and the head plate of the reactor provide sufficient options for additions or inoculation. Tubing is clear c-flex suitable for tube welding and available in different sizes. The sampling is done via Luer-actuated sampling ports or via the harvest line at the bottom of the bioreactor.

Included with the platform is a "start-up kit". This kit contains tubing clamps, connection pieces, sample syringes.

BioXpert Lite software is included in the 3 liter platform and can be used to log data. In the detailed functional description (see table), the possibilities of BioXpert Lite are listed. The *ez-Control* provides the possibility to communicate with a computer, through an Ethernet connection. With the optional version of BioXpert 2 or BioXpert XP it is possible to perform supervisory control (SCADA).



# **1.2** Detailed part list

# 1. Bioreactor AppliFlex 20L

Description

# **Bioreactor**

1

Z650000310 CellReady Bioreactor 3 Liter, 6pcs

### **Agitation**

1	Z510000010	Stirrer motor P100
1	Z510120010	Stirrer motor adapter

# Temperature

1 Z350230310 Silicone heating blanket

# 2. Control and actuator system, ez-Control

Quantity Article Description

# **Basic Controller**

1	Z310110011	Basic <i>ez-Control</i>
1	Z310110110	Basic power module

# 3. Sensors

Quantity		Description
	Dissolved Oxyge	<u>n</u>
1	Z010023520	Sensor Dissolved Oxygen, Low drift, L=235 mm
1	Z100200012	Cable DO sensor, L= 2 m, K9-BNC Blue
	<u>рН</u>	
1	Z001023551	Sensor pH+, gel-filled, L=235 mm
1	Z100200010	Cable pH sensor, L= 2 m, K9-BNC Red
	<u>Temperature</u>	
1	Z034150010	Sensor Temperature, OD =6 mm, 1.5 m cable

# 4. Actuators

Quantit	y Article	Description
	Additions	
1	Z310116060	Pump and pump head assembly, 20rpm
2	Z310116040	Blindplate pump position
1	Z364220500	Tubing clear c-flex 1/8"ID x 1/4"OD
1	Z364221000	Tubing clear c-flex 1/4"ID x 3/8"OD
1	Z811301909	Liquid addition bottle 0,5 Liter



	<u>Aeration</u>	
1	Z3RM002020	Rotameter, Direct read, 500L/min Air
1	Z3RM002011	Rotameter, Direct read, 50 ml/min $O_2$
1	Z3RM002051	Rotameter, Direct read, 100 ml/min CO <sub>2</sub>
3	Z310112010	Solenoid valve Air, O <sub>2</sub> , CO <sub>2</sub>
1	Z310112030	Pressure safety for CellReady
1	Z310372030	Basic gas selection block
2	Z311302060	Solenoid valve Air, $O_2$ , $CO_2$

### **Temperature**

1	Z310111020	Heating control assembly <i>ez</i> -Control
---	------------	---

# 5. Software

Quantity	/ Article	Description
1	Z590007200	BioXpert Lite, Data acquisition software for Windows XP, Vista

## **6.Spare Parts & Services**

Quantity	/ Article	Description
	Spare parts	
1	Z811000310	Start-up kit, CellReady 3L

# 7.Optional Add-on packs (not included)

Quantity	y Article Aeration	Description
x	Z310112020	Mass flow controller assembly 24V
	Additions	
х	Z310116050	Advanced pump and pump head assembly
1	Z310116060	Additional fixed speed pump and pumphead (for feed)
1	Z310113010	Bottle rack 3x 0.5L
	<u>System</u>	
1	Z310113030	Set lifting Brackets for <i>ez-Control</i>
	Analog/Digital o	control option
1	Z310114010	AD DA board
	Filter heater	
1	Z310117100	Connection for filter heater
1	Z350002420	Filter heater for CellReady
-	2330002720	The heater for centeday



### 2 **Bioreactor**

# 2.1 CellReady Bioreactor

# Z650000310 CellReady 3L stirred tank single use bioreactor

The CellReady is a stirred tank 3L single use bioreactor. It can be used for non-GMP process development runs for mammalian cell cultures.

# **Bioreactor configuration**

- 1x lipseal stirrer (up to 300 rpm) •
- 1x 3" marine impeller scoping

Head plate

- 2x PG13.5 sensor ports (sensor length 235mm) ٠
- 1x thermopocket for temperature measurement
- 1x addition line ID 3.1 mm (clear c-Flex) •
- 1x addition line ID 4.8 mm (clear c-Flex)
- 1x overlay line with hydrophobic filter •
- 1x off gas line with hydrophobic filter

Side

- 2x luer lock sample ports
- ٠ 2x addition lines with check valve (clear c-Flex)

### Bottom

- 1x drain line ID 4.8 mm (clear c-Flex) ٠
- 1x open pipe sparger with check valve •
- 1x microsparger with check valve •

### **Specifications**

- Total volume
- Minimum working volume :0.6L •
- Maximum working volume
- Maximum temperature
- Maximum operating pressure
- : 70°C

: 3.0L

: 2.4L

- Gamma irradiated •



: < 1 psi, 0,2 barg.



# 2.2 Agitation

# Z510000010 Stirrer motor P100, with encoder

The P100 stirrer motor delivers up to 100 watts of power for agitation. The motor is placed on top of the stirrer assembly without the use of tools. A flexible coupling ensures proper orientation of the motor on the stirrer assembly. A few of the features of the motor include:

- Long life
- High uniform and continuous torque
- Accurate speed control
- Low heat generation and low noise

An encoder feedback signal, which is included in the motor, is used to provide a very accurate control of the motor speed The P100 motor is capable of running up to 1,250 rpm and is also very accurate up to 300 rpm for cell culture applications. The motor complies with Class 1 Safety Standards and comes with a Declaration of Conformity complying with CE requirements.



### TECHNICAL SPECIFICATIONS:

•	Torque	:	0.20 Nm
•	Power	:	100 Watt
•	Diameter	:	55 mm
•	Overall height	:	170 mm
•	Weight	:	1.6 kg

The stirrer is placed on the motor adapter (Z510120010) which is mounted on the bioreactor head plate and smoothens the rotating action.

# 2.3 Temperature

# Z350230310 Silicone heating blanket 230V, 3L CellReady

The silicone heating-blanket is used for temperature control of the single use bioreactor and placed around working volume of bioreactor. Optimal heat transfer is ensured by the tight fixation.

The Pt100 temperature sensor (in the sensor module) is used to measure the temperature in the bioreactor medium. Control is carried out by the temperature control loop of the *ez*-Control.

The heating blanket is connected to the 230 VAC relay output of the *ez*-Control. For safety purposes a thermo cut-off (80°C) is included.

Specifications:

- Materials: Silicone
- Power: 110 Watt
- Weight: Approx. 500 g
- Dimensions (W x D) 180 x 475 mm
- Thermo cut-off @ 80°C



# 3 Control system

# 3.1 ez-Control

# Z310110011 *ez-*Control

The *ez-Control* is a sophisticated controller for running bioprocesses in any bioreactor, presenting the user immediate information of current process values or a graphical display of the historical trend of process parameters. The touch screen operation is user friendly, intuitive and easy to operate. Operator errors are avoided: the controller does not accept additional settings that are out of range.

The *ez*-Control has five control loops:

- pH,
- Temperature,
- Dissolved oxygen,
- Level / Anti-Foam (contact or no-contact, not used),
- Stirrer speed / rocking frequency (manual or remote control)

The control algorithm for pH, Temperature and DO<sub>2</sub> is based on three ingredients (PID):

- "P" Proportional control (controller output relates to current deviation from set point)
- "I" Integral control (controller output relates to integrated deviation from set point)
- "D" Derivative control (controller output relates to the deviation trend)

The controller can be switched to adaptive control to find the optimal PID settings for the operation of the bioreactor.

### **SENSOR INPUT SPECIFICATIONS:**

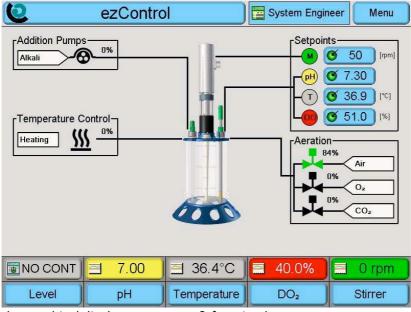
The installed input amplifiers have the following specifications:

pH amplifier:	
Range:	0 - 14 pH
Accuracy:	± 0.01 pH
R <sub>in</sub> :	> 10 <sup>15</sup> Ω
Temperature amplifier:	
Type:	Pt-100
Range:	0 - 150°C
Accuracy:	± 0.1°C
Accuracy.	- 0.1 C
dO <sub>2</sub> amplifier:	
Туре:	Polarographic
Range:	0 - 500 % (air)
Accuracy:	± 0.1 %
Level amplifier:	
Туре:	On/Off signal
Sensitivity	Firmware selectable
High:	> 26 µS — 100 %
Low:	> 200 µS — 100 %





### View of the ez-Control touch screen



Showing the graphical display, parameter & function keys.

### Connections of the ez-Control

At the side and rear of the *ez-Control* connections can be found for sensors, I/O and mains:

### Side connections:

•

- sensor connections
  - pH
    - Temp
  - DO2
  - foam/level
  - Stirrer control
- Heating Blanket
- Filter heater

### Rear side connections:

Gas connections

Air

02

•

•

- N2 (2 barg) : 6 mm Festo quick connector (optional)
  - (2 barg) : 6 mm Festo quick connector
    - : 6 mm Festo quick connector
  - CO2 (2 barg)

(2 barg)

- : 6 mm Festo quick connector
- Ethernet connection (to SCADA)
- USB connection (Firmware update)
- Alarm connector : 9-pin D-sub
- Main power : 230 V
- Fuses

- : 4x 5A slow blow
- ADDA card (Optional) : 37-pin D-sub, 25-pin D-sub (optional)
- page 12 of 18

- : BNC
- : 3-pin Audio
- : BNC
- : 2-pin Audio (not used)
  - : 5-pin audio (stirrer), 8-pin Audio (encoder)
  - : 3-pin AC-connector
- : 2-pin audio connector (optional)



# 4 Sensors

# 4.1 Dissolved oxygen

# Z010023520 Dissolved Oxygen sensor, Low Drift

The AppliSens Low Drift DO sensor offers a guaranteed low drift.

### Features:

The sensor is constructed using FDA approved materials

- Cable connector, identical to the one as with the pH sensor
- 12mm diameter body
- PG13.5 connector, free spinning (easy mounting)
- a Long-Life code print (engraved serial number) is present on the sensor head
- Optimal cleanability (fully electropolished surface (Ra <0.8\*m)
- Each sensor is accompanied by a certificate (good for validation; FDA / GLP).

The combination of a small cathode with a composite membrane along with

a highly permeable reinforced silicon membrane results in:

- low flow dependency
- good response time
- high mechanical strength
- maintenance free operation over several months
- easy maintenance

# 4.2 pH

# Z001023551 sensor pH+

The AppliSens pH+ sensor is the ultimate pH sensor for bioprocess measurement. The pH+ sensor has a fixed sleeve diaphragm. Compared to other diaphragm types, the sleeve diaphragm offers increased measuring accuracy and precision, resulting in excellent performance:

- No cross contamination
- Precise calibration
- Not sensitive to fouling
- No need to recalibrate
- Low and constant offset
- Stable signal over time

The sensor is constructed using FDA approved materials, like the non-toxic solid gel electrolyte. Furthermore this sensor has an internal pressure, which reduces cross contamination in culture experiments. The pH sensor is designed to withstand repeated sterilization cycles without failure. AppliSens sensors have a Long-Life code print (engraved serial number) on the sensor head and are accompanied by a certificate (good for validation; FDA / GLP).

nead and are decompanied by a certificate (good for variation, i bit) o

The electrode has a 12 mm body and a PG13.5 connector.



# 4.3 Temperature

## Z034150010 Temperature sensor, Pt100.

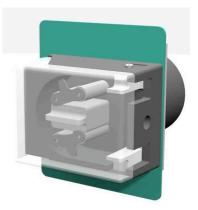
The Pt100 temperature sensor is a platinum RTD probe. The sensor length is 200mm combined with a cable of 1.5 meter length. The cable is a three-wire assembly to compensate for resistance of the cable and it terminates with 3 pins audio connector. The sensor sheath has a diameter of 6 mm and is designed to fit into a CellReady temperature pocket. The temperature sensor is according to type PT100  $\frac{1}{2}$  Class B.

# 5 Actuators

# 5.1 Pumping

## Z310116060 Fixed speed pump, 20 RPM and pump head standard

The pump drive is installed within the *ez*-Control and is controlled by one of the control loops. Via the touch screen operation it is possible to exclude the pump from the control loop. In manual mode the pump can be primed (to fill the tubing) or used for dedicated additions of reagents. In case the pump is excluded from the control loop it could be operated by a SCADA program, for custom additions to the bioreactor. The pump drive operates at a fixed rate of 20 rpm and is powered by 24 V. The pump is supplied with a Watson and Marlow pump head 102R. Flow rate is dependent upon tubing which is being used. Pump tubing sizes 13, 14, 16 and 25 can applied. The tubing is placed in the tubing bed, between the rollers and housing of the pumphead, where it is occluded. When the pump is activated, the rollers on the rotor move across the tubing, pushing the fluid. The tubing behind the rollers recovers its shape, creates a vacuum and draws fluid in behind it.



### Z310116040 Blind plate

This blind plate is used to cover any unused positions in the *ez-Control* when a pump drive is not installed. The blind plate can be removed and a pump drive may be installed in this location in the future.

- 1 Z364220500 Tubing clear c-flex 1/8"ID x 1/4"OD
- 1 Z364221000 Tubing clear c-flex 1/4"ID x 3/8"OD

### Z36422xx00 Clear c-flex tubing

This tubing is used with the standard applied pump heads as present in the *ez-Control*. The clear c-flex tubing is FDA approved and meets FDA classification FDA 21 CFR 177.1810. It has an excellent biocompatibility and has good physical compression capability. This tubing offers a long lifetime with good flow consistency. The tubing is excellent for tube welding. The tubing contains no additives or plasticizers and is weather resistant as well as resistant for ozone (corona) and radiation. It is odourless, is non-toxic and resistant for fungi. The tubing is translucent and light amber. Silicone tubing can be autoclaved and has a temperature range of -73 to 135°C and is easy to clean with distilled water. The tubing is delivered in rolls of 7.5 m and in 2 different sizes:

-Size 1/8"ID x 1/4"OD for small liquid and gas additions

-Size 1/4"ID x 3/8"OD for larger liquid and gas additions



# Z811301909 Liquid addition bottle, volume = 0.5 liter.

The liquid addition bottle is applied to make sterile additions and typically is connected to an addition pipe in the bioreactor by means of silicone tubing. The addition bottle is sterilised in the autoclave e.g. in combination with the bioreactor. The bottle includes a suction unit located in the cap of the bottle. The cap is sealed by a silicone o-ring. When liquid is pumped into the bioreactor, vacuum in the bottle is relieved through the vent, which is located in the cap with a sterile filter attached to it. Extra addition bottles can be sterilised separately and connected to the bioreactor during the process using a flaming technique or a tube welder.

Material of construction (bottle): BorosMaterial of construction suction unit: PeekConnection for tubing: 3 andAdvised tubing size: ID 4.8

Borosilicate glass
Peek
3 and 6mm serrated hose barb
ID 4.8 mm (size 25 to filter), ID 1.6 mm (size 14 to pump)

# 5.2 Aeration

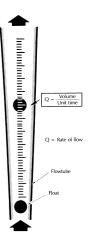
# **Rotameter Direct Reading Scale**



The rotameter assembly is used to measure and adjust gas flow rates. The scale length is 60 mm which allows for greater precision in determining actual flow rate.

A contrasting yellow background enhances readability.

The rotameter assembly comes with a high precision-metering valve that is located at the outlet position of the rotameter assembly. This needle valve allows for adjustment of the flow rate and provides high sensitivity control and resolution. Direct reading scales indicate flowrates in *direct* engineering units such as millilitres per minute [ml/min]. Such scales are designed exclusively for a specific gas at a given set of pressure and temperature conditions and are valid for the associated units of flow.



# SPECIFICATIONS:

- Scale:
- Accuracy:

direct reading ± 5%, full scale

Z3RM002016Rotameter Direct Reading, 500 ml/min (Air)Z3RM002006Rotameter Direct Reading, 50 ml/min (O2)Z3RM002046Rotameter Direct Reading, 100 ml/min (CO2)

# Z310112010 Solenoid valve for Air, O<sub>2</sub> and CO<sub>2</sub>

To control the gas flow through a rotameter, a solenoid valve is installed on the inlet side of the rotameter. The solenoid valve is controlled by a signal from the *ez-Control*. The solenoid valve operates on 24 VDC. The valves are closed during overpressure in the bioreactor.



page 15 of 18



# Z310372030 Basic gas selection block

The gas selection block is build into the ez-Control and allows the customer to change the flow of the gasses between the sparger and overlay connection. During the start of the cultivation the gasses can be directed over the head space of the bioreactor and when more aeration is required the flow can be switched to the sparger line by turning the valve in the gas selection block. The gas lines exit the ez-Control using the bulkhead connectors (Z311302060).

# Z310112030 Pressure switch ez-Control

The pressure switch is build into the *ez-Control console* and applied to avoid overpressure in the bioreactor. All gasses are lead to a manifold of which the outlet is connected to the gas inlet of the bioreactor.

A pressure sensor, also connected to the manifold, controls the gas pressure in the bioreactor. In case the pressure in the bioreactor increases above 0.06 barg, the switch automatically closes the solenoid valves, thus stopping the gas flow to the CellReady bioreactor. When the pressure decreases below this setpoint, the valves will be opened again. During the time the valves are closed, the controller will interrupt the I-Time of the PID control to avoid high controller outputs.

# 5.3 Temperature

# Z310111020 Heating blanket assembly

The heating blanket assembly is located in the bottom section of the *ez-Control*. It contains the 230V connection for the heating blanket and a transformer for safety purposes. The connector for the heating blanket is mounted at the side of the *ez-Control*.



# 6 BioXpert Lite

6.1 FEATURES	BioXpert Lite		
GENERAL			
Operating system	Windows XP, Vista		
Communication drivers included	ADI 1010, <i>ez-</i> Control, AppliFlex Rocker		
Measurement of process values from process controllers	Yes		
Control of process setpoints in process controllers	No		
Starting and stopping of control loops	No		
Programming of local process controllers	No		
Reading of calibration data	No		
21 CFR part 11 compliant	No		
GAMP 4 compliant	Yes		
ISA S88 standard	No		
Password protection	No		
User definable access rights	No		
Auto start after power failure	No		
DATA MANAGEMENT			
On line data collection	Yes		
Off line data collection	Yes		
Additional drivers available separately	No		
Data storage system	Proprietary file format		
FEATURES			
Minimum sampling frequency	1 minute		
Sample frequency selectable per parameter	No		
Data export to Excel	Yes		
Data export in ASCII format	Yes		
Graph export in BMP format	Yes		
On-line calculations using on-line and off-line data	No		
DATA DISPLAY			
Line graphs	Yes		
Bar graphs	Yes		
Synoptic	Yes		
Procedure flow chart	No		
Combination of current and historic data in graphs	Yes		
Combination of different active batches in graphs	Yes		
Measured data table display	Yes		
Scatter plots	Yes		
Storage of predefined graph settings	Yes		



6.1 FEATURES	BioXpert Lite
SUPERVISORY CONTROL	
Programming of time based actions	No
Programming of event based actions	No
Profiling of setpoints	No
Manual setting of local control setpoints	No
Recipe definition	No
OTHER	
Notebook for process and equipment remarks	Yes
Event viewer for system comments	Yes
Audit trail	No
Batch reports supported	No

# 7 Spare parts

# Z811000310 Start-up kit

This kit contains several parts included in a box

- different Luer connectors
- different tubing reducers
- cable ties
- different T-connectors
- 6 tubing clamps
- syringes for sampling



### BIO-PHARM

# **Clean-In-Place (CIP) Systems**

A Custom CIP Solution at a Cost-Effective Price

**Sani-Matic CIP Systems** are engineered to your specific plant application and utility requirements for effective and efficient cleaning of process equipment. Proper CIP design and sizing ensures sufficient flow and appropriate pressure to thoroughly remove residue and rinse effectively while saving cycle time, reducing operating costs, and promoting worker safety.

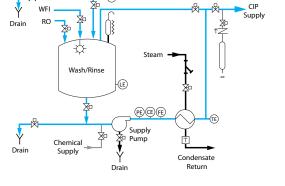
## Why Choose a Sani-Matic CIP System?

- · Engineered for each unique plant and application requirement
- Programming provides integration of CIP functions with existing control systems
- · Construction by our Wisconsin craftsmen to meet ASME-BPE
- Control panels built in our UL authorized panel shop (#E115505)
- · Complete documentation to comply with regulatory and validation requirements
- · Data acquisition and printout to collect and report data
- · Full technical support during and after installation

# One-Tank

Single-Use

- Single-use application source of cleaning solution and rinse water
- · Lower capital investment
- · Portable or stationary design
- Once-through or recirculated
- · Lower space requirement



- CIP Return

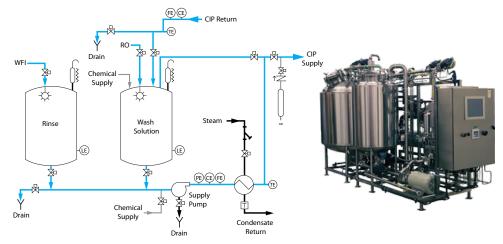
FECE



# Multi-Tank

Wash and Rinse

- Single-use application source of cleaning solution and rinse water
- Portable or stationary design
- Once-through or recirculated
- Used where water utilities are limited
- Decreases cycle time by filling rinse tank during wash step





## BIO-PHARM

# Controls

Sani-Matic has in-house programmers and a UL panel shop to design, manufacture, pre-test, startup and support all types of control systems for cleaning needs. Because the team specializes in cleaning applications, Sani-Matic has developed expertise and efficiencies that have advantages over other fabricators or process integrators. Sani-Matic has designed, manufactured and supported thousands of CIP systems and other cleaning related systems.

Understanding the unique aspects of an effective cleaning program, Sani-Matic developed a flexible and easy-to-understand OP-Code Recipe Editor that allows the customer to manipulate the system hardware to optimize their cleaning programs. This can result in shorter cycle times, lower water and chemical usage, more precise control of setpoints, and defined alarms that reduce troubleshooting time.

# Chemical Skids

- · Eliminates chemical drum handling
- Utility source for all CIP skids
- Integrated into CIP system controls
- · Can be designed as a bulk distribution system or with multiple chemical pumps for targeted delivery

# **Spray Balls**

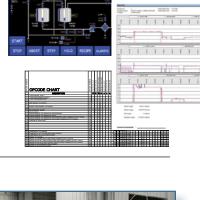
- Custom engineered in 3D
- · Precision drilled on CNC machine
- Pass Riboflavin testing first time
- Documented for future replacement without revalidating

# **Documentation**

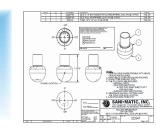
- · Operation and maintenance manuals
- · Recommended spare parts list
- Instrument lists
- Instrumentation calibration procedures
- Performance data
- Material certificates
- · Weld qualification and inspection records
- Inspection test results, reports and certificates
- ASME data
- Component catalog cut sheets
- · As built assembly drawings
- As built process and instrumentation diagrams
- As built electrical drawings
- Annotated PLC ladder diagrams

# **OPTIONAL**

- (FRS/FDS) Functional Design Specifications
- Control System Design Specification (HRS and SRS)
- (FAT) Factory Acceptance Test report
- (SAT) Site Acceptance Test document
- IQ/OQ installation and operation gualification
- Traceability matrix
- ISA Data Sheet
- Cleaning and passivation report
- Weld video record (Boroscope)













SANI+MATIC

# **Corning Life Sciences Selection Guide**



Drug Discovery

Genomics

General Labware



# Introduction

Corning Life Sciences is pleased to present our Life Sciences Selection Guide. In this guide, you will find a selection of Corning's newest and most requested products.

For up-to-date information on Corning Life Sciences' comprehensive range of products and services, go to **www.corning.com/lifesciences** where you can access:

- New Products Information
- Technical Information including:
  - Application Notes
  - Instruction Manuals
  - Product Bulletins
- Educational Opportunities
- Product Catalog Information
- Product Literature
- Complete Distributor Information

For additional product information, please visit **www.corning.com/ lifesciences**, or contact our customer services team listed on the back cover.

# **Ordering Information**

Corning products are available as follows:

• Directly from Corning's European Distribution Centre. To place your order, simply contact us as follows:

**France** t 0800 916 882 f 0800 918 636 ServiceClients@ corning.com **Germany** t 0800 101 1153 f 0800 101 2427 Kundenbetreuung@ corning.com **The Netherlands and All Other Countries** t +31 20 659 6051 f +31 20 659 7673 cceurnl@corning.com

# United Kindgom

t 0800 376 8660 f 0800 279 1117 UKCustomerService@ corning.com

Through any Corning Distributor – please visit our website for a full listing. To place an order, simply contact the Distributor of your choice. For each requested product, provide the Corning catalogue number, product description, and desired quantity.



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# Cell Culture

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# Overview

### **DESIGNED FOR PERFORMANCE**

Corning Life Sciences offers a full line of cell culture products that are manufactured under strict process controls guaranteeing consistent product performance. All Corning Life Sciences plastics manufacturing facilities are ISO 9002 registered. ISO registration is recognized worldwide as a standard of excellence for quality systems.

In addition, customers can now request a Certificate of Quality for any Corning<sup>®</sup> or Costar<sup>®</sup> cell culture product. This certificate details lot-specific information on component materials, sterility testing, pyrogen testing, cell attachment, and growth characteristics.

Also available are detailed product descriptions and drawings that highlight product dimensions and testing procedures. All are available simply by calling your local Corning Life Sciences office.

### ADDITIONAL QUALITY ASSURANCES

### Nonpyrogenic Certification



<u>nn</u>

Most Corning and Costar cell culture products are certified nonpyrogenic with a documented endotoxin level of equal to or less than 0.1 EU/mL. Endotoxins have been shown to cause variability in cell culture. Nonpyrogenic certification is just another way Corning helps ensure consistent cell culture results. Corning also offers a detailed technical bulletin on the effects of endotoxins in cell culture. This may be obtained by calling your local Corning Life Sciences office or by downloading the bulletin from the Corning web site www.corning.com/lifesciences.

### Lot Number Traceability

To ensure accurate lot number traceability in biotechnology research and production facilities, all Corning and Costar cell culture flasks and most roller bottles feature a lot number individually printed on each product. Lot number traceability helps simplify quality assurance procedures for tracking and monitoring production and research processes.

### **Consistent Surface Chemistry**

All Corning and Costar cell culture products are produced in FDA-registered facilities. Cell culture products are made from USP Class VI materials in accordance with documented manufacturing procedures. By carefully controlling both the materials we use and our manufacturing process, Corning is able to provide consistent surface chemistries across our entire line of cell culture products. This consistency increases the researcher's ability to produce reliable results.

# **Cell Culture Flasks**

Corning® and Costar® flasks are available in a variety of sizes, designs and cap styles to meet your needs.

- Manufactured from optically clear virgin polystyrene
- Treated for optimal cell attachment
- Printed with lot numbers for ease in traceability
- ▶ 100% integrity tested
- Sterilized by gamma irradiation
- Certified nonpyrogenic

### **Flask Cap Styles**



**Plug seal caps** feature one-piece linerless construction and are designed for use in closed systems, providing a liquidand gas-tight seal. When loosened, this cap can also be used in open systems. This cap design was a Corning innovation that first appeared in 1974.



open systems requiring gas exchange. With the caps slightly loosened, gas is exchanged between the environments inside and outside of the flask.

Phenolic style caps are designed (when loosened) for use in

Vent caps contain a 0.2  $\mu$ m nonwettable membrane sealed to the cap, providing consistent, sterile gas exchange while minimizing the risk of contamination. These caps are highly recommended for use in all CO<sub>2</sub> incubators, especially for longterm use. The vent cap was a Corning innovation that first appeared in 1988.

### **Flask Neck Styles**

|--|--|--|

Straight neck flasks are ideal for larger medium volumes since this design reduces medium sloshing into the cap.



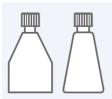
Canted neck flasks allow easier pouring and improved access to the flask for pipetting or scraping. The canted neck design was a Corning innovation that first appeared in 1974.



Angled neck improves pipette access and reduces medium sloshing into the neck. This patented design was a Corning innovation that first appeared in 1988.

### **Flask Shapes**

Choosing a flask shape is usually a matter of personal preference:



Triangular and modified triangular flasks offer good pipette and cell scraper access to the corners. The wider base provides added stability.



Rectangular flasks have a ramp from the bottom to the canted neck for easier pouring and pipette access. Most canted neck flasks also have an antitip skirt to enhance stability.



Angled neck and traditional straight neck flasks utilize the entire bottom area for cell growth. Their design saves on space and reduces medium sloshing into the neck.



RoboFlask" vessels are robotics-compatible cell culture flasks offering 92.6 cm<sup>2</sup> cell growth surface area. The flasks are designed for use in automated cell culture systems utilizing a microplate-size format.



**3056** 25 cm<sup>2</sup> Triangular Flask with Vent Cap



**430639** 25 cm<sup>2</sup> Canted Neck Flask with Vent Cap



### 25 cm<sup>2</sup> Growth Area Flasks

Cat. No	o. Surface	Flask Style	Neck Style	Cap Style	Qty/Pk	Qty/Cs
430168	ТС	Rectangular	Canted	Plug Seal	20	500
430372	ТС	Rectangular	Canted	Phenolic-Style	20	500
430639	ТС	Rectangular	Canted	Vent Cap	20	200
3055	ТС	Triangular	Angled	Phenolic-Style	20	500
3056	ТС	Triangular	Angled	Vent Cap	10	200
3289	Corning® CellBIND® Surface	Rectangular	Canted	Vent Cap	20	200

# 75 cm<sup>2</sup> Growth Area Flasks

Cat. No	. Surface	Flask Style	Neck Style	Cap Style	Qty/Pk	Qty/Cs
430641	ТС	Rectangular	Canted	Vent Cap	5	100
430720	TC	Rectangular	Canted	Plug Seal	5	100
430725	TC	Rectangular	Canted	Phenolic-Style	5	100
3275	TC	Modified triangular	Straight	Phenolic-Style	5	100
3276	TC	Modified triangular	Straight	Vent Cap	5	100
3375	TC	Rectangular	Canted	Phenolic-Style	5	100
3376	TC	Rectangular	Canted	Vent Cap	5	100
3290	Corning CellBIND Surface	Rectangular	Canted	Vent Cap	5	100



**430641** 75 cm<sup>2</sup> Canted Neck Flask with Vent Cap



**3376** 75 cm<sup>2</sup> Canted Neck Flask with Vent Cap



**3275** 75 cm<sup>2</sup> Triangular Flask with Phenolic-Style Cap



**3070** RoboFlask<sup>™</sup> Cell Culture Vessel with Septum Cap



**431306** 175 cm<sup>2</sup> Bar Coded Flask with Vent Cap



**430823** 150 cm<sup>2</sup> Canted Neck Flask with Plug Seal Cap

### 92.6 cm<sup>2</sup> Growth Area RoboFlask<sup>™</sup> Vessels

Cat. No.	Description	Qty/Pk	Qty/Cs
3070	RoboFlask Cell Culture Vessel for automation, tissue culture treated, with bar code, septum cap, sterile	20	100
3071	RoboFlask Cell Culture Vessel for manual use, tissue culture treated, with bar code, flat cap (without septum), sterile	20	100
3069	RoboFlask Cell Culture Vessel for automation, tissue culture treated, with bar code, septum cap, sterile	10	50
3059	RoboFlask Cell Culture Vessel for manual use, tissue culture treated, with bar code, flat cap (without septum), sterile	10	50
3067	RoboFlask Cell Culture Vessel for automation, Corning® CellBIND® surface treatment with bar code, septum cap, sterile	20	100
3068	RoboFlask Cell Culture Vessel for automation, Corning CellBIND surface treatment with bar code, septum cap, sterile	10	50

### 150 cm<sup>2</sup> Growth Area Flasks

Cat. No.	Surface	Flask Style	Neck Style	Cap Style	Qty/Pk	Qty/Cs
430823	ТС	Rectangular	Canted	Plug Seal	5	50
430824	ТС	Rectangular	Canted	Phenolic-Style	5	50
430825	ТС	Rectangular	Canted	Vent Cap	5	50
3291	Corning CellBIND Surface	Rectangular	Canted	Vent Cap	5	50

### 175 cm<sup>2</sup> Growth Area Flasks

Cat. No.	Surface	Flask Style	Neck Style	Cap Style	Qty/Pk	Qty/Cs
431079	ТС	Rectangular	Angled	Plug Seal	5	50
431080	TC	Rectangular	Angled	Vent Cap	5	50
431085	ТС	Rectangular	Angled	Phenolic-Style	5	50
431306*	ТС	Rectangular	Angled	Vent Cap	7	84
431328*	Corning CellBIND Surface	Rectangular	Angled	Vent Cap	7	84
3292	Corning CellBIND Surface	Rectangular	Angled	Vent Cap	5	50
3298	CorningCellBIND Surface	Rectangular	Angled	Phenolic-Style	5	50

\*Flask prelabeled with bar code, validated for use with Selec  $T^{\,{}_{\rm TM}}$  Robotic System.

## Cell Culture Flask Application Tip

Corning recommends 0.2 to 0.3 mL of medium per  $cm^2$  of growth area.

## Cell Culture Flask Selection Tip

The 235 cm<sup>2</sup> Expanded Surface flask has the same footprint as the 175 cm<sup>2</sup> flasks.



**431346** 235 cm<sup>2</sup> Expanded Growth Area Flask with Bar Code

5



**431082** 225 cm<sup>2</sup> Angled Neck Flask with Vent Cap



**3001** 225 cm<sup>2</sup> Canted Neck Flask with Vent Cap

### 225 cm<sup>2</sup> Growth Area Flasks

Cat. No.	Surface	Flask Style	Neck Style	Cap Style	Qty/Pk	Qty/Cs
431081	TC	Traditional	Canted	Plug Seal	5	25
431082	ТС	Traditional	Canted	Vent Cap	5	25
3000	TC	Rectangular	Canted	Phenolic-Style	4	24
3001	TC	Rectangular	Canted	Vent Cap	4	24
3293	Corning CellBIND Surface	Traditional	Angled	Vent Cap	5	25

### 235 cm<sup>2</sup> Expanded Growth Area Flask

Cat. No.	Surface	Flask Style	Neck Style	Cap Style	Qty/Pk	Qty/Cs
431346*	Corning® CellBIND® Surface	Rectangular	Angled	Vent Cap	7	42

\*Flask prelabeled with bar code, validated for use with SelecT^{\rm TM} Robotic System.

### Cell Yields and Recommended Medium Volume

Corning <sup>®</sup> and Costar <sup>®</sup> Flasks	Approximate Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Recommended Medium Volume (mL)	Maximum Working Volume (mL)†
25 cm <sup>2</sup>	25	$2.5 \ge 10^6$	5 - 7.5	10
75 cm <sup>2</sup> Canted neck	75	$7.5 \ge 10^6$	15 - 22.5	60
75 cm <sup>2</sup> Straight neck	75	$7.5 \ge 10^6$	15 - 22.5	90
RoboFlask <sup>™</sup> Vessel	93	$9.4 \ge 10^6$	20 - 30	70
150 cm <sup>2</sup>	150	$1.5 \ge 10^7$	30 - 45	210
162 cm <sup>2</sup>	162	$1.6 \ge 10^7$	32 - 48	175
175 cm <sup>2</sup>	175	$1.75 \ge 10^7$	35 - 52.5	250
225 cm <sup>2</sup>	225	2.25 x 10 <sup>7</sup>	45 - 67.5	370
235 cm <sup>2</sup>	235	$2.35 \ge 10^7$	47 - 70.5	250

\*Assumes an average yield of 1 x 10<sup>5</sup> cells/cm<sup>2</sup> from a 100% confluent culture. Yields from many cell types can be lower than this. † Maximum working volume is the amount a flask can hold in the horizontal position when filled to the neck.

# **Cell Culture Dishes**



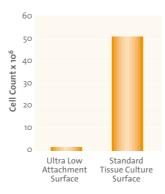
**3261 and 3262** Ultra Low Attachment Dishes

### **Ultra Low Attachment Dishes**

The Ultra Low Attachment surface is a unique covalently bonded hydrogel surface that is hydrophilic and neutrally charged. It minimizes cell attachment, protein absorption and enzyme activation. The surface is noncytotoxic, biologically inert and nondegradable.

Cat. No.	Dish Style (mm)*	Height (mm)	Growth Area (cm <sup>2</sup> )	Qty/Pk	Qty/Cs
3261	60	15	21	5	20
3262	100	20	55	5	2.0

\*60 mm dish = 51.4 mm; 100 mm dish = 80.5 mm



### Comparison of Cell Attachment in Ultra Low vs. Standard Tissue Culture Treated Plates

Vero cells plated at 2.6 x  $10^6$  cells per well grown for 4 days at 37°C in a 5% CO<sub>2</sub> environment show a 99% reduction in cellular attachment vs. standard culture treated product.



**3296** Corning<sup>®</sup> CellBIND<sup>®</sup> Surface 100 mm Dishes



430196 Gridded 60 mm Dish



430167 100 mm Dish

## **Corning® Cell Culture Treated Dishes**

- Manufactured from optically-clear virgin polystyrene
- Treated for optimal cell attachment
- Sterilized by gamma radiation
- Certified nonpyrogenic
- Have stacking beads to aid in handling
- > Supplied with vents to provide consistent gas exchange

### Corning Cell Culture Dish Ordering Information

Cat. No.	Surface	Dish Style <sup>a</sup> (mm)	Approx. Height (mm)	Growth Area (cm <sup>2</sup> )	Qty/Pk	Qty/Cs
3294	Corning® CellBIND® Surface	35	10	8	10	210
430165	ТС	35	10	8	20	500
430166	TC	60	15	21	20	500
3295	Corning CellBIND Surface	60	15	21	7	126
3261	Ultra Low Attachment	$60^{b}$	20	21	5	20
3262	Ultra Low Attachment	$100^{b}$	20	55	5	20
430196	ТС	60 with 2 mm grid	15	21	20	500
3296	Corning CellBIND Surface	100	20	55	5	40
430167	TC	100	20	55	20	500
430293 <sup>c</sup>	TC	100	20	55	10	480
430599	ТС	150	25	151	5	60
431110 <sup>d</sup>	TC	245	25	500	4	16
431112 <sup>e</sup>	TC	245	25	500	4	16

<sup>*a*</sup> Dish style (mm) = actual growth surface diameters: 35 mm dish = 33.9 mm; 60 mm dish = 51.4 mm; 100 mm dish = 80.5 mm; 150 mm dish = 138.7 mm.

<sup>b</sup>This covalently bonded hydrogel surface minimizes cell attachment, protein absorption, enzyme activiation, and cellular activation. The surface is noncytotoxic, biologically intert, and nondegradeable.

<sup>c</sup> Cat. No. 430293 consists of 6-pack carriers, each containing 6 packages of 10 dishes each.

<sup>d</sup>Cat. Nos. 431110 and 431112 are square dishes with interior bottom plate dimensions of 224 mm x 224 mm.

<sup>e</sup> Cat. No. 431112 is a square dish featuring a removable spillguard.



**431110** 500 cm<sup>2</sup> Cell Culture Dish



**431112** 500 cm<sup>2</sup> DW Spillguard Dish

### **Cell Culture Dish Application Tips**

• The 150 and 245 mm culture dishes make excellent carriers and incubator trays for 35 and 60 mm dishes. This helps prevent spills and reduces opportunities for contamination.

Corning recommends 0.2 to 0.3 mL of medium per cm<sup>2</sup> of growth area.

3260 IVF Culture Dish

# **Corning® Nontreated Cell Culture Dishes**

- Manufactured from optically clear virgin polystyrene
- Not cell culture treated for applications where cell attachment is not desired
- Have stacking beads to aid in handling
- Supplied with vents to provide consistent gas exchange
- Sterilized by gamma radiation
- Certified nonpyrogenic

### Corning Nontreated Cell Culture Dish Ordering Information

Cat. No.	Dish Style* (mm)	Height (mm)	Approx. Growth Area (cm <sup>2</sup> )	Qty/Pk	Qty/Cs
430588	35	10	8	20	500
430589	60	15	21	20	500
430591	100	20	55	20	500
430597	150	25	148	5	60
431111†	245	25	500	4	16

\*Note: Dish style (mm) = actual growth surface diameters: 35 mm dish = 33.9 mm; 60 mm dish = 51.4 mm; 100 mm dish = 80.5 mm; 150 mm dish = 134.5 mm.

<sup>†</sup>Cat. No. 431111 is a square dish with interior bottom plate dimensions of 224 mm x 224 mm.

### **Expected Cell Yields and Recommended Medium Volumes**

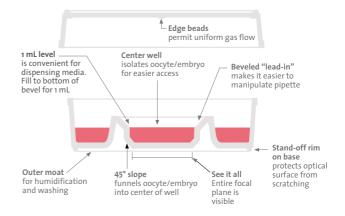
Corning Dishes	Approximate Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Recommended Medium Volume (mL) <sup>†</sup>
35 mm	8	8.0 x 10 <sup>5</sup>	1.6 - 2.4
60 mm	21	2.1 x 10 <sup>6</sup>	4.2 - 6.3
100 mm	55	$5.5 \ge 10^6$	11 - 16.5
150 mm	148	$1.48 \ge 10^7$	30 - 45
245 mm (square)	500	$5.0 \ge 10^7$	100 - 150

\*Assumes an average yield of 1 x 10<sup>5</sup> cells/cm<sup>2</sup> from a 100% confluent culture.

<sup>†</sup>Yields from many cell types can be lower than this.

# **Costar® IVF Culture Dish**

- ▶ 20 mm center well
- Inner well holds 3 mL of medium while the outer well holds 10 mL
- Treated for optimal cell attachment
- Sterilized by gamma radiation
- Certified nonpyrogenic
- For research use only



### Costar IVF Culture Dish Ordering Information

Cat. No.	Size (mm)	Description (mm)	Center Well (mm)	Qty/Pk	Qty/Cs
3260	60	60 x 15	20	20	500

# **Multiple Well Plates**



3516 6 Well Culture Plate



3513 12 Well Culture Plate



3524 24 Well Culture Plate



3548 48 Well Culture Plate

## Costar<sup>®</sup> 6, 12, 24, and 48 Well Cell Culture Plates

- Flat bottoms
- Nonreversible lids with condensation rings to reduce contamination
- Individual alphanumerical codes for well identification
- Uniform footprint for ease in stacking
- Treated for optimal cell attachment (except where noted)
- Sterilized by gamma irradiation
- Certified nonpyrogenic

### 6, 12, 24, and 48 Well Plates Ordering Information

Cat. No.	Surface	Plate Type	Qty/Pk	Qty/Cs
6 Well Pl	lates			
3335	Corning <sup>®</sup> CellBIND <sup>®</sup> Surface	Standard clear plate	5	50
3506	ТС	Standard clear plate	5	100
3516	ТС	Standard clear plate	1	50
3471	Ultra Low Attachment	Standard clear plate with hydrogel*	1	24
12 Well	Plates			
3336	Corning CellBIND Surface	Standard clear plate	5	50
3512	ТС	Standard clear plate	5	100
3513	TC	Standard clear plate	1	50
24 Well 1	Plates			
3337	Corning CellBIND Surface	Standard clear plate	5	50
3524	ТС	Standard clear plate	1	100
3526	TC	Standard clear plate	1	50
3527	TC	Standard clear plate	5	100
3473	Ultra Low Attachment	Standard plate with hydrogel*	1	24

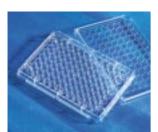
<b>T</b> <sup>o</sup> , , <b>o</b> , <b>i</b> , <b></b>				
3548	TC	Standard clear plate	1	100
*This covalently b	onded hydrogel surface minimi	zes cell attachment, protein absorption, enzyme activatio	n and cellular	activation.

<sup>1</sup> I his covalently bonded hydrogel surface minimizes cell attachment, protein absorption, enzyme activation and cellular activation The surface is noncytotoxic, biologically inert and nondegradable.

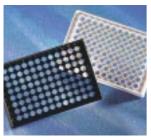
### Well Dimensions, Expected Cell Yields, and Recommended Medium Volumes

		Single Well Only				Entire Plate		
Cell Culture Plates	Well Diameter (Bottom, mm)	Approx. Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Total Well Volume (mL)	Working Volume (mL)	Approx. Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Working Volume (mL)
6 well	34.8	9.5	9.5 x 10 <sup>5</sup>	16.8	1.9 - 2.9	57	$5.7 \ge 10^{6}$	11.4 - 17.1
12 well	22.1	3.8	$3.8 \ge 10^5$	6.9	0.760 - 1.14	45.6	$4.56 \ge 10^6$	9.1 - 13.7
24 well	15.6	1.9	$1.9 \ge 10^5$	3.4	0.380 - 0.570	45.6	$4.56 \ge 10^6$	9.1 - 13.7
48 well	11	0.95	$8.0 \ge 10^4$	1.6	0.19 - 0.285	45.6	$38.4 \ge 10^6$	9.1 - 13.7

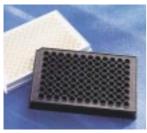
\*Assumes an average yield of  $1 \times 10^5$  cells/cm<sup>2</sup> from a 100% confluent culture. Yields from many cell types can be lower than this.



3596 96 Well Culture Plate



**3610 and 3603** 96 Well Clear Bottom Plates



**3917 and 3916** 96 Well Solid Plates

# Corning<sup>®</sup> and Costar<sup>®</sup> 96 Well Cell Culture Plates

- Flat bottoms (except where noted)
- Nonreversable lids with condensation rings to reduce contamination (except where noted)
- Treated for optimal cell attachment (except where noted)
- Sterilized by gamma radiation
- Certified nonpyrogenic
- > Individual alphanumeric codes for well identification

Black plates are designed to lower background in fluorescent assays and reduce crosstalk. White plates are designed for luminescent assays. Some plates have a poly-D-lysine coating to enhance cell attachment. Corning offers many other 96 well plate types for applications other than cell culture; for a complete listing, check the catalog at **www.corning.com/lifesciences**.

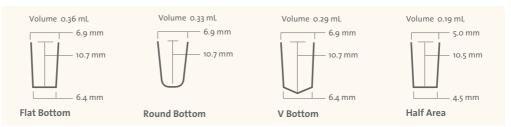
### 96 Well Plate Ordering Information

Clear H           3300         0           3596         3997           3598         3599	Plates Corning® CellBIND® Surface TC TC	Standard clear plate		
3596 3997 3598	TC	Standard clear plate		
3997 3598			5	50
3598	TC	Standard clear plate	1	50
	IC	Standard clear plate	10	50
3599	TC	Standard clear plate	5	100
5577	TC	Standard clear plate	1	100
3585	TC	Standard clear plate with special low evaporation lid	5	50
3595	TC	Standard clear plate with special low evaporation lid	1	50
3594	TC	Standard clear plate without lid	1	100
3697	TC	96 well half area clear plate	20	100
3790	TC	96 well round bottom, polypropylene plate with polystyrene lid	1	50
3799	TC	96 well round bottom clear plate	1	50
3894	TC	96 well V-bottom clear plate	1	50
3665	poly-D-lysine	Standard clear plate, coated	25	100
9102	TC	8-well strip plate, assembled 12 strips per plate	1	50
3474	Ultra Low Attachment	Standard clear plate with hydrogel*	1	24
White .	Plates			
3917	TC	Solid white plate	20	100
3362	TC	Solid white plate without lid	25	100
3688	TC	96 well half area solid white plate	20	100
3610	TC	White plate with clear bottom	1	48
3903	TC	White plate with clear bottom	20	100
3666	poly-D-lysine	White plate with clear bottom	25	100
Black H	A 7 7	Å		
3340	Corning CellBIND Surface	Black plate with clear bottom with lid	5	50
3916	TC	Solid black plate	20	100
3603	ТС	Black plate with clear bottom	1	48
3904	ТС	Black plate with clear bottom	20	100
3667	poly-D-lysine	Black plate with clear bottom	25	100
3614	TC	Black plate with special optics, ultrathin, clear bottom, without lid	25	100
Lids an	nd Tape			
3099	L _	Universal lid	25	50
3345	_	Breathable Sealing tape, Sterile	50	500
3930	_	Rigid styrene lid with condensation rings	1	100
3931	_	Rigid styrene lid with condensation rings	25	50

\*This covalently bonded hydrogel surface minimizes cell attachment, protein absorption, enzyme activation and cellular activation. The surface is noncytotoxic, biologically inert and nondegradable.

## **96 Well Cell Culture Plates**

### Well Geometry



### Well Dimensions, Expected Cell Yields, and Recommended Medium Volume

		Single Well Only				Entire Plate		
Cell Culture Plates	Well Diameter (Bottom, mm)	Approx. Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Total Well Volume (mL)	Working Volume (mL)	Approx. Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Working Volume (mL)
96 well flat bottom	6.4	0.32	3.2 x 10 <sup>4</sup>	0.36	0.100 - 0.200	30.7	3.07 x 10 <sup>6</sup>	9.6 - 19.2
96 well round bottom	6.4	NA <sup>†</sup>	NA†	0.33	0.100 - 0.200	$\mathrm{NA}^{\dagger}$	$\mathrm{NA}^{\dagger}$	9.6 - 19.2
96 well V bottom	6.4	0.38	3.8 x 10 <sup>4</sup>	0.29	0.100 - 0.200	36.5	3.65 x 10 <sup>6</sup>	9.6 - 19.2
96 half are	a 4.5	0.16	$1.6 \ge 10^4$	0.19	0.050 - 0.100	15.4	$1.54 \ge 10^{6}$	4.8 - 9.6

\*Assumes an average yield of 1 x  $10^5$  cells/cm<sup>2</sup> from a 100% confluent culture. Yields from many cell types can be lower than this. <sup>†</sup>Because these wells are round, the surface area available for cell attachment is dependent on the medium volume used.

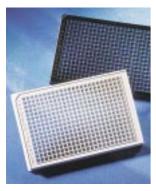
## **384 Well Cell Culture Plates**

- Flat bottoms
- Nonreversible lids
- > Treated for optimal cell attachment
- Sterilized by gamma radiation
- Certified nonpyrogenic

Black plates are designed to lower background in fluorescent assays and reduce crosstalk. White plates are designed for luminescent assays. Some plates have a poly-D-lysine coating to enhance cell attachment. Corning offers many other 384 well plate types for applications other than cell culture; for a complete listing, check the catalog at **www.corning.com/lifesciences**.

### 384 Well Cell Culture Plate Ordering Information

Cat. No.	Surface	Description	Qty/Pk	Qty/Cs
Clear Pla	ites			
3701	ТС	Standard clear plate	20	100
3662	poly-D-lysine	Standard clear plate	25	100
White Pl	lates			
3704	TC	Solid white plate	20	100
3707	TC	White plate with clear bottom	20	100
3663	poly-D-lysine	White plate with clear bottom	25	100
Black Pla	ites			
3709	TC	Solid black plate	20	100
3712	TC	Black plate with clear bottom	20	100
3664	poly-D-lysine	Black plate with clear bottom	25	100
3683	Corning <sup>®</sup> CellBIND <sup>®</sup> Surface	Black plate with clear bottom with lid	10	50



**3707 and 3712** 384 Well Clear Bottom Plates

**3955 and 3954** 1536 Well Culture Plates

Well Dimensions, Expected Cell Yields, and Recommended Medium Volumes

		Single Well Only				Entire Plat	e	
Cell Culture Plates	Well Diameter (Bottom, mm)	Approx. Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Total Well Volume (mL)	Working Volume (mL)	Approx. Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Working Volume (mL)
384 well	$2.7 \ge 2.7^{+}$	0.056	$5.6 \ge 10^3$	0.125	.025050	21.5	$2.15 \ge 10^6$	9.6 - 19.2

\*Assumes an average yield of 1 x  $10^5$  cells/cm<sup>2</sup> from a 100% confluent culture. Yields from many cell types can be lower than this. †These wells are square.

### **1536 Well Cell Culture Plates**

- Flat bottoms with no lids (Top plate serves as lid for plate underneath.)
- Eight extra wells on left and right sides that can be used for running controls
- Treated for optimal cell attachment
- Sterilized by gamma radiation
- Certified nonpyrogenic

Black plates are designed to lower background in fluorescent assays and reduce crosstalk. White plates are designed for luminescent assays. Corning offers other 1536 well plate types for applications other than cell culture; for a complete listing, check the catalog at **www.corning.com/lifesciences**.

### 1536 Well Cell Culture Plate Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
3853	Standard clear plate	20	100
3855	Solid white plate	20	100
3854	Solid black plate	20	100

### Well dimensions, Expected Cell Yields, and Recommended Medium Volumes

		Single Well Only				Entire Plate	
WellCellDiametricCulture(BottomPlatesmm)			Total Well Volume (µL)	Working Volume (µL)	Approx. Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Working Volume (mL)
1536 well 1.2	0.011	$1.2 \ge 10^3$	2.3	1.0 - 1.5	16.9	$1.69 \ge 10^6$	1.5 - 2.3

\*Assumes an average yield of 1 x 10<sup>5</sup> cells/cm<sup>2</sup> from a 100% confluent culture. Yields from many cell types can be lower than this.

# Transwell<sup>®</sup> Permeable Supports



Transwell cell culture inserts are convenient, easy-to-use permeable support devices for the study of both anchorage-dependent and anchorage-independent cell lines.

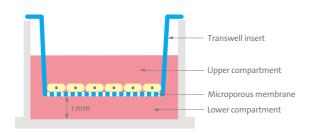
- Designed to produce a cell culture environment that closely resembles the *in vivo* state
- Allows polarized cells to feed basolaterally and thereby carry out metabolic activities in a more natural fashion
- Unique patented self-centered hanging design prevents medium wicking between the insert and outer well.
- Permits access to the lower compartment through windows in the insert wall
- Suspended design allows for undamaged co-culturing of cells in the lower compartment
- Available in a range of pore sizes and different membranes to satisfy diverse experimental requirements

### Characteristics of Transwell® Membranes

Characteristics	Polyester (PET)	Polycarbonate	<b>PTFE/Collagen</b>
Optical properties	Clear	Translucent	Clear when wet
Cell visibility	Good	Poor	Cell outlines
Tissue culture treated	Yes	Yes	No
Membrane thickness	10 µm	10 µm	50 µm
Matrix/ECM coatable	Yes	Yes	Yes
Collagen treated	No	No	Yes
Available Pore Sizes (µm)	0.4, 3.0	0.1, 0.4, 3.0, 5.0, 8.0, 12.0	0.4, 3.0

### **Chemical Compatibility**

All of the Transwell membranes are compatible with histological fixatives including methanol and formaldehyde. The polyester Transwell membranes have the best overall chemical resistance. These membranes (but not the polystyrene housings) are compatible with many alcohols, amines, esters, ethers, ketones, oils and some solvents, including many halogenated hydrocarbons and DMSO but are not recommended for use with strong acids and bases.



### **Pore Density**

Of the three types of Transwell membranes, only the PTFE does not have a defined pore density because it is a tortuous path membrane. The two membranes with a nominally defined pore density are polycarbonate and polyester. The polyester Transwell membranes do not have as high a pore density as the polycarbonate Transwell but have better optical clarity as a result. The nominal pore densities for Corning<sup>®</sup> Polycarbonate and Polyester (PET) membranes are given in the following table.

### Nominal Pore Densities for Transwell Polyester and Polycarbonate Membranes

	Nominal F	Pore Density
Pore Size	Polycarbonate Membrane Transwell (pores/cm <sup>2</sup> )	Transwell-Clear Polyester Membrane (pores/cm <sup>2</sup> )
0.1 µm	$3 \ge 10^8$	n/a
0.4 μm	1 x 10 <sup>8</sup>	$4 \ge 10^{6}$
3.0 µm	2 x 10 <sup>6</sup>	2 x 10 <sup>6</sup>
5.0 μm	4 x 10 <sup>5</sup>	n/a
8.0 µm	1 x 10 <sup>5</sup>	n/a
12.0 μm	$1 \ge 10^5$	n/a

Growth Areas and Recommended Medium Volumes for Transwell Permeable Supports

Transwell Insert Diameter (mm)	Insert Membrane Growth Area (cm <sup>2</sup> )	Multiple Well Plate or DishType	Volume Added per Plate Well	Volume Added to Inside of Transwell Insert (mL)
4.26	0.143	96 HTS	_	_
6.5	0.33	24 well	0.6	0.1
12	1.12	12 well	1.5	0.5
24	4.67	6 well	2.6	1.5
75	44	100 mm dish	13	9

# Transwell<sup>®</sup> Permeable Supports Tip

Check the Corning web site (www.corning. com/lifesciences) for an extensive list of references, listed by application, citing the use of Transwell permeable supports in cell culture research.



**3401** 12 mm Polycarbonate Transwell Insert



**3419** 75mm Polycarbonate Transwell Insert



**3450** 24 mm Transwell-Clear Insert

# **Transwell® Polycarbonate Membrane Insert**

- 10 μm translucent membrane
- Pore sizes ranging from 0.1 μm to 12 μm
- Treated for optimal cell attachment
- Supplied in multiple well plates
- Membrane must be stained for cell visibility
- Sterilized by gamma radiation

### Transwell Polycarbonate Membrane Permeable Support Ordering Information

Cat. No.	Membrane Diameter (mm)	Growth Surface Area (cm <sup>2</sup> )	Membrane Pore Size (µm)	Tissue Culture Treated	Inner Packaging*	Inserts/Cs
3413	6.5	0.33	0.4	Yes	12/plate*	48
3415	6.5	0.33	3.0	Yes	12/plate*	48
3421	6.5	0.33	5.0	Yes	12/plate*	48
3422	6.5	0.33	8.0	Yes	12/plate*	48
3423	6.5	0.33	0.1	No	12/plate*	48
3401	12	1.12	0.4	Yes	12/plate	48
3402	12	1.12	3.0	Yes	12/plate	48
3403	12	1.12	12.0	Yes	12/plate	48
3412	24	4.67	0.4	Yes	6/plate	24
3414	24	4.67	3.0	Yes	6/plate	24
3428	24	4.67	8.0	Yes	6/plate	24
3419	75	44	0.4	Yes	1/dish	12
3420	75	44	3.0	Yes	1/dish	12

\*6.5 mm membrane diameter are packaged 12 inserts in a 24 well plate, 4 plates per case.

### **Transwell-Clear Polyester Membrane Insert**

- 10 μm transparent membrane
- Treated for optimal cell attachment
- Excellent visibility under phase contrast microscopy
- Supplied in multiple well plates
- Sterilized by gamma radiation

### Transwell-Clear Insert Ordering Information

Cat. No.	Membrane Diameter (mm)	Growth Surface Area (cm <sup>2</sup> )	Membrane Pore Size (µm)	Inner Packaging*	Inserts/Cs
3450	24	4.67	0.4	6/plate	24
3452	24	4.67	3.0	6/plate	24
3460	12	1.12	0.4	12/plate	48
3462	12	1.12	3.0	12/plate	48
3470	6.5	0.33	0.4	12/plate*	48
3472	6.5	0.33	3.0	12/plate*	48

\*6.5 mm membrane diameter are packaged 12 inserts in a 24 well plate, 4 plates per case.



**3491** 24 mm Transwell-COL Collagen-Coated Insert



3407 12 mm Snapwell Inserts

# Transwell<sup>®</sup>-COL Collagen-Coated Membrane Insert

- Transparent collagen treated PTFE membrane
- Promotes cell attachment and spreading
- Equimolar mixture of types I and III collagen
- Individually packaged
- Multiple well plates included in each case
- Supplied sterile

### Transwell-COL Insert Ordering Information

Cat. No.	Membrane Diameter (mm)	Growth Surface Area (cm <sup>2</sup> )	Membrane Pore Size (µm)	Inner Packaging	Cluster	Inserts/Cs
3491	24	4.7	0.4	Individual	6 well	24
3492	24	4.7	3.0	Individual	6 well	24
3493	12	1.1	0.4	Individual	12 well	24
3494	12	1.1	3.0	Individual	12 well	24
3495*	6.5	0.3	0.4	Individual	24 well	24
3496*	6.5	0.3	3.0	Individual	24 well	24

\*Includes twenty-four 6.5 mm inserts packaged separately with two 24 well plates.

# **Snapwell™ Inserts**

- A modified Transwell<sup>®</sup> permeable support containing a 12 mm diameter membrane supported by a detachable ring
- Once cells are grown to confluence on the Snapwell insert, the ring can be placed in a vertical or horizontal diffusion chamber\*
- Sterilized by gamma radiation
- Packaged in 6 well plates

### **Snapwell Insert Ordering Information**

Cat. No.	Membrane Pore Size (µm)	Membrane	Inner Packaging	Inserts/Cs
3407	0.4	Polycarbonate	6/plate	24
3802	3.0	Polycarbonate	6/plate	24
3801	0.4	Clear Polyester	6/plate	24

\*Diffusion Chambers are available through Harvard Apparatus (*www.harvardapparatus.com*)



**3396** 6.5 mm HTS Transwell Polycarbonate Insert

# Corning<sup>®</sup> HTS Transwell<sup>®</sup>-24 Membrane Insert

- Treated for optimal cell attachment
- $\blacktriangleright$  Available in two pore sizes: 0.4 and 3.0  $\mu m$  and, membrane types polycarbonate (PC) and polyester (PET)
- Individual or bulk pack
- Individual pack has 2 HTS Transwell-24 units loaded into 24 well plates and two open reservoirs
- Bulk pack has 12 HTS Transwell-24 units loaded into 24 well plates only. Reservoirs may be purchased separately
- > Sterilized by gamma radiation

#### HTS Transwell Insert Ordering Information

Cat. No.	Description	Membrane Pore Size (μm)	Membrane	Qty/Pk	Plates/Cs
3396	HTS Transwell-24, individual	0.4	PC	1	2
3397	HTS Transwell-24, bulk	0.4	PC	12	12
3398	HTS Transwell-24, individual	3.0	PC	1	2
3399	HTS Transwell-24, bulk	3.0	PC	12	12
3395	HTS Transwell nontreated reservoir	r –	PC	12	48
3378	HTS Transwell-24, bulk	0.4	PET	12	12
3379	HTS Transwell-24, individual	0.4	PET	1	2

### Corning HTS Transwell-96 Tissue Culture Systems

- 96 well system, polycarbonate (PC) membrane, 0.4 μm pore size
- 96 well system, polyester (PET) membrane, 1.0 μm pore size
- 0.143 cm<sup>2</sup> membrane area per well, providing 20 to 50% more surface area for cell growth than other commercially available systems
- Large apical and basolateral access ports allow efficient media sampling and facilitate automated or manual access
- Optimized for automation, with multichannel feeder ports, improved gripping surface, and standard bar codes

#### HTS Transwell-96 Systems Ordering Information

Cat. No.	Product Description	Qty/Pk	Qty/Cs
3380	HTS Transwell-96 System, 1.0 µm PET membrane, reservoir, and receiver plates, with 2 sterile lids	1	1
3392	HTS Transwell-96 System, 1.0 µm PET membrane, reservoir, and receiver plates, with 2 sterile lids	1	5
3381	HTS Transwell-96 System, 0.4 µm PC membrane, reservoir, and receiver plates, with 2 sterile lids	1	1
3391	HTS Transwell-96 System, 0.4 µm PC membrane, reservoir, and receiver plate, with 2 sterile lids	1	5
3382	HTS Transwell-96 Receiver Plate with lid	10	10
3383	HTS Transwell-96 Reservoir Plate (Feeder) with removable media stabilizer and lid	10	10
3389	Micromatic 8 Channel Aspirator for HTS Transwell-96 System, Autoclavable	1	1



HTS Transwell-96 System



Micromatic<sup>™</sup> 8 Channel Aspirator



Netwell Inserts

# **Netwell<sup>™</sup> Inserts**

- Costar<sup>®</sup> Netwell inserts have polyester mesh bottoms attached to polystyrene inserts
- They are used as tissue carriers, supports and strainers for culture of small organs, tissue slices or explants at the air-media interface
- Handy carrier during immunocytochemical staining of tissue slices (see accessories below)
- Provides coarse filtration of tissue homogenates, cell suspensions and microcarriers
- Available in two mesh sizes and diameters
- Supplied sterile and preloaded in 6- or 12-well microplates
- > 24 mm Netwell inserts fit in Corning 50 mL plastic centrifuge tubes

#### Netwell Inserts Ordering Information

Cat. No.	Membrane Dia. (mm)	Polyester Membrane Mesh Size (μm)	Sterile	Inner Packaging	Inserts/ Cs
3477	15	74	Yes	12/plate	48
3478	15	500	Yes	12/plate	48
3479	24	74	Yes	6/plate	48
3480	24	500	Yes	6/plate	48

# **Netwell Accessories**

- Specially designed Netwell carriers and handles allow simultaneous processing of up to 12 samples per carrier
- Polystyrene reagent trays are available in white for colorimetric reaction contrast, or black for better visibility of tissue sections
- Each carrier kit contains eight carriers and eight handles

#### **Netwell Accessories Ordering Information**

Cat. No.	Description	Qty/Cs
3517	Netwell Reagent Tray, black	200
3519	Netwell Reagent Tray, white	200
3520	Netwell Carrier Kit, 15 mm	8
3521	Netwell Carrier Kit, 24 mm	8

# **Culture Tubes**



Manufactured from optically clear polystyrene

**Culture Tubes** 

- > Threaded plug seal caps prevent leakage
- Cell culture treated tubes supplied racked
- Untreated tubes provided bulk packed
- Sterilized by gamma radiation
- Certified nonpyrogenic

#### Culture Tube Ordering Information

Cat. No.	Treated	Size (mm)	Cap Style	Qty/Pk	Qty/Cs
430157	No	16 x 125	Screw top	25	500
430172	Yes	16 x 125	Screw top	50	500

430172 Culture Tube



# **Roller Bottles**



**430849** 850 cm<sup>2</sup> Roller Bottle

# **Roller Bottles**

- Manufactured from virgin polystyrene
- Treated for optimal cell attachment
- One piece seamless construction
- Most bottles have printed graduations.
- All bottles have printed lot numbers to aid in product traceability.
- Sterilized by gamma radiation
- Certified nonpyrogenic

# **Roller Bottle Ordering Information**

Cat. No	. Surface	Surface Area (cm <sup>2</sup> )	) Cap Style	Graduations	Qty/Pk	Qty/Cs
430195	TC	490	Plug Seal	No	2	40
430699	TC	1,750	Easy Grip	Yes	10	20
430849	TC	850	Easy Grip	Yes	2	36
431133	TC	850	Easy Grip	Yes	20	20
431198	TC	850	Easy Grip Ven	t Yes	2	36
430851	TC	850	Easy Grip	Yes	6	36
3907	Corning <sup>®</sup> CellBIND <sup>®</sup> Surfa	ice 850	Easy Grip	Yes	2	36
431329	Corning CellBIND Surfac	e 850	Easy Grip Ven	t Yes	2	36

# **Expanded Surface Roller Bottles**

- Same features as standard roller bottles
- Ribbed design provides twice the surface area with the same exterior dimensions

#### Expanded Surface Roller Bottle Ordering Information

Cat. No.	Surface	Surface Area (cm <sup>2</sup> )	) Cap Style	Graduations	Qty/Pk	Qty/Cs
430852	TC	1,700	Easy Grip	Yes	2	36
430853	ТС	1,700	Easy Grip	Yes	6	36
431134	Corning CellBIND Surface	ce 1,700	Easy Grip	Yes	20	20
431135	TC	1,700	Easy Grip	Yes	20	20
431191	ТС	1,700	Easy Grip Ven	t Yes	20	20

#### Expected Cell Yields and Recommended Medium Volumes

Corning <sup>®</sup> Roller Bottles	Approximate Growth Area (cm <sup>2</sup> )	Average Cell Yield*	Recommended Medium Volume (mL)
490 cm <sup>2</sup> roller bottle	490	$4.9 \ge 10^7$	100 - 150
850 cm <sup>2</sup> roller bottle	850	8.5 x 10 <sup>7</sup>	170 - 255
1700 cm <sup>2</sup> roller bottle	1,700	$1.7 \ge 10^8$	340 - 510
1750 cm <sup>2</sup> roller bottle	1,750	$1.75 \ge 10^8$	350 - 525

\*Assumes an average yield of 1 x 10<sup>5</sup> cells/cm<sup>2</sup> from a 100% confluent culture. Yields from many cell types can be lower than this.



**430852** Expanded Surface Roller Bottle

# **Polyethylene Roller Bottle Caps**

Caps are sold separately and are available individually wrapped in either Easy Grip or Easy Grip Vent Cap designs

Cat. No.	Cap Style	Qty/Pk	Qty/Cs
430698	Easy Grip	1	100
431132	Easy Grip Vent	1	300

# Roller Bottle Application Tips

- Corning recommends 0.2 to 0.3 mL of medium per cm<sup>2</sup> of growth area.
- Corning recommends setting roller rack speeds to provide 0.5 to 1.0 RPM.



**Easy Grip Cap** features large knurls designed for ergonomic handling.



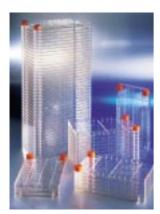
**Easy Grip Vent Cap** is designed for applications requiring consistent gas exchange.



**Plug Seal Cap**, designed for use in closed systems, provides a liquid- and gas-tight seal. When loosened, this cap can be used in open systems.

**Corning is committed to partnering with you,** our customer, to provide solutions that increase your efficiency and productivity. We offer the ability to customize packaging and cap design to meet your specific requirements. Minimum order quantities apply. Please call us or contact your local Corning Office for more details. See back cover for contact information.

# Corning<sup>®</sup> CellSTACK<sup>®</sup> Culture Chambers



Corning CellSTACK Culture Chambers

- Available in Five Sizes
  - 1-Stack with 636 cm<sup>2</sup> cell growth area
  - 2-Stack with 1,272 cm<sup>2</sup> cell growth area
  - 5-Stack with 3,180 cm<sup>2</sup> cell growth area
  - 10-Stack with 6,360 cm<sup>2</sup> cell growth area
  - 40-Stack with 25,440 cm<sup>2</sup> cell growth area
- Greater Chamber Durability
  - Superior mechanical strength and structural integrity
  - Self-venting caps prevent pressure build-up during transport
  - 100% leak tested prior to shipping
- Greater Cleanliness
  - Improved assembly procedures reduce particulates
  - Certified nonpyrogenic and sterilized by gamma irradiation
- Continuous Supply Reliability
  - Manufactured in USA under GMP conditions
- Easier to Use
  - Larger openings with threaded closures and vented caps
  - Footprint identical to competitor's product

CellSTACK Chamber, 4o-Stack

#### Qty/ Pk Growth Pk/ Cat. No. Surface Area (cm<sup>2</sup>) Description Cs 3330 Corning<sup>®</sup> CellBIND<sup>®</sup> Surface 636 CellSTACK Chamber, 1-Stack 1 8 3268 636 CellSTACK Chamber, 1-Stack 8 TC 1 3310 Corning CellBIND Surface 1,272 CellSTACK Chamber, 2-Stack 5 1 5 3269 TC 1,272 CellSTACK Chamber, 2-Stack 1 3311 Corning CellBIND Surface 3,280 CellSTACK Chamber, 5-Stack 1 2 3319 CellSTACK Chamber, 5-Stack 2 TC 3,280 1 3313 TC CellSTACK Chamber, 5-Stack 8 3,280 1 2 3312 CellSTACK Chamber, 10-Stack Corning CellBIND Surface 6,360 1 3320 Corning CellBIND Surface 6,360 CellSTACK Chamber, 10-Stack 6 1 3270 TC CellSTACK Chamber, 10-Stack 2 6,360 1 TC CellSTACK Chamber, 10-Stack 1 6,360 6

25,440

25,440

CellSTACK Chamber, 40-Stack

CellSTACK Chamber, 40-Stack

2

2

1

1

#### Corning CellSTACK Filling Accessories Ordering Information

TC

Corning® CellSTACK® Culture Chambers Ordering Information

Cat. No.	Description	Qty/ Pk	Qty/ Cs
3331	Stacking Device, ABS, nonsterile	1	5
3332	Universal Cap*, with vented overcap, sterile	1	4
3279	Solid cap, sterile	1	5
3280	Vent cap, 0.2 mm membrane, sterile	1	5
3281	Vent cap, <sup>3</sup> /8" (9.5 mm) ID tubing, 7 cm length, Pall® Acro 50, PVDF filter, sterile	1	5
3282	Fill cap, 1/8" (3.2 mm) ID tubing, female luer lock with male luer plug, sterile	1	5
3283	Fill cap, <sup>3</sup> /8" (9.5 mm) ID tubing and <sup>5</sup> /16" (7.94 mm) barbed fitting, sterile	1	5
3284	Vent cap, <sup>3</sup> /8" (9.5 mm) ID tubing, 7 cm length, Pall Bacterial Air Vent, sterile	1	4
3324	Two vented over caps and one solid over cap for the Universal Cap, sterile	1	5
3333	Fill cap*, <sup>1</sup> /4" (6.4 mm) ID tubing, 70 cm length, male MPC coupling with female end cap, sterile	1	4
3328	Fill cap, female MPC coupling, 1/4" (6.4 mm) ID barbed fitting with male end cap, sterile	1	4
3329	Fill cap, female MPC coupling, <sup>3</sup> /8" (9.5 mm) ID barbed fitting with male end cap, sterile	1	4
3334	Fill cap, male MPC coupling, <sup>1</sup> /4" (6.4 mm) ID barbed fitting with female end cap, sterile	1	4
3339	Fill cap, male MPC coupling with male end cap, <sup>3</sup> /8" (9.5 mm) ID barbed fitting with female end cap, sterile	1	4

\*All caps are 33 mm thread caps.





CellSTACK Accessories



3328 Fill Cap, Female MPC Coupling

# CellCube<sup>®</sup> Systems



The CellCube System provides a fast, simple, and compact method for the mass culture of attachment-dependent cells. It uses a tissue culture treated growth surface for cell attachment, and continually perfuses the cells with fresh medium for increased cell productivity. The CellCube System is comprised of four pieces of capital equipment: the system controller, oxygenator, circulation, and media pumps and is designed to use disposable CellCube Modules. Performance data from the CellCube System can be easily scaled to the production system. Please inquire about CellCube System pricing. Corning provides on-site technical support for the CellCube System.

The CellCube Modules provide a traditional tissue culture treated surface for the growth of attachment dependent cells. The CellCube System provides an

environment which more closely simulates *in vivo* conditions and reliably distributes nutrients and oxygen with low differential gradients across all cells within the modules.

#### **CellCube Ordering Information**

Cat. No.	Description	Qty/Cs
3143	CellCube System; for use with CellCube Modules 3200, 3201, 3202, or 3203; consists of the following components:	
3220	CellCube System Controller	1
3101	CellCube Single Module System 6 Liter Oxygenator, Complete	1
3222	CellCube Digital Single Module System Circulation Pump	1
3221	CellCube Digital System Media Pump	1
3139	CellCube Single Module System Secondary Oxygen Probe (25 x 70 mm)	1
3138	CellCube Single Module System Secondary Oxygen Probe Holder	1
3144	CellCube Single Module System Oxygen Probe Cable	1
3165	CellCube Single Module System 12 mm Dissolved Oxygen Probe Membrane Kit	1
3166	CellCube System 25 mm Dissolved Oxygen Probe Membrane Kit	1
3136	CellCube Single Module System Stainless Steel Stand	1
3135	CellCube Single Module System Setup Kit	1

# **Corning® E-Cube™ Culture System**



Corning E-Cube Culture System

The E-Cube system provides a simple method to determine if your cells will grow in the CellCube<sup>®</sup> module prior to investing in the resources and funding that would be necessary for the larger, automated CellCube system.

#### Corning E-Cube Culture System Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
3286	E-Cube System Kit (without CellCube module)	1	1
3200	CellCube Module 10-Stack	1	2

#### Corning E-Cube Culture System Accessories Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
430518	1 L Storage Bottle with cap	2	24
401654	45 mm Cap with 2 stainless steel ports	1	1
3287	E-Cube Fittings	1	1

# Spinner Flasks



Disposable Spinner Flasks

# **Corning<sup>®</sup> Disposable Spinner Flasks**

- The Corning disposable spinner flask system comes ready-to-use with paddle and integrated magnet, eliminating the need for time-consuming assembly or cleaning and reassembly.
- Molded from virgin polystyrene and gamma-irradiated, each spinner flask system assures a clean sterile unit. No more concerns with detergent residues or contamination.
- Made of USP XXXIII Class VI polystyrene, the vessel is comparable to conventional glass spinner flasks for growth of suspension cell lines and any attachment-dependent cultures using microcarrier beads.
- The paddle size and height is optimized for each vessel size. A unique integrated magnet provides smooth, even rotation at required speeds on any laboratory stir-plate. Heat build-up in the vessel is reduced by means of a specially designed flange that raises the vessel off the stir-plate surface.

#### Corning Disposable Spinner Flasks Ordering Information

Cat. No.	Description	Capacity (mL)	Center Neck (mm)	Sidearm Neck (mm)	Qty/Cs
3152	Disposable Spinner Flask	125	70	25	12
3153	Disposable Spinner Flask	500	100	45	12

# **ProCulture® Glass Spinner Flask with Angled Sidearms**

- Baffles enhance aeration and agitation of contents of the flask.
- Unique impeller design ensures optimal stirring.
- Sidearm designs permit easy access of 25 and 50 mL pipettes
- > Visit www.corning.com/lifesciences to view additional Corning spinner flask accessories

### ProCulture Spinner Flasks with Angled Sidearms Ordering Information

Cat. No.	Description	Capacity	Center Neck (mm)	Sidearm Neck (mm)	Qty/Cs
4500-125	Spinner	125 mL	70	32	1
4500-250	Spinner	250 mL	70	32	1
4500-500	Spinner	500 mL	100	45	1
4500-1L	Spinner	1L	100	45	1
4500-3L	Spinner	3L	100	45	1
4500-6L	Spinner	6L	100	45	1
4500-8L	Spinner	8L	100	45	1
4500-15L	Spinner	15L	100	45	1
4500-36L	Spinner	36L	100	45	1
4502-3L	Spinner	3L	120	45	1
4502-6L	Spinner	6L	120	45	1
4502-8L	Spinner	8L	120	45	1
4502-15L	Spinner	15L	120	45	1
4502-36L	Spinner	36L	120	45	1
4504-3L	Spinner	3L	140	45	1
4504-6L	Spinner	6L	140	45	1
4504-8L	Spinner	8L	140	45	1
4504-15L	Spinner	15L	140	45	1
4504-36L	Spinner	36L	140	45	1

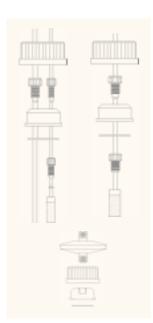
Retrofit Kits are available for converting older Corning® ProCulture Spinner Flasks to fit newer dual-bearing impellers.



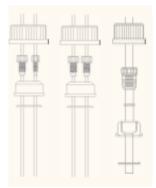
**4500-1L and 4500-250** Spinner Flasks



ProCulture Spinner Flasks



Vertical Sidearm Fittings, Gas Delivery and Venting



Vertical Sidearm Fittings, Media Handling

#### ProCulture Spinner Flasks with Vertical Sidearms Ordering Information

Cat. No.	Capacity	Center Neck (mm)	Number of Vertical Sidearms	Sidearm Neck (mm)	Qty/Cs
4510-8L	8L	100	4	45	1
4510-15L	15L	100	4	45	1
4510-36L	36L	100	6	45	1
4512-8L	8L	120	4	45	1
4512-15L	15L	120	4	45	1
4512-36L	36L	120	6	45	1
4514-15L	15L	140	4	45	1
4514-36L	36L	140	6	45	1

## **Gas Handling Fittings, Vertical Sidearm Flasks**

- Used to provide gases into larger spinner flasks with vertical sidearms
- > Fittings are comprised of a PET insert with a Viton® O-Ring and a polypropylene sealing cap
- Gas filters are PTFE, 0.2 micron porosity
- > The 316 stainless steel tubes are held in place by Noryl® nuts with integrated ferrules
- The fittings are completely autoclavable

Cat. No.	Description	Dimension	Qty/Cs
4519-100	Sidearm fitting, gas delivery	1/8" Inlet	1
4519-102	Sidearm fitting, gas delivery	<sup>1</sup> /4" Inlet	1
4519-104	Sidearm fitting, delivery and vent	1/8" and 1/4"	1
4519-106	Sidearm fitting, vent cap, 0.2 µ	50 mm filter	1
4519-177	Sidearm fitting, vent cap, 0.2 μ, Sanitary	50 mm filter	1

# Media Handling Fittings, Vertical Sidearm Flasks

- > Used to introduce medium aseptically into large spinner flasks with vertical sidearms
- Fittings are comprised of a PET insert with a Viton O-Ring and a polypropylene sealing cap
- Gas filters are PTFE, 0.2 micron porosity
- > The 316 stainless steel tubes are held in place by Noryl nuts with integrated ferrules
- The fittings are completely autoclavable

Cat. No.	Description	Flask Size	Tubing O.D. (inches)	Qty/ Case
4519-112	Sidearm fitting, dual, media handling	8L,15L	1/8"	1
4519-114	Sidearm fitting, dual, media handling	36L	1/8"	1
4519-116	Sidearm fitting, dual, media handling	8L,15L	1/4"	1
4519-118	Sidearm fitting, dual, media handling	36L	1/4"	1
4519-120	Sidearm fitting, combo, media handling	8L,15L	1/8", 1/4"	1
4519-122	Sidearm fitting, combo, media handling	36L	1/8", 1/4"	1
4519-124	Sidearm fitting, single, media handling	8L,15L	1/2"	1
4519-126	Sidearm fitting, single, media handling	36L	1/2"	1
4519-176	Sidearm fitting, dual, media handling, EPDM	8L,15L	1/4"	1



Dual Angled Sidearm Fittings



- Dual angled sidearm fittings can be used for aseptically transferring medium into or out of angled sidearm spinner flasks or for sparging the medium with gases.
- Fittings are comprised of a PET insert with a Viton® O-ring and a polypropylene sealing cap
- Two 316 stainless steel tubes which extend to the bottom of the flask, are held in place by Noryl® nuts with integrated ferrules
- The fittings are completely autoclavable

Cat. No.	Description	Flask Size	Tubing O.D. (inches)	Qty/ Case
4519-150	SA fitting, Dual	1L	1/8"	1
4519-151	SA fitting, Dual	3L	1/8"	1
4519-152	SA fitting, Dual	6L	1/8"	1
4519-153	SA fitting, Dual	8L	1/8"	1
4519-173	SA fitting, Dual	1L	1/8", 1/4"	1
4519-121	SA fitting, Dual	8L	1/8", 1/4"	1
4519-174	Sidearm fitting, Dual	500 mL	<sup>1</sup> /8" angled to 125 mL level, <sup>1</sup> /4	" 1
4519-154	Sidearm fitting, Dual	1L	1/4"	1
4519-155	Sidearm fitting, Dual	3L	1/4"	1
4519-156	Sidearm fitting, Dual	6L	1/4"	1
4519-157	Sidearm fitting, Dual	8L	1/4"	1
4519-170	Sidearm fitting, Dual	15L	1/4"	1

# Gas or Media Handling Fittings, Angled Sidearm Flasks, Combination Style

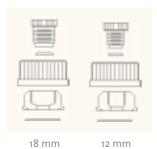
- Used to aseptically transfer medium, sparge the cell culture medium directly or add gases to the head space above the cell culture medium
- > Fittings are comprised of a PET insert with a Viton O-ring and a polypropylene sealing cap
- One or two 316 stainless steel tubes extend to the bottom of the flask; the other is a shorter 6" length
- Both tubes are held in place by Noryl nuts with integrated ferrules

The fittings are completely autoclavable

			Tubing O.D.	
Cat. No.	Description	Flask Size	(inches)	Qty/Case
4519-158	Sidearm fitting, combination	1L	1/8"	1
4519-159	Sidearm fitting, combination	3L	1/8"	1
4519-160	Sidearm fitting, combination	6L	1/8"	1
4519-161	Sidearm fitting, combination	8L	1/8"	1
4519-162	Sidearm fitting, combination	1L	1/4''	1
4519-163	Sidearm fitting, combination	3L	1/4''	1
4519-164	Sidearm fitting, combination	6L	1/4''	1
4519-165	Sidearm fitting, combination	8L	1/4"	1
4519-171	Sidearm fitting, combination	15L	1/4''	1
4519-166	Sidearm fitting, combination, triple	1L	1/8"	1
4519-167	Sidearm fitting, combination, triple	3L	1/8"	1
4519-168	Sidearm fitting, combination, triple	6L	1/8"	1
4519-169	Sidearm fitting, combination, triple	8L	1/8"	1

Combination and Triple Angled Sidearm Fittings





Sidearm Fittings for Sensors



Impeller Assembly

# **Fittings for Insertion Probes, Vertical Sidearm Flasks**

- Used to secure pH, O<sub>2</sub>, or temperature sensors in large spinner flasks with vertical sidearms
- Fittings are comprised of a PET insert with a Viton® O-ring and a polypropylene sealing cap
- > The 316 sensors are held in place by Noryl® nuts with integrated ferrules
- The fittings are completely autoclavable

Cat. No.	Description	Sensor O.D. (mm)	Qty/Cs
4519-108	Sidearm fitting, sensor, O <sub>2</sub> probes	12	1
4519-128	Sidearm fitting, sensor, temperature probes	12	1
4519-110	Sidearm fitting, sensor, pH probes	12	1
4519-172	Sidearm fitting, sensor, pH or $O_2$	18	1

# Impeller Assembly for Magnetically-Driven Bioreactor

Stainless steel impeller shaft with modified impeller blade for use with probes to create a small bioreactor.

Cat. No.	Description	Qty/Cs
402648	Impeller assembly, stainless steel, dual bearing, modified for probes, 3L	1
402649	Impeller assembly, stainless steel, dual bearing, modified for probes, 6L	1
401392	Impeller assembly, stainless steel, dual bearing, modified for probes, 8L	1
401661	Impeller assembly, stainless steel, dual bearing, modified for probes, 15L	1
402650	Impeller assembly, stainless steel, dual bearing, modified for probes, 36L	1

# **Cap Assembly for Magnetically-Driven Bioreactor**

Cap assembly for small biorecator with various fitting arrangements.

Cat. No.	Description	Qty/Cs
402579	Cap Assembly, 120 mm, Noryl, 3 (3/8"), 1 (1/4") fittings	1
402576	Cap Assembly, 120 mm, Noryl, 2 (12 mm), 2 (1/4") fittings	1
402577	Cap Assembly, 120 mm, Noryl, 2 (12 mm), 2 (¼4"), 1 (3/8") fittings	1

# **Spare Parts for Sidearm Fittings**

Securing Caps		
Cat. No.	Description	Qty/Cs
402681	Cap, securing, 45 mm, bored, orange	1
402720	Cap, securing, 45 mm, bored, for injection septum, white	1
1395-32LTC	Cap, securing, 32 mm, orange	1
1395-45LTC	Cap, securing, 45 mm, orange	1
1395-45LTR	Drip ring, 45 mm, clear	1
1395-45LTMC	Cap, vented, securing, 45 mm, .22 PTFE, grey	10
Fitting inserts		
Cat. No.	Description	Qty/Cs
402678	Insert, 45 mm, PET, for single 1/8" inlet	1
402685	Insert, 45 mm, PET, for single 1/4" inlet	1
402063	Insert, 45 mm, PET, for 50 mm filter	1
402068	Insert, 45 mm, PET, for 12 mm insert probe	1
402688	Insert, 45 mm, PET, for 18.9 mm insert probe	1
402690	Insert, 45 mm, PET, for 10 mm insert probe	1
402072	Insert, 45 mm, PET, for dual <sup>1</sup> /8" inlet	1
402074	Insert, 45 mm, PET, for dual 1/4" inlet	1
402076	Insert, 45 mm, PET, for fitting 1/8" and 1/4"	1



# Spare Parts for Sidearm Fittings (continued)

# Fitting Nuts

0		
Cat. No.	Description	Qty/Cs
402682	Nut, ½", Noryl®	1
402686	Nut, ¼", Noryl	1
402069	Nut, 12.4 mm, Noryl	1
402689	Nut, 18.9 mm, Noryl	1
402691	Nut, 10 mm, Noryl	1
Fitting O-rin	igs	
Cat. No.	Description	Qty/Cs
402679	O-ring, insert, Viton® #026	1
402071	O-ring, for 12.4 mm nut	1
402692	O-ring, for 10 mm nut	1
Fitting Filter	rs and Sparging Stones	
Cat. No.	Description	Qty/Cs
402064	Filter, 50 mm, PTFE, 0.2 µm, double NPT	1
Sidearm Sep	tum Fittings	
Cat. No.	Description	Qty/Cs
402711	Septum, GL-45, black butyl rubber	1
Straight Stai	inless Steel Tubing	
Cat. No.	Description	Qty/Cs
402684	Tubing, 316 stainless steel, 1/8" OD, 18", straight	1
402073	Tubing, 316 stainless steel, 1/8" OD, 21", straight	1
402698	Tubing, 316 stainless steel, 1/8" OD, 6", straight	1
402687	Tubing, 316 stainless steel, 1/4" OD, 18", threaded straight	1
402075	Tubing, 316 stainless steel, 1/4" OD, 21", straight	1
402077	Tubing, 316 stainless steel, 1/2" OD, 18", straight	1
402078	Tubing, 316 stainless steel, <sup>1</sup> /2" OD, 21", straight	1
Angled Stain	less Steel Tubing	
Cat. No.	Description	$\Omega t v / C s$

Cat. No.	Description	Qty/Cs
401637	Tubing, 316 stainless steel, 1/8", 500 mL, angled, to 250 mL level	1
401640	Tubing, 316 stainless steel, 1/8", 1L, angled, to 250 mL level	1
402694	Tubing, 316 stainless steel, 1/8", 1L, angled	1
402695	Tubing, 316 stainless steel, 1/8", 3L, angled	1
402696	Tubing, 316 stainless steel, 1/8", 6L, angled	1
402697	Tubing, 316 stainless steel, 1/8", 8L, angled	1
401651	Tubing, 316 stainless steel, 1/4", 500 mL, angled	1
401638	Tubing, 316 stainless steel, 1/4", 1L, angled	1
401643	Tubing, 316 stainless steel, 1/4", 3L, angled	1
402699	Tubing, 316 stainless steel, ¼", 6L, angled	1
402700	Tubing, 316 stainless steel, 1/4", 8L, angled	1

## **Spare Parts for Center Neck Cap Fittings**

Center Neck	Compression Fitting Parts	
Cat. No.	Description	Qty/Cs
402103	Fitting, ¼4", bulkhead type, modified	1
Fitting Plugs		
Cat. No.	Description	Qty/Cs
402079	Plug, 1/8", Delrin	1
402099	Plug, 1/4", Delrin	1



**Direct Drive Motor** 



Direct Drive Shaft/Cap Assembly



Direct Drive Paddle Assembly

# **Direct Drive Motors**

- High torque, low rpm stirrer designed to maintain constant low speed
- Gearhead stirrer delivers 14.5 in-lbs of torque
- Maximum speed is 350 rpm
- Weight of motor is 9 lbs (4.1kg)
- Available with 120VAC 60Hz or 230VAC 50Hz

Cat. No.	Description	Qty/Cs
400640	120VAC, 60 Hz Motor	1
402645	230VAC, 50 Hz Motor	1

# **Direct Drive Shaft/Cap Assemblies**

- For 8L, 15L, or 36L paddle assemblies
- Used on all series 4510 and 4512 Spinner flasks

Cat. No.	Description	Qty/Cs
4520-104	For 100 mm Neck Flasks	1
4520-106	For 120 mm Neck Flasks	1

# **Direct Drive Paddle Assemblies**

- For series 4510, 4512, and 4514 Spinner flasks when coupled to a direct drive motor
- Paddle assemblies will couple to 100 mm and 120 mm cap assemblies

Cat. No.	Description	Qty/Cs
4515-8L	Paddle assembly only for 8L flask	1
4515-15L	Paddle assembly only for 15L flask	1
4515-36L	Paddle assembly only for 36L flask	1

# **Erlenmeyer Flasks**



431146 1L Erlenmeyer Flask

# Shaker Flask Application Tip

Corning recommends starting with a shaking rate of 75-125 RPM (orbital shaker) and a medium volume of 30-40% of the nominal flask capacity.



431256 2L Erlenmeyer Flask



**431253** 3L Fernbach Culture Flask

# **Erlenmeyer Flasks**

- Made from optically clear polycarbonate
- Ideal for shaker culture applications
- Two-position polypropylene plug seal cap can be opened for gas exchange or closed for a liquid-tight seal
- > Vent caps available for applications requiring sterile gas exchange
- Sterilized by gamma radiation
- Certified nonpyrogenic

# Erlenmeyer Flask Ordering Information

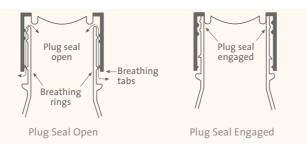
Cat. No.	Capacity (mL)	Graduation (mL)	Neck Diameter (mm)	Cap Style	Qty/Pk	Qty/Cs
430421	125	25	26	Plug seal	1	50
431143	125	25	26	Vent cap	1	50
430183	250	25	31	Plug seal	1	50
431144	250	25	31	Vent cap	1	50
430422	500	50	43	Plug seal	1	25
431145	500	50	43	Vent cap	1	25
431146	1000	50	43	Plug seal	1	25
431147	1000	50	43	Vent cap	1	25

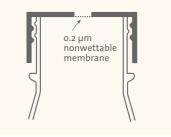
# 2L and 3L Polycarbonate Flasks

- Made from optically clear polycarbonate
- Ideal for shaker culture applications
- Available in baffled and nonbaffled bottoms
- > Vent caps supplied in every case of product for applications requiring sterile gas exchange
- Sterilized by gamma radiation
- Certified nonpyrogenic

## Polycarbonate Flask Ordering Information

Cat. No.	Description	Sterile	Qty/Cs
431255	Erlenmeyer Flask, 2L, polycarbonate	Yes	6
431256	Erlenmeyer Flask, 2L, polycarbonate, baffled bottom	Yes	6
431252	Fernbach Culture Flask, 3L, polycarbonate	Yes	4
431253	Fernbach Culture Flask, 3L, polycarbonate, baffled bottom	Yes	4
431339	Cap, Vented, 48 mm for 2L flask	Yes	24
431340	Cap, Vented, 70 mm for 3L flask	Yes	24





**Breathable two-position plug seal caps** feature one-piece linerless construction with a flexible plug for a gas- and liquid-tight seal. In addition, the unique breathable cap design allows use in either an open or closed mode.

Vent caps contain a 0.2 µm nonwettable membrane sealed to the cap, providing consistent, sterile gas exchange while minimizing the risk of contamination.

# **Cell Scrapers and Lifters**



3008 Cell Lifter

# **Cell Scrapers and Cell Lifters**

- Useful for the manual harvesting of cells
- Blade design minimizes cell damage and ensures even contact with the growth surface
- Cell lifter is useful for harvesting cells in dishes
- Scrapers designed for use in flasks
- Individually wrapped
- Sterilized by gamma radiation
- Certified nonpyrogenic

### Cell Scraper and Lifter Ordering Information

Cat. No.	Description	Blade Length (cm)	Handle Length (cm)	Qty/Pk	Qty/Cs
3008	Cell lifter	1.9	18	1	100
3010	Small scraper	1.8	25	1	100
3011	Large scraper	3.0	39	1	100

# 3010 Small Cell Scraper

# Spatulas and Microspatulas



Spatulas



Microspatulas

# • Corning<sup>®</sup> spatulas are designed to save researcher's time and to provide them with contamination-free samples

- Each spatula is individually packaged, certified RNase-/DNase-free, nonpyrogenic, antistatic, and sterile
- They are specifically targeted toward researchers interested in eliminating the recycling and resterilizing necessary with reusable spatulas
- > Spatulas are available in five different configurations

### Spatulas Ordering Information

Cat. No.	Description	Qty/Cs
3003	Spatula, Tapered Blade/Spoon	100
3004	Spatula, Small Spoon/Spoon	100
3005	Spatula, Round End/Spoon	100
3006	Spatula, V-Scoop/Spoon	100
3007	Spatula, Flat End/Spoon	100
3012	Microspatula, tapered end/scoop	50
3013	Microspatula, rounded end/scoop	50

# Pipets



Stripette Serological Pipets



Three packaging options



Exclusive Antidrip Tip

# Stripette<sup>®</sup> Serological Pipets

- Exclusive antidrip tip assures accurate delivery
- Available in 25, 50, and 100 mL sizes
- Color-coded magnifier stripes make volume reading easier
- Bidirectional graduations provide choice of ascending and descending scales
- Negative graduations allow additional working volume
- Four packaging options:
  - Individually wrapped, clear plastic
  - Individually wrapped, paper/plastic
  - Bulk packed for large-scale sterile and nonsterile liquid handling applications
  - Clean room packed; individually wrapped, paper/plastic, triple bagged

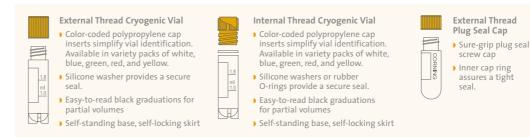
#### **Stripette Pipets Ordering Information**

Cat. No.	Capacity (mL)	Graduations (mL)	Negative Grads. (mL)	Color Coded Stripe	Qty/Pk	Qty/Cs
Individually	Wrapped, Cl	ear Plastic Wrap				
4011	1	1/100	0.2	Yellow	100/bag	1,000
4012	1	1/100	0.2	Yellow	100/bag	200
4021	2	1/100	0.2	Green	100/bag	1,000
4051	5	1/10	2.5	Blue	50/bag	200
4101	10	1/10	3.0	Orange	50/bag	200
4492*	10	1/10	3.0	Orange	50/bag	200
4251	25	2/10	10.0	Red	50/bag	200
4501	50	1/2	10.0	Purple	25/bag	100
4484	100	1	N/A	Aqua	10/bag	100
Individually	Wrapped, Pa	per/Plastic Wrap				
4485	1	1/100	0.2	Yellow	50/bag	1,000
4486	2	1/100	0.2	Green	50/bag	1,000
4487	5	1/10	2.5	Blue	50/bag	200
4488	10	1/10	3.0	Orange	50/bag	200
4489	25	2/10	10.0	Red	25/bag	200
4490	50	1/2	10.0	Purple	25/bag	100
4491	100	1/1	N/A	Aqua	10/bag	100
Bulk Packed	l in Bags					
4010	1	1/100	0.2	Yellow	50/bag	1,000
4020	2	1/100	0.2	Green	50/bag	1,000
4050	5	1/10	2.5	Blue	50/bag	500
4100	10	1/10	3.0	Orange	50/bag	500
4250	25	2/10	10.0	Red	25/bag	200
4500	50	1/2	10.0	Purple	25/bag	100
Clean Room	Pack, Indivia	lually Wrapped, P	aper/Plastic, Triple	Bagged		
7015	10	1/10	3.0	Orange	50/bag	200
7016	25	2/10	10.0	Red	25/bag	200
7017	50	1/2	10.0	Purple	25/bag	100
7000	100	1/1	N/A	Aqua	10/bag	100

\*Cat. No. 4492 features a wide tip for handling viscous fluids.

# **Cryogenic Vials and Accessories**

Corning offers three styles of cryogenic vials as well as storage racks and boxes.



Warning! Do not use cryogenic vials for storage in the liquid phase of liquid nitrogen. Only store vials in the vapor phase above the liquified gas. Always use appropriate safety equipment when removing vials from cryogenic storage.

# **External Thread Cryogenic Vials**

- Manufactured from polypropylene to withstand temperatures down to -196°C
- Larger marking spot
- Black graduations
- ▶ Certified RNase-/DNase-free
- Vials have a silicone washer for a secure seal.
- Vials may be color coded with inserts (Cat. No. 430499)
- Self-standing vials have a special base design allowing them to be locked into cryogenic rack and tray (Cat. No. 430525 or 431131) for single-handed manipulation
- Sterilized by gamma radiation
- Certified nonpyrogenic
- Free foam rack with each case

#### External Thread Cryogenic Vials Ordering Information

Cat. No.	Capacity (mL)	Style	Self-Standing	Qty/Pk	Qty/Cs
430658	1.2	Conical Bottom	Yes	50	500
430659	2.0	Round Bottom	Yes	50	500
430661	2.0	Round Bottom	No	50	500
430662	4.0	Round Bottom	Yes	50	500
430663	5.0	Round Bottom	Yes	50	500
*** * * **			<u> </u>		

Warning! Do not use cryogenic vials for storage in the liquid phase of liquid nitrogen. Only store vials in the vapor phase above the liquified gas. Always use appropriate safety equipment when removing vials from cryogenic storage.



External Thread Cryogenic Vials

# Cryogenic Vial Safety Tip

Appropriate safety equipment (gloves, face shields, biological safety cabinets, hoods, etc.) should always be used to protect personnel when removing vials or ampules from cryogenic storage systems.



Internal Thread Cryogenic Vials

# **Internal Thread Cryogenic Vials**

- Manufactured from polypropylene to withstand temperatures down to -196°C
- Larger marking spot
- Black graduations
- Certified RNase-/DNase-free
- Vials have a silicone washer or rubber O-ring for a secure seal
- Vials may be color coded with inserts (Cat. No. 430499)
- Self-standing vials have a special base design allowing them to be locked into cryogenic rack and tray (Cat. No. 430525 or 431131) for single-handed manipulation
- Sterilized by gamma radiation
- Certified nonpyrogenic
- Free foam rack with each case

## Internal Thread Cryogenic Vials Ordering Information

Cat. No.	Capacity (mL)	Style	Self- Standing	Seal Type	Qty/Pk	Qty/Cs
430487	1.2	Conical Bottom	Yes	Washer	50	500
2012	1.2	Conical Bottom	Yes	O-Ring	50	250
430488	2.0	Round Bottom	Yes	Washer	50	500
430489	2.0	Round Bottom	No	Washer	50	500
2027	2.0	Round Bottom	No	O-Ring	50	250
2028	2.0	Round Bottom	Yes	O-Ring	50	250
430490	4.0	Round Bottom	No	Washer	50	500
430491	4.0	Round Bottom	Yes	Washer	50	500
430492	5.0	Round Bottom	No	Washer	50	500
430656	5.0	Round Bottom	Yes	Washer	50	500
2051	5.0	Round Bottom	No	O-Ring	50	250

Warning! Do not use cryogenic vials for storage in the liquid phase of liquid nitrogen. Only store vials in the vapor phase above the liquified gas. Always use appropriate safety equipment when removing vials from cryogenic storage.

# **External Thread Cryogenic Vials with Plug Seal Cap**

- Manufactured from polypropylene to withstand temperatures down to -196°C
- Vials feature an external thread with a traditional plug seal cap design for a secure seal
- Cap does not accept color-coded inserts
- Sterilized by gamma radiation
- Certified nonpyrogenic

## External Thread Cryogenic Vials with Plug Seal Cap Ordering Information

Cat. No.	Capacity (mL)	Style	Self-Standing	Qty/Pk	Qty/Cs
430289	2.0	Round Bottom	No	50	500

Warning! Do not use cryogenic vials for storage in the liquid phase of liquid nitrogen. Only store vials in the vapor phase above the liquified gas. Always use appropriate safety equipment when removing vials from cryogenic storage.



**430289** External Thread Cryogenic Vials with Plug Seal Cap



**430499** Color-Coded Cap Inserts

# **Cap Inserts for Cryogenic Vials**

- Caps inserts provide color coding for easy sample identification
- Inserts are packaged in resealable bags
- Nonsterile
- Cap inserts fit all Corning® cryogenic vials except Cat. No. 430289

## Cryogenic Vials Cap Inserts Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
430499	Assorted colors, polypropylene cap inserts: 100 each of white, blue, red, green, and yellow	50	500
2015	White polypropylene cap inserts	50	500
2016	Blue polypropylene cap inserts	50	500
2017	Red polypropylene cap inserts	50	500
2018	Green polypropylene cap inserts	50	500
2019	Yellow polypropylene cap inserts	50	500

# **Cryogenic Vial Racks and Storage Boxes**

- Reusable racks are designed for use with most cryogenic vials
- Cat. No. 430525 has a locking feature for use with all Corning self-standing vials

#### Cryogenic Vial Racks and Storage Boxes Ordering Information

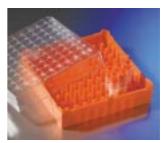
Cat. No.	Description	Qty/Pk	Qty/Cs
430525	Polycarbonate rack and tray, holds 30 vials; self-locking design in ice/water bath	1	1
430526	Polycarbonate rack only, holds 30 vials; self-locking design	1	1
431131	Reusable orange polypropylene vial rack, holds 50 vials; self-locking design	2	2
431119	81 count (9 x 9 array) Cryogenic Box, for 1-2 mL vials	5	10
431120	81 count (9 x 9 array) Cryogenic Box, for 4-5 mL vials	5	10
431121*	100 count (10 x 10 array) Cryogenic Box, for 1-2 mL vials	5	10

\*431121 accepts internally threaded cryogenic vials only.



431119 Cryogenic Storage Box

431120 Cryogenic Storage Box



431121 Cryogenic Storage Box



**430525 and 431131** Cryogenic Vial Racks

# **Centrifuge Tubes**



15 mL Centrifuge Tube

#### **15 mL Centrifuge Tubes**

- Corning® 15 mL centrifuge tubes feature black printed graduations and a large white marking spot.
- Tubes are available with your choice of cap styles; the original plug seal or flat cap.
- Tubes are available in racks or bulk packed in ziplock, resealable sleeves
  - Sterile, certified nonpyrogenic, and RNase-/DNase-free
  - Foam racks also available separately

#### **Centrifuge Tubes Ordering Information**

Cat. No.	Material	Cap Style	Max. RCF	Qty/Pk	Qty/Cs
430053	PET	Plug Seal	3,600	25/Sleeve	500
430055	PET	Plug Seal	3,600	50/Rack	500
430052	PP	Plug Seal	8,400	50/Rack	500
430766	PP	Plug Seal	8,400	25/Sleeve	500
430790	PP	Flat Top	8,400	50/Rack	500
430791	PP	Flat Top	8,400	25/Sleeve	500
431355	Foam Cent	rifuge Tube Rack, 15	5 mL		20

PP = Polypropylene, PET = Polyethylene Terephthalate, RCF = Relative Centrifugal Force (x g).

## 50 mL Centrifuge Tubes

- Corning<sup>®</sup> 50 mL centrifuge tubes feature black printed graduations and a large white marking spot
- These tubes are available with your choice of cap styles; the original plug seal or flat cap
- Tubes are available in racks or bulk packed in ziplock, resealable sleeves
- Sterile, certified nonpyrogenic, and RNase-/DNase-free
- Foam racks also available separately

#### 50 mL Centrifuge Tubes Ordering Information

Cat. No.	Material	Cap Style	Max. RCF	Qty/Pk	Qty/Cs
430290	PP	Plug Seal	9,400	25/Rack	500
430291	PP	Plug Seal	9,400	25/Sleeve	500
430304	PET	Plug Seal	3,600	25/Rack	500
430828	PP	Flat Top	9,400	25/Rack	500
430829	PP	Flat Top	9,400	25/Sleeve	500
4558	PP	CentriStar <sup>™</sup> Cap	15,500	25/Universal Rack*	300
4365	Foam Ce	ntrifuge Tube Rack, 50	mL	_	20
DD DI	I DET DI	J. J. T. J.J. L. DOD	D L C C C		

PP = Polypropylene, PET = Polyethylene Terephthalate, RCF = Relative Centrifugal Force (x g).

\*New innovative universal rack can hold 50 mL and 15 mL tubes securely, allowing researchers to work with and store both size tubes in the same rack, saving bench and storage space.



50 mL Centrifuge Tube



Self Standing 50 mL Centrifuge Tube



500 and 250 mL Centrifuge Tubes

# Self-Standing 50 mL Centrifuge Tubes

- All Corning<sup>®</sup> 50 mL centrifuge tubes feature black printed graduations and a large white marking spot.
- Available with your choice of cap styles; the original plug seal or flat cap.
- Tubes are bulk packed in ziplock, resealable sleeves
- > Sterile, certified nonpyrogenic, and RNase-/DNase-free.

#### Self-Standing 50 mL Centrifuge Tubes Ordering Information

Cat. No.	Material	Cap Style	Max. RCF	Qty/Pk	Qty/Cs
430897	PP	Plug Seal	3,000	25	500
430921	PP	Flat Top	3,000	25	500

PP = Polypropylene, RCF = Relative Centrifugal Force (x g).

## 250 mL and 500 mL Centrifuge Tubes and Support Cushions

- Corning 250 mL and 500 mL polypropylene tubes are ideal for applications requiring largevolume centrifugation.
- Each case of tubes contains a rack to facilitate handling.
- Support cushions must be used with this product unless the rotor has appropriately shaped V-bottom holders.
- Tubes are sterile and certified nonpyrogenic.

#### 250 mL and 500 mL Centrifuge Tubes Ordering Information

Cat. No.	Description	Material	Cap Style	Max RCF	Qty/Pk	Qty/Cs
430776	250 mL Tube	PP	Plug	6000	6	102
430236	250 mL Support Cushion	PEI	n/a	n/a	n/a	6
431123	500 mL Tube	PP	Plug	6000	6	36
431124	500 mL Support Cushion	PEI	n/a	n/a	n/a	6

PP = Polypropylene, PEI = Polyetherimide, RCF = Relative Centrifugal Force (x g).

# **Technical Appendix**

# CHARACTERISTICS OF CORNING PLASTICWARE

		Polystyrene	Polyethylene (High Density)	Polypropylene	Polycarbonate	Nylon	P.T.F.E. (Teflon®)
Physical Characteristics	Basic Properties	Biologically inert, hard, excellent optical qualities	Biologically inert, high chemical resistance	Biologically inert, high chemical resistance, exceptional toughness	Clear, very tough, inert, high temperature resistance	Tough, heat resistant, machinable, high moisture vapor transmission	Biologically and chemically inert, high resistant slippery surface
	Clarity	Clear	Opaque	Translucent	Clear	Opaque	Opaque
	Autoclave Results	Melts	May distort	Withstands several cycles	Withstands one cycle	OK	ОК
	Heat Distortion Point	147-175°F 64-80°C	250°F 121°C	275°F 135°C	280-290°F 138-143°C	300-356°F 150-180°C	250°F 121°C
	Burning Rate	Slow	Slow	Slow	Self- extinguishing	Self- extinguishing	None
Effects of	Weak Acids	None	None	None	None	None	None
Laboratory Reagents	Strong Acids	Oxidizing acids attack	Oxidizing acids attack	Oxidizing acids attack	May be attacked	Attacked	None
	Weak Alkalies	None	None	None	None	None	None
	Strong Alkalies	None	None	None	Slowly attacked	None	None
	Organic Solvents	Soluble in aromatic chlorinated hydrocarbons	Resistant below 80°C	Resistant below 80°C	Soluble in chlorinated hydrocarbons; partly soluble in aromatics	Resistant	Resistant
Gas Permeability	O <sub>2</sub>	Low	High	High	Very low	Very low	_
of Thin Wall	N <sub>2</sub>	Very low	Low	Low	Very low	Very low	-
Products*	CO <sub>2</sub>	High	Very high	Very high	Low	_	_

Portions of this table courtesy of Modern Plastics Encyclopedia. Most data are from tests by A.S.T.M. methods. Tables show averages or ranges. Many properties vary with manufacturer, formulation, testing laboratory, and the specific operating conditions. \*Obtained from a table which lists gas permeability in CC/100 sq. inches per 24 hrs./mil.

### CHEMICAL COMPATIBILITY OF CORNING® PLASTICWARE

	PS	PP	PVC	СА	PC	CN	NY	MCE	PTFE	PET
Acids										
Hydrochloric acid (25%)	G	G	G	Ν	R	R	Ν	0	R	R
Hydrochloric acid (concentrated)	F	G	F	Ν	R	Ν	Ν	Ν	R	0
Nitric acid (concentrated)	Р	Р	Р	Ν	R	Ν	Ν	Ν	0	Ν
Nitric acid (25%)	Р	G	F	Ν	R	L	Ν	0	R	R
Alcohols										
Butanol	G	G	G	R	R	R	R	R	R	R
Ethanol	G	G	G	R	R	Ν	R	0	R	R
Methanol	G	G	G	R	R	Ν	R	0	R	R
Aniline	G	G	Р	Ν	Ν	R	R	Ν	R	0
Dimethylformamide	Р	G	F	Ν	Ν	Ν	R	Ν	R	Ν
Bases										
Ammonium hydroxide (25%)	F	G	G	R	Ν	R	R	0	Ν	0
Ammonium hydroxide (1N)	F	G	G	Ν	Ν	R	R	0	Ν	Ν
Sodium hydroxide	G	G	G	Ν	Ν	Ν	R	Ν	R	Ν
Hydrocarbons										
Hexane	Р	G	F	R	R	R	R	R	R	R
Toluene	Р	G	Р	R	0	R	R	R	R	Ν
Xylene	Р	F	Р	R	R	R	R	R	R	Ν
Dioxane	Р	G	Р	Ν	Ν	Ν	R	Ν	R	R
Dimethylsulfoxide (DMSO)	Р	G	Р	Ν	Ν	Ν	R	Ν	R	0*
Halogenated Hydrocarbons										
Chloroform	Р	G	Р	Ν	Ν	R	R	Ν	R	R
Methylene chloride	Р	F	Р	Ν	Ν	R	R	Ν	R	Ν
Ketones										
Acetone	Р	G	Р	Ν	0	Ν	R	Ν	R	R
Methyl ethyl diketone	Р	G	Р	Ν	0	Ν	R	0	R	R

\*Can be used with aqueous solutions containing up to 20% DMSO.

R = Recommended, L = Limited Resistance, N = Not Recommended, O = Testing Advised, F = Fair, G = Good, P = Polypropylene, PVC = Polyvinyl Chloride, CA = Cellulose Acetate, PC = Polycarbonate, PTFE = Polytetrafluoroethylene PS = Polystyrene, CN = Cellulose Nitrate, NY = Nylon, MCE = Mixed Cellulose Esters, PET = Polyethylene Terephthalate.

# CHARACTERISTICS OF CORNING **CENTRIFUGE TUBES**

The following information is provided to serve as a general guideline for determining suitability of Corning centrifuge tubes for your applications. In addition, Corning recommends following the procedures outlined by the centrifuge manufacturer, as well as conducting a trial run to determine proper conditions before beginning any critical applications.

Corning centrifuge tubes are tested for leakage. They should not break or leak if used in a properly balanced rotor with suitable carriers, holders, and adapters that fully support the tubes when run in accordance with the guidelines in this section. These tubes are intended for one-time use only; reuse is not recommended as breakage or leakage may occur.

The recommended working temperature range for Corning centrifuge tubes is 0 to 40°C. The suitability of these tubes for storage below 0°C depends on both the solution and the storage conditions. In general, the polypropylene and PET tubes are more resistant to stress at low temperatures than polystyrene. It is strongly recommended that a trial run be performed under actual conditions to test the suitability of the tubes for frozen storage.

#### **Suggestions for Safe Centrifugation**

- *Caution*: When centrifuging pathogenic organisms, clinical specimens known or suspected of being infectious, or any other potentially biohazardous materials, approved safety containment systems should be used. Contact your centrifuge manufacturer for appropriate accessories or recommendations.
- Read protocols and instruction manuals carefully. Do not confuse speed or revolutions per minute (RPM) with relative centrifugal force (RCF). Instructions for centrifuging a sample at a given RPM and time are incomplete unless the rotor or radius is specified. Protocols should always state the time and RCF value for centrifuging a sample.

Proper balancing and distribution of the load in a centrifuge is critical for optimum performance and to prevent damage to the tubes or centrifuge. Opposing buckets or loads should always be balanced within the range specified by the manufacturer. Tubes should always be distributed in the buckets with respect to the center of rotation as well as the pivotal axis of the bucket. Failure to do this may prevent the bucket from achieving a horizontal position during the centrifugation run. Uneven separations or tube failure may result.

These centrifuge tubes are intended for use by persons knowledgeable in safe laboratory practices. Failure can result from surface damage, exceeding the specified RCF values, using unsuitable support systems, improper temperatures, or incompatible chemicals.

The RCF ratings for Corning<sup>®</sup> disposable centrifuge tubes have been established at room temperature using tubes filled

to nominal capacity with water and spun in a horizontal rotor centrifuge for 5 minutes. The centrifuge must be equipped with the recommended carriers, adapters, and cushions that fully support the tubes. If an angle head rotor is used or proper support is not provided, RCF values will be lower. Use of liquid other than water may also lower RCF values. Please consult your centrifuge specifications and the nomogram table (page 39) to determine speeds at which maximum RCF is achieved.

#### Chemical Compatibility of Disposable Plastic Centrifuge Tubes

The mechanical strength, flexibility, color, weight and dimensional stability of all plastic centrifuge tubes are affected to varying degrees by the chemicals with which they come in contact. Specific operating conditions, especially temperature, RCF, rotor type, carrier design, and run length will also affect tube performance.

#### Physical Properties of Disposable Plastic Centrifuge Tubes

	Clear Polypropylene	Opaque Polypropylene	New Polyethylene Terephthalate
Recommended Working Temp*	0-40°	0-40°	0-40°
Heat Distortion Point	121°	121°	70°
Flexibility	Moderate	Moderate	Rigid
Transparency	Clear	Opaque	Clear
Maximum RCF:			
15 mL Tube	8,400 x g	_	3,600 x g
50 mL Tube	9,400 x g	_	3,600 x g
250 mL Tube	_	6,000 x g	_
500 mL Tube	—	6,000 x g	—

\*At room temperature for 24 hours.

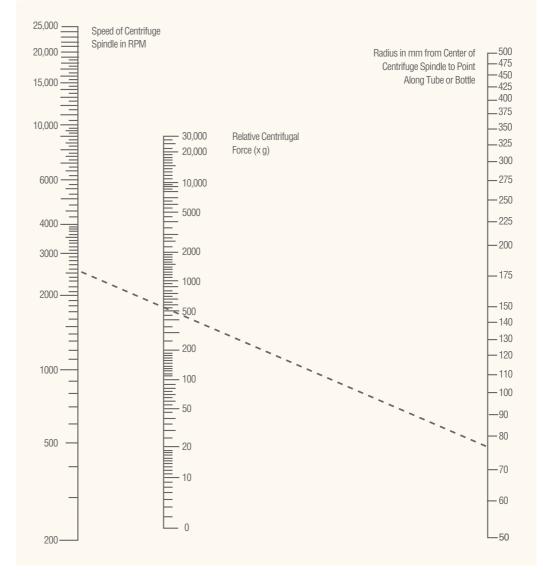
#### Chemical Resistance of Disposable Plastic Centrifuge Tubes\*

Chemical Class	Polyethylene Terephthalate	Polypropylene	Polyethylene Caps
Acids (weak)	1	1	1
Acids	3	1	1
Alcohols	1	1	1
Aldehydes	3ª	2ª	1
Bases	3	1	1
Esters	2	2	2
Hydrocarbons:			
Aliphatic	1	2	3
Aromatic	3	3 <sup>b</sup>	3
Halogenated	2	3	3
Ketones	2	2°	2

\*At room temperature for 24 hours.

1 = Recommended; 2 = Suitable for most applications. However, a trial run under specific operating conditions is recommended; 3 = Not recommended.

Note: a = Formaldehyde, rated 1; b = Phenol, rated 1; c = Acetone, rated 1.



Nomogram for Computing Relative Centrifugal Force

To calculate the RCF value at any point along the tube or bottle, measure the radius, in mm, from the center of the centrifuge spindle to the particular point. Draw a line from the radius value on the right hand column to the appropriate centrifuge speed on the left-hand column. The RCF value is the point where the line crosses the center column. The nomogram is based on the formula:

 $RCF = (11.17 \times 10^{-7}) RN^2$ 

where:

R = Radius in mm from centrifuge spindle to point in tube bottom N = Speed of spindle in RPM

### **CORNING® CELL CULTURE SURFACES**

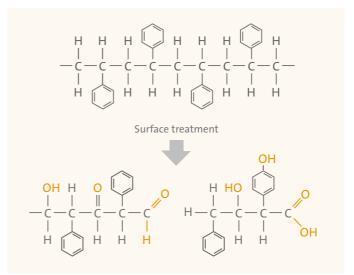
#### Introduction

For over eighty years Corning has been developing products and surfaces for cell culture. Corning currently offers five polystyrene-based surfaces (Table 1) for growing cells including the most recent technology revolution, the patented Corning CellBIND® surface (U.S. Patent 6,617,152):

Most of these early plastic vessels were made from polystyrene, a long carbon chain polymer with benzene rings attached to every other carbon. Polystyrene was chosen because it has excellent optical clarity, is easy to mold and is relatively inexpensive. However, it also has one significant drawback: it is a very hydrophobic (nonwettable) polymer to which cells have difficulty attaching. Fortunately, the surface of polystyrene can be easily modified by a variety of chemical (sulfuric acid) and physical (corona discharge, gas-plasma or irradiation) methods). Using these methods, hydroxyl, ketone, aldehyde, carboxyl and amine groups can readily be grafted onto the polymer (Figure 1). These groups modify the surface characteristics changing the uncharged hydrophobic surface into a more ionic hydrophilic surface. Polystyrene can also be modified through chemical reactions to allow the covalent attachment of a variety of reactive groups that can be used for the subsequent covalent immobilization of biomolecules. For additional information, please check the References.

#### **Untreated Polystyrene Surface**

Natural, unmodified polystyrene surfaces are hydrophobic and only bind cells and biomolecules through passive hydrophobic interactions. Corning offers untreated polystyrene culture dishes and microplates for growing cells in stationary suspension or other applications where reduced cell attachment is desired. However, these untreated vessels are sterilized by low dose gamma irradiation, which slightly increases the wettability of the surface. Since some transformed cell lines (CHO-k1, for example) and macrophages will attach and grow on these hydrophobic surfaces, Corning also offers an Ultra Low Attachment Surface (see below) for use in situations where cell attachment must be kept to an absolute minimum.



**Figure 1.** Polystyrene can be surface modified by the addition of a variety of different chemical groups, by breaking the carbon chain backbone, or by opening the benzene ring (not shown).

#### Ultra Low Attachment Coated Polystyrene Surface

The Corning Ultra Low Attachment surface is a covalently bound hydrogel layer that is hydrophilic and neutrally charged. Since proteins and other biomolecules passively adsorb to polystyrene surfaces through either hydrophobic or ionic interactions, this hydrogel surface naturally inhibits nonspecific immobilization via these forces, thus inhibiting subsequent cell attachment. This surface is very stable, noncytotoxic, biologically inert and nondegradable. Corning offers the Ultra Low Attachment surfaces on dishes and microplates.

This Ultra Low Attachment surface has been shown to successfully inhibit attachment of anchorage dependent MDCK, VERO, and C6 cells grown for a period of time equal to that necessary to obtain confluent cell growth on the control surface (standard tissue culture treated polystyrene; Figure 2). This surface has also been shown to inhibit the attachment and activation of macrophages and neutrophils.

Corning Surface	Binding Interaction	Sample Properties
Untreated polystyrene	Hydrophobic	Significantly reduces the attachment of most cells
Ultra Low Attachment coated polystyrene	Hydrophilic and nonionic	Hydrogel layer prevents the attachment of almost all cells
Tissue culture treated polystyrene	Hydrophilic and ionic (negatively charged)	Allows cell attachment and binding to polystyrene
Corning CellBIND modified polystyrene surface	Hydrophilic and ionic (negatively charged)	Improves cell attachment and binding to polystyrene
Poly-D-lysine coated polystyrene	Hydrophilic and ionic (positively charged)	Improves cell attachment and binding to polystyrene

#### Table 1. Corning Cell Culture Surfaces

Ultra Low Attachment culture vessels are useful for:

- Studying tissue-specific functions of certain cancer cells (i.e., MCF-7 breast cancer cells)
- Preventing stem cells from attachment-mediated differentiation
- Selectively culturing tumor or virally transformed cells as unattached colonies (substitute for soft agar assays)

#### Standard Tissue Culture Treated Polystyrene Surface

Standard Corning<sup>®</sup> polystyrene cell culture vessels are surface modified using either corona discharge (flasks, dishes and microplates) or gas-plasma (roller bottles and culture tubes). These processes generate highly energetic oxygen ions which graft onto the surface polystyrene chains (Figure 1) so that the surface becomes hydrophilic and negatively charged when placed in medium. Corning offers the standard tissue culture treated surface on flasks, dishes, multiple well plates, CellSTACK<sup>®</sup> Culture Chambers, roller bottles and culture tubes.

#### Corning CellBIND® Modified Polystyrene Surface

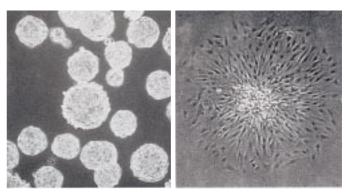
The Corning CellBIND culture surface, the first novel cell culture surface treatment in over 20 years, is designed to improve cell attachment under difficult conditions, such as reduced-serum or serum-free medium, resulting in higher cell yields. It is also useful for growing "difficult" cells, such as primary cultures or transfected cells over expressing proteins (Figure 3). Developed by Corning scientists, this patented technology (U.S. Patent 6,617,152) uses a novel microwave plasma process for treating the culture surface. This process improves cell surface than traditional plasma or corona discharge treatments, rendering it more hydrophilic (wettable) and increasing the stability of the surface.

Unlike biological coatings, the Corning CellBIND surface is a nonbiological surface that requires no special handling or storage. Because the polymer is treated, rather than coated, the surface is more consistent and stable. This enhanced cell performance has already led to a major biotechnology company choosing Corning roller bottles with the Corning CellBIND surface for producing a new FDA approved protein therapeutic.

Corning CellBIND surface benefits:

- Gives more consistent and even cell attachment for difficult to attach cell lines, especially transfected cells
- Quickly adapts cells to reduced serum or serum-free conditions
- Reduces premature cell detachment from confluent cultures especially in roller bottles and during cell-based assays
- May eliminate the need for tedious, time-consuming, expensive and low stability biological coatings
- Stable at room temperature, requires no refrigeration or special handling

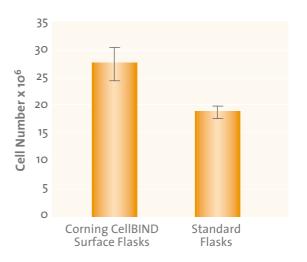
The Corning CellBIND surface is available on flasks, multiple well plates, CellSTACK Culture Chambers, roller bottles, 96 well plates, 384 well plates, and dishes.



**Figure 2.** Single cell derived colonies of C6 glioma cells grow as flattened attached colonies in standard tissue culture treated surface (left panel) but form unattached spherical colonies on the ultra low attachment surface (right panel).

#### **Poly-D-lysine Coated Surface**

Some assays and procedures require enhanced binding of cells to polystyrene. Corning poly-D-lysine (PDL) microplates are coated with PDL (molecular weight range of 70 to 150 kDa) by a proprietary method. This synthetic polymeric coating creates a uniform net positive charge on the plastic surface which, for some cell types, can enhance cell attachment, growth and differentiation, especially in serum-free and low serum conditions. PDL surfaces often improve attachment and growth of primary neurons, glial cells, neuroblastomas, and a variety of transfected cell lines, including HEK-293. Corning offers poly-D-lysine coated 96 and 384 well microplates.



**Figure 3.** The first new cell culture treatment in over 20 years, the Corning CellBIND surface helps cells (such as the HEK-293 cells shown here) attach under difficult conditions and improves cell yields.



# Microplates

	<b>RVIEW</b>
96	NELL MICROPLATES
	General Assay
(	Cell Culture 51
-	mmunoassay
	Storage
384	WELL MICROPLATES
	General Assay 57
	Cell Culture
	Gtorage
153	WELL MICROPLATES61
PRC	TEIN CRYSTALLIZATION MICROPLATES 63
	TEIN CRYSTALLIZATION MICROPLATES63ROPLATE ACCESSORIES64
MIC	-
MIC	ROPLATE ACCESSORIES64
MIC	ROPLATE ACCESSORIES         64           Lids         64
MIC	ROPLATE ACCESSORIES       64         Lids       64         Storage Mats and Accessories       64
MIC	ROPLATE ACCESSORIES       64         Lids       64         Storage Mats and Accessories       64         Robolids       65
TEC	ROPLATE ACCESSORIES64Lids64Storage Mats and Accessories64Robolids65Gealing Tapes65
MIC	ROPLATE ACCESSORIES64Lids64Georage Mats and Accessories64Robolids65Gealing Tapes65HNICAL APPENDIX66

# Overview

#### **DESIGNED FOR PERFORMANCE**

Corning has been setting the standard for excellence in life science labware for over 85 years. With our comprehensive line of plasticware, including assay products, we continue to be an industry leader. Corning strives for the highest standards in product design and plastics molding.

Corning Life Sciences microplates and accessories are manufactured under strict process controls guaranteeing consistent product performance. Our manufacturing facility is located in Kennebunk, Maine, registered to the ISO 9001 2000 standards. ISO registration is recognized worldwide as a standard of excellence for quality systems.

Customers can request a Certificate of Compliance for any Corning<sup>®</sup> microplate. Also available are detailed product descriptions and drawings that highlight product dimensions and testing procedures. All are available by contacting your local Corning Life Sciences office. See the back cover of this guide for a listing.

### CORNING MICROPLATE EQUIPMENT COMPATIBILITY PROGRAM

The increasing use of automated laboratory equipment demands consumables that have been qualified for fit and function. Corning microplates are designed with automation compatibility in mind and meet industry standards. In addition, Corning has a comprehensive equipment compatibility program in which leading equipment manufacturers certify the compatibility of our microplates with their instruments.

For the most up-to-date information on equipment compatibility, Corning maintains a *Microplate Equipment Compatibility Guide* on our web site at **www.corning.com/lifesciences**. This on-line guide is searchable by instrument type, plate type, and by manufacturer name.

# LIFE SCIENCES EARLY ACCESS TO DEVELOPMENT -CORNING'S L.E.A.D. PROGRAM

Corning is committed to meeting the rapidly evolving needs of the life sciences laboratory. We are continually developing new and innovative products that are compatible with the latest advances in technology and instrumentation. Our L.E.A.D. program gives researchers access to these products and special pricing prior to their full market release. Contact your local Corning Life Sciences office or representative for more information about the products currently available through this program.

#### SELECTING THE BEST CORNING® MICROPLATE FOR YOUR APPLICATION

Corning offers a range of microplates in a variety of well designs and sizes, polymer materials and colors, and surface treatments. This guide includes 96, 384, and 1536 well microplates. Information on Corning plates in lower density formats (e.g., 24 and 48 well plates) can be found in our on-line product catalog at **www.corning.com/lifesciences**.

There are three simple steps for selecting the best Corning microplate for your application:

- <sup>1</sup> Choose the Corning microplate format and well design
- <sup>2</sup> Choose the Corning microplate material and color
- <sup>3</sup> Choose the Corning surface treatment

### Choose the Corning Microplate Format and Well Design

Corning microplate dimensions meet industry standards, ensuring compatibility with all microplate equipment and automation. Our microplates feature an A-1 corner notch design. The A-1 corner notch allows for quick visual orientation of plates when setting up automation runs, thereby reducing chances for robotics problems and lost productivity.

Corning microplates are available in several well shapes, optimized to meet different application requirements.

- > Flat bottom for bottom reading plate readers and cell culture applications
- Round bottom for improved mixing and washing
- **V-bottom** for easier removal of total well contents
- ▶ Easy Wash<sup>TM</sup> bottom (round to narrowed flat well bottom) for improved washing in immunoassays

In addition, Corning offers Half Area microplates for the 96 well format and Low Volume microplates for the 384 well format. These microplates are ideal for assays using reduced working volumes and can provide savings in reagent and compound use.

#### Well Shape Selection Chart

	Microplate Format						
Well Shape	96 Well	96 Well Stripwell™	Half Area 96 Well		Low Volume 384 Well	1536 Well	2 μL 1536 Well
Flat bottom							
Round bottom							
V-bottom							
Easy Wash bottom							

Detailed information about well volume, working volumes, and plate dimensions for Corning 96, 384, and 1536 well microplates are provided throughout this guide.

# **2** Choose the Corning Microplate Material and Color

Corning uses different polymers for microplates to support various application requirements. Selection of the appropriate polymer material and color can improve assay performance. Additional technical information on key polymers can be found in the appendix at the end of this guide.

#### **Material Selection Chart**

	Microplate Format						
Plate Material	96 Well	96 Well Stripwell	Half Area 96 Well	384 Well	Low Volume 384 Well	1536 Well	2 μL 1536 Well
Clear polystyrene							
Solid black or white polystyrene							
Clear bottom black or white polystyrene							
Polypropylene							
Solid black or white polypropylene				*			
Flexible vinyl (PVC)							
UV							

\*Only available in black polypropylene

Corning<sup>®</sup> microplates are available in different materials:

- Clear polystyrene microplates are used for cell culture and colorimetric (absorbance) assays.
- Black and white polystyrene microplates can be used for fluorescent and luminescent assays. Solid black polystyrene plates are designed to reduce well-to-well crosstalk and background for fluorescent assays. Solid white polystyrene plates are designed to reduce well-to-well crosstalk, enhance luminescent signals and reduce background for luminescent assays. Both black and white plates are available with clear bottoms for use in cell-based assays and microscopy applications, and allow top or bottom reading capabilities.
- **Polypropylene microplates** are ideal for compound storage or assays that require high resistance to solvents including DMSO and ethanol. The Corning ClearPro<sup>™</sup> 96 well microplate is also available and has greater clarity than standard polypropylene for easier visual inspection of samples.
- Black and white polypropylene microplates can be used for fluorescent and luminescent assays and reduce nonspecific binding problems observed with polystyrene plates. The polypropylene material is also highly resistant to many commonly used solvents.
- Flexible vinyl (PVC) microplates are economical, nonsterile general assay 96 well plates. Due to their flexible nature, these microplates are not compatible with automation.
- UV microplates allow UV absorbance readings with low background especially at 260 to 280 nm, and are ideal for determining protein or nucleic acid concentration.

# **3** Choose the Corning Surface Treatment

Corning offers polystyrene microplates with a variety of modified surfaces. These surfaces can support binding or covalent immobilization of cells, proteins, nucleic acids, and other biomolecules. Additional information on these surfaces can be found in the Technical Appendix at the end of this guide.

	Microplate Format						
		96	Half		Low		$2\mu L$
Surface Treatment	96 Wall	Well	Area			1536 Wall	1536 Wall
Surface Treatment	wen	Stripwell™	90 wen	Well	384 Well	wen	Well
For General Assay							
Not Treated (medium binding)							•
High Binding							
Nonbinding (NBS™)							
Sulfhydryl (Sulfhydryl-BIND™) Binding							
Carbohydrate (Carbo-BIND™) Binding							
Photo-reactive (Universal-BIND <sup>™</sup> ) Binding							
Amine Binding							
For Cell Culture							
Tissue Culture (TC) Treated							
Ultra Low Attachment							
Corning <sup>®</sup> CellBIND <sup>®</sup> Surface							
Poly-D-Lysine							

#### Surface Treatment Selection Chart

Corning offers various surface treatments for microplates:

- Not treated (or medium binding) polystyrene surface is hydrophobic in nature and binds biomolecules through passive interactions. It is suitable primarily for the immobilization of large molecules, such as antibodies, that have large hydrophobic regions that can interact with the surface.
- High binding surface is capable of binding medium (>10 kD) and large biomolecules that possess ionic groups and/or hydrophobic regions.
- Nonbinding NBS surface is a Corning proprietary treatment technology used on polystyrene microplates to create a nonionic hydrophilic surface (polyethylene oxide-like) that minimizes molecular interactions. Ideal for reducing protein and nucleic acid binding at low concentrations, and increasing assay signal to noise.

- Corning<sup>®</sup> CellBIND<sup>®</sup> Surface treatment can provide improved consistency and even cell attachment.
- Tissue culture treated (TC-Treated) surface is used for the attachment and growth of anchorage-dependent cells.
- Ultra Low Attachment surface has a covalently bonded hydrogel designed to minimize cell attachment, protein absorption, enzyme activation and cellular activation. This surface is noncytotoxic, biologically inert and nondegradable.
- **Poly-D-lysine coated surface** can improve attachment of difficult-to-attach cells.
- ▶ Sulfhydryl (Sulfhydryl-BIND<sup>™</sup>) binding surface has covalently-linked maleimide groups that covalently couple to sulfhydryl groups via SH moieties. Ideal for assays requiring site-directed orientation of a biomolecule, especially antibodies.
- ▶ Carbohydrate (Carbo-BIND<sup>TM</sup>) binding surface has hydrazide groups covalently coupled to carbohydrate groups. Ideal for assays requiring site-directed orientation of a biomolecule (oxidized antibodies, carbohydrates, and glycosylated proteins) while maintaining enzymatic or immunological activity.
- ▶ Photo-reactive (Universal-BIND<sup>TM</sup>) surface covalently immobilizes biomolecules via abstractable hydrogens using UV illumination, resulting in a carbon-carbon bond. Although linkage is nonspecific and does not allow for site-directed orientation of a biomolecule, this surface may be useful for immobilization of double stranded DNA, antigens of unknown structure, and mixtures of biomolecules (e.g., cell lysates).
- Amine surface has positively charged amine groups (2 x  $10^{13}$  reactive sites/cm<sup>2</sup>) that can be used for covalent immobilization via bifunctional crosslinkers.

# **BAR CODE CUSTOMIZATION**

#### What is a Bar Code\*?

The same kind of bar codes you see in stores and supermarkets can be very useful to your lab. Consisting of a series of black bars and light spaces representing letters and/or numerals, a bar code is an easy-to-use vehicle for data collection. The specific arrangement of these bars and spaces follows strict rules known as a "symbology."

#### How Does a Bar Code Work?

Bar codes reflect spots of light into a scanner in varying amounts. These differences in reflection are translated into electrical signals by a light detector inside the scanner. The signals are converted into binary ones and zeros, which are used in various combinations to stand for specific numbers and letters.

#### **Custom Designed Bar Codes**

Corning will assist in designing and implementing a bar code label to meet your exact specifications. We will provide bar code label test samples at the front end of a project, to confirm decodability and ensure flawless performance in your end-use process. Our other customization features include:

- > Flexible bar code and corresponding human readable layout/orientation on the bar code label, for compatibility with the internal bar code scanner inside your automated instruments
- Color coding
- Superior print quality and resolution
- Flexible bar code label positioning
- Resistant to most commonly used organic solvents

#### **Dependable Durability**

Bar codes have been quality tested for optimal readability, chemical resistance, and temperature variation.

#### **Expert Advice**

Most Corning® microplates are suitable for bar code customization. Contact Corning Life Sciences or your local representative for more information.

\*Information provided by Computype, Inc.



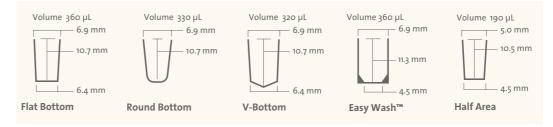
# 96 Well Microplates

Corning offers a complete line of 96 well microplates for laboratory miniaturization and automation. These microplates are grouped by application into four key areas:

- 1 General assays Not treated, NBS<sup>™</sup>, covalent binding, high binding, flexible vinyl (PVC), and UV microplates
- 2 Cell culture and cell-based assays Tissue culture treated, Corning<sup>®</sup> CellBIND<sup>®</sup> Surface, poly-D-lysine, and Ultra Low Attachment polystyrene microplates
- 3 Immunoassays EIA/RIA and Stripwell<sup>™</sup> polystyrene plates
- **4 Storage** Polypropylene microplates and cluster tubes

This selection guide does not include 96 well microplates for PCR and genomics. Please refer to the Corning Genomics Selection Guide or our web site (**www.corning.com/lifesciences**) for additional information on these products.

#### 96 Well Geometry and Dimensions



- Recommended working volume of 96 well standard plates is 75 to 200 μL.
- Recommended working volume of 96 well Half Area plates is 25 to 100 µL.
- Corning 96 well polystyrene microplates have plate dimensions (length x width x height) of 127.76 x 85.48 x 14.22 mm that meet proposed industry standards.

For additional microplate information, refer to *Selecting the Best Corning Microplate for Your Application* in the Overview section of this guide.

## 96 WELL GENERAL ASSAY MICROPLATES

Corning offers a wide variety of general assay microplates. They are organized into five groups:

- ▶ 96 Well Clear Polystyrene Microplates
- > 96 Well Solid Black and White Polystyrene Microplates
- > 96 Well Clear Bottom Black and White Polystyrene Microplates
- > 96 Well Clear Flexible Vinyl (PVC) Microplates
- ▶ 96 Well UV Microplates

### 96 Well Clear Polystyrene Microplates

- $\blacktriangleright$  Standard well volumes: flat bottom 360  $\mu L;$  round bottom 330  $\mu L;$  V-bottom 320  $\mu L;$  recommended working volumes of 75 to 200  $\mu L$
- ) Half Area microplate has well volume of 190 μL; working volumes of 25 to 100 μL.
- Lids available where indicated. (Information on lids and other microplate accessories can be found beginning on page 64.)

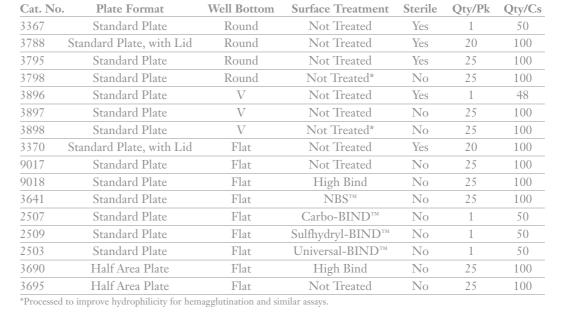
# Tip for Reducing Reagent Use

Corning<sup>®</sup> 96 Well Half Area Microplates can save on valuable reagents by reducing the amount of reagent needed per well, while still retaining the ability to be read in standard plate readers. These microplates have a suggested working volume as low as 25 µL and are available untreated or with tissue culture, high bind, or NBS treatment.





96 Well Clear Polystyrene Microplates



# 96 Well Clear Polystyrene Microplate Ordering Information

# 96 Well Solid Black and White Polystyrene Microplates

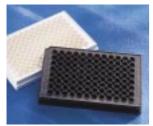
- Designed to reduce well-to-well crosstalk
- White plates enhance luminescent signals and have low background luminescence and fluorescence
- Black plates have low background fluorescence and minimize light scattering
- $\blacktriangleright$  Standard well volumes: flat bottom 360  $\mu L;$  round bottom 330  $\mu L;$  recommended working volumes of 75 to 200  $\mu L$
- Half Area microplate has well volume of 190 µL; working volumes of 25 to 100 µL
- Lids available where indicated. (Information on lids and other microplate accessories can be found beginning on page 64.)

#### 96 Well Solid Black and White Polystyrene Microplate Ordering Information

Cat. No.	<b>Plate Format</b>	Well Bottom Surface Treatment		Sterile	Qty/Pk	Qty/Cs
Black Poly.	styrene Microplates					
3792	Standard Plate	Round	Not Treated	No	25	100
3915	Standard Plate	Flat	Not Treated	No	25	100
3925	Standard Plate	Flat	High Bind	No	25	100
3650	Standard Plate	Flat	NBS	No	25	100
3694	Half Area Plate	Flat	Not Treated	No	25	100
3686	Half Area Plate	Flat	NBS	No	25	100
White Poly	ystyrene Microplates					
3789	Standard Plate	Round	Not Treated	No	25	100
3605	Standard Plate	Round	NBS	No	25	100
3912	Standard Plate	Flat	Not Treated	No	25	100
3922	Standard Plate	Flat	High Bind	No	25	100
3600	Standard Plate	Flat	NBS	No	25	100
3693	Half Area Plate	Flat	Not Treated	No	25	100

#### **NBS Binding Performance**

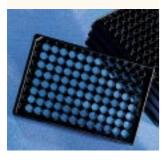
Binding in ng/cm <sup>2</sup>	<sup>125</sup> I-IgG	<sup>125</sup> I-BSA	<sup>125</sup> I-Insulin	<sup>32</sup> P-oligo DNA	<sup>32</sup> P-λ phage DNA
Polystyrene	400	450	310	22	6
Polypropylene	380	440	370	3	<2
NBS on Polystyrene	<2.5	<2.5	5	<2	<2



96 Well Black and White Polystyrene Microplates

#### Tip for Improving **Optical Performance** in Fluorescent Assays

Corning<sup>®</sup> Special Optics 96 Well Microplates have black walls with ultra thin, clear bottoms for sharp, clear images and minimal background in fluorescent assays.



# 96 Well Clear Bottom Black and White Polystyrene Microplates

- Bottoms are 60% thinner than conventional polystyrene plates, resulting in lower background fluorescence and enabling readings down to 340 nm
- Opaque walls prevent well-to-well crosstalk
- > Optically clear flat bottom permits direct microscopic viewing
- Can be used for both top and bottom reading instruments
- Standard well volume: flat bottom 360 μL; recommended working volumes of 75 to 200 μL
- Half Area microplate has well volume of 205 μL; working volumes of 25 to 100 μL
- Lids available where indicated. (Information on lids and other microplate accessories can be found beginning on page 64.)

#### 96 Well Clear Bottom Black and White Polystyrene Microplate Ordering Information

Cat. No. **Plate Format** Well Bottom Surface Treatment Sterile Qty/Pk Qty/Cs Black Clear Bottom Polystyrene Microplates Special Optics Plate, with Lid Not Treated 3615 Flat No 25 100 3631 Standard Plate Flat Not Treated 25 No 100 3601 Standard Plate Flat High Bind No 25 100 Standard Plate NBS™ 25 3651 Flat No 100 Not Treated 3880 Half Area Plate 25 Flat No 100 3881 Half Area Plate Flat NBS No 25 100 White Clear Bottom Polystyrene Microplates

W DILL GILL	ar Dollom I oryslyrene ivillio	puncs				
3604	Standard Plate	Flat	NBS	No	25	100
3632	Standard Plate	Flat	Not Treated	No	25	100
3883	Half Area Plate	Flat	Not Treated	No	25	100
3884	Half Area Plate	Flat	NBS	No	25	100

# 96 Well Clear Flexible Vinyl (PVC) Microplates

- PVC microplates are very economical untreated plates for solution-based assays, serial dilutions, and general storage applications.
- Well volume of 250 µL (260 µL for V-bottom); working well volumes of 50 to 150 µL
- Lids are not available. (Information on lids and other microplate accessories can be found beginning on page 64.)

Qty/Cs 100

100

100

96 Well Cl	ear Flexible PVC M	icroplate Ordering	Information	
Cat. No.	Plate Format	Well Bottom	Sterile	Qty/Pk
2897	Standard Plate	V	No	25

#### Standard Plate No 2797 Round 25 2595 Standard Plate Flat No 25

## **96 Well UV Microplates**

The Corning 96 well UV microplate has a UV-transparent well bottom and is ideal for determining protein and/or nucleic acid concentrations.

- Certified DNase- and RNase-free
- UV-transparent bottom is molded directly to an acrylic base for greater strength and maximum leak resistance
- Standard well volume: flat bottom  $-360 \,\mu\text{L}$ ; recommended working volumes of 75 to 200  $\mu\text{L}$
- Half Area microplate has well volume of 205 μL; working volumes of 25 to 100 μL
- Allows UV absorbance readings with low background, especially at 260 to 280 nm
- Lids are available separately. (Information on lids and other microplate accessories can be found beginning on page 64.)



96 Well UV Microplate - Certified DNase- and RNase-free

#### 96 Well UV Microplate Ordering Information

Cat. No.	Plate Format	Well Bottom	Sterile	Qty/Pk	Qty/Cs
3635	Standard Plate	Flat	No	25	50
3679	Half Area Plate	Flat	No	25	50

# 2 96 WELL CELL CULTURE MICROPLATES

Corning<sup>®</sup> tissue culture treated microplates have the same surface treatment used on other Corning culture vessels. In addition to this traditional surface, Corning offers three additional surfaces: Corning CellBIND<sup>®</sup> Surface treatment for improving consistency and even cell attachment, a poly-D-lysine coating for enhancing attachment of difficult-to-attach cell lines, and an Ultra Low Attachment surface for minimizing cell attachment.

This section is organized into three groups:

- > 96 Well Clear Polystyrene Cell Culture Microplates
- > 96 Well Solid Black and White Polystyrene Cell Culture Microplates
- > 96 Well Clear Bottom Black and White Polystyrene Cell Culture Microplates

### 96 Well Clear Polystyrene Cell Culture Microplates

- $\blacktriangleright$  Standard well volumes: flat bottom 360  $\mu L$ ; round bottom 330  $\mu L$ ; V-bottom 320  $\mu L$ ; recommended working volumes of 75 to 200  $\mu L$
- Half Area microplate has well volume of 190 μL; working volumes of 25 to 100 μL
- > Sterilized by gamma radiation and certified nonpyrogenic
- Most plates have lids (Information on lids and other microplate accessories can be found beginning on page 64.)

#### 96 Well Clear Cell Culture Microplate Ordering Information

Cat. No	. Plate Format	Well Bottom	Surface Treatment	Sterile	Qty/ Pk	Qty/ Cs
3360	Standard Plate, no Lid	Round	TC-Treated	Yes	25	100
3799	Standard Plate, with Lid	Round	TC-Treated	Yes	1	50
3894	Standard Plate, with Lid	V	TC-Treated	Yes	1	50
3628	Standard Plate, with Lid	Flat	TC-Treated	Yes	20	100
3596	Standard Plate, with Lid	Flat	TC-Treated	Yes	1	50
3997	Standard Plate, with Lid	Flat	TC-Treated	Yes	10	50
3598	Standard Plate, with Lid	Flat	TC-Treated	Yes	5	100
3599	Standard Plate, with Lid	Flat	TC-Treated	Yes	1	100
3585	Standard Plate, with Lid*	Flat	TC-Treated	Yes	5	50
3595	Standard Plate, with Lid*	Flat	TC-Treated	Yes	1	50
9102	8-Well Strip Plate, with Lid	Flat	TC-Treated	Yes	1	50
3665	Standard Plate, with Lid	Flat	Poly-D-Lysine	Yes**	25	100
3300	Standard Plate, with Lid	Flat	Corning CellBIND Surface	Yes	5	50
3474	Standard Plate, with Lid	Flat	Ultra Low Attachment	Yes	1	24
3696	Half Area Plate, with Lid	Flat	TC-Treated	Yes	1	50
3697	Half Area Plate, with Lid	Flat	TC-Treated	Yes	20	100
*Special lo	ow evaporation lid					

\*\*Aseptically manufactured

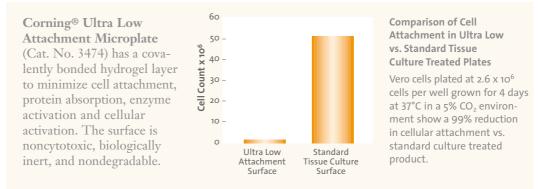


#### 96 Well Clear Tissue Culture Treated Microplates

### Corning Cell Culture Products are Certified Nonpyrogenic

All cell culture products are certified nonpyrogenic with documented endotoxin levels of less than 0.5 EU/mL. Corning offers a detailed technical bulletin on the effects of endotoxins in cell culture, plus a complete cell culture product listing at www.corning.com/ lifesciences.





# 96 Well Solid Black and White Cell Culture Microplates

- White walled plates enhance luminescent signals and have low background luminescence and fluorescence
- Black walled plates have low background fluorescence and minimal light scatter
- Standard well volume: flat bottom 360 μL; recommended working volumes of 75 to 200 μL
- Half Area microplate has well volume of 190 μL; working volumes of 25 to 100 μL
- > Sterilized by gamma radiation and certified nonpyrogenic
- Lids available where indicated. (Information on lids and other microplate accessories can be found beginning on page 64.)

#### 96 Well Solid Black and White Cell Culture Microplate Ordering Information

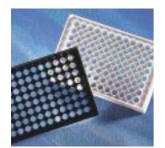
Cat. No.	Plate Format	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
Black Cell	Culture Microplates					
3916	Standard Plate, with Lid	Flat	TC-Treated	Yes	20	100
3875	Half Area Plate, with Lid	Flat	TC-Treated	Yes	20	100
White Cell	l Culture Microplates					
3917	Standard Plate, with Lid	Flat	TC-Treated	Yes	20	100
3362	Standard Plate, no Lid	Flat	TC-Treated	Yes	25	100
3688	Half Area Plate, with Lid	Flat	TC-Treated	Yes	25	100

## 96 Well Clear Bottom Black and White Cell Culture Microplates

- Bottoms are 60% thinner than conventional polystyrene plates, resulting in lower background fluorescence and enabling readings down to 340 nm.
- Opaque walls to prevent well-to-well crosstalk
- Optically clear flat well bottom permits direct microscopic viewing
- Can be used for both top and bottom reading instruments
- Standard well volume: flat bottom 360 μL; recommended working volumes of 75 to 200 μL
- **•** Half Area microplate has well volume of 205 μL; working volumes of 25 to 100 μL
- Sterilized by gamma radiation
- Certified nonpyrogenic
- Lids available where indicated. (Information on lids and other microplate accessories can be found beginning on page 64.)



96 Well Black and White Tissue Culture Treated Microplates



96 Well Clear Bottom Black and White Microplates

## *Corning*<sup>®</sup> *CellBIND*<sup>®</sup> *Surface*

- Available in 96 and 384 well black clear bottom plate formats
- Surface treatment improves consistency and even cell attachment
- May improve attachment of many difficult-to-attach cell lines
- Not a coating, requires no special handling, and is stable at room temperature
- Sterilized by gamma radiation and certified nonpyrogenic



96 Well EIA/RIA Microplates

#### 96 Well Clear Bottom Black and White Cell Culture Microplate Ordering Information

o. Plate Format	Well Bottom	Surface Treatment	Sterile	Qty/ Pk	Qty/ Cs
lear Bottom Cell Culture Microp	lates				
Standard Plate, with Lid	Flat	TC-Treated	Yes	1	48
Standard Plate, with Lid	Flat	TC-Treated	Yes	20	100
Special Optics Plate, no Lid	Flat	TC-Treated	Yes	25	100
Standard Plate, with Lid	Flat	Corning CellBIND Surface	Yes	5	50
Standard Plate, with Lid	Flat	Poly-D-Lysine	Yes*	25	100
Half Area Plate, no Lid	Flat	TC-Treated	Yes	25	100
Half Area Plate, with Lid	Flat	TC-Treated	Yes	20	100
Clear Bottom Cell Culture Micro	plates				
Standard Plate, with Lid	Flat	TC-Treated	Yes	1	48
Standard Plate, with Lid	Flat	TC-Treated	Yes	20	100
Standard Plate, with Lid	Flat	Poly-D-Lysine	Yes*	25	100
Half Area Plate, no Lid	Flat	TC-Treated	Yes	25	100
Half Area Plate, with Lid	Flat	TC-Treated	Yes	20	100
	lear Bottom Cell Culture Microp Standard Plate, with Lid Standard Plate, with Lid Special Optics Plate, no Lid Standard Plate, with Lid Standard Plate, with Lid Half Area Plate, no Lid Half Area Plate, with Lid Clear Bottom Cell Culture Microp Standard Plate, with Lid Standard Plate, with Lid Standard Plate, with Lid Half Area Plate, no Lid	Plate FormatBottomlear Bottom Cell Culture MicroplatesStandard Plate, with LidFlatStandard Plate, with LidFlatSpecial Optics Plate, no LidFlatStandard Plate, with LidFlatStandard Plate, with LidFlatStandard Plate, with LidFlatIdard Plate, with LidFlatHalf Area Plate, no LidFlatClear Bottom Cell Culture MicroplatesStandard Plate, with LidFlatStandard Plate, with LidFlatStandard Plate, with LidFlatAndard Plate, with LidFlatStandard Plate, with LidFlatStandard Plate, with LidFlatHalf Area Plate, no LidFlatHalf Area Plate, no LidFlat	Plate FormatBottomTreatmentlear Bottom Cell Culture MicroplatesStandard Plate, with LidFlatTC-TreatedStandard Plate, with LidFlatTC-TreatedSpecial Optics Plate, no LidFlatTC-TreatedStandard Plate, with LidFlatCorning CellBIND SurfaceStandard Plate, with LidFlatPoly-D-LysineHalf Area Plate, no LidFlatTC-TreatedHalf Area Plate, with LidFlatTC-TreatedClear Bottom Cell Culture MicroplatesStandard Plate, with LidFlatStandard Plate, with LidFlatTC-TreatedStandard Plate, with LidFlatTC-TreatedStandard Plate, with LidFlatTC-TreatedHalf Area Plate, no LidFlatTC-TreatedHalf Area Plate, no LidFlatTC-TreatedHalf Area Plate, no LidFlatTC-TreatedStandard Plate, with LidFlatPoly-D-LysineHalf Area Plate, no LidFlatTC-Treated	Plate FormatBottomTreatmentSterilelear Bottom Cell Culture MicroplatesStandard Plate, with LidFlatTC-TreatedYesStandard Plate, with LidFlatTC-TreatedYesSpecial Optics Plate, no LidFlatTC-TreatedYesStandard Plate, with LidFlatCorning CellBIND SurfaceYesStandard Plate, with LidFlatPoly-D-LysineYes*Half Area Plate, no LidFlatTC-TreatedYesHalf Area Plate, no LidFlatTC-TreatedYesClear Bottom Cell Culture MicroplatesTC-TreatedYesStandard Plate, with LidFlatTC-TreatedYesStandard Plate, with LidFlatTC-TreatedYesHalf Area Plate, with LidFlatTC-TreatedYesStandard Plate, with LidFlatTC-TreatedYesHalf Area Plate, with LidFlatTC-TreatedYesHalf Area Plate, no LidFlatPoly-D-LysineYes*Half Area Plate, no LidFlatPoly-D-LysineYes*	D.Plate FormatBottomTreatmentSterilePklear Bottom Cell Culture MicroplatesStandard Plate, with LidFlatTC-TreatedYes1Standard Plate, with LidFlatTC-TreatedYes20Special Optics Plate, no LidFlatTC-TreatedYes25Standard Plate, with LidFlatCorning CellBIND SurfaceYes5Standard Plate, with LidFlatPoly-D-LysineYes25Half Area Plate, no LidFlatTC-TreatedYes25Half Area Plate, with LidFlatTC-TreatedYes20Clear Bottom Cell Culture MicroplatesTC-TreatedYes1Standard Plate, with LidFlatTC-TreatedYes1Standard Plate, with LidFlatTC-TreatedYes1Standard Plate, with LidFlatTC-TreatedYes1Standard Plate, with LidFlatTC-TreatedYes20Standard Plate, with LidFlatTC-TreatedYes20Standard Plate, with LidFlatTC-TreatedYes20Standard Plate, with LidFlatPoly-D-LysineYes20Standard Plate, no LidFlatTC-TreatedYes20Standard Plate, no LidFlatTC-TreatedYes20Standard Plate, no LidFlatTC-TreatedYes25Half Area Plate, no LidFlatTC-TreatedYes25Half Area Plate, no L

\*Aseptically manufactured

## 3 96 WELL IMMUNOASSAY MICROPLATES

Corning offers 96 well EIA/RIA plates and Stripwell<sup>™</sup> plates manufactured from a special medical grade polystyrene for uniform binding, high optical clarity, and low background absorption.

#### **High Binding Plate Certification**

Certification Standards	High Binding	Medium Binding (Not Treated)
Well-to-well coefficient of variation (CV)	≤3%	≤5%
Average high and low wells from the mean	≤8%	≤15%
Background absorbance units from the mean	±0.005	±0.005

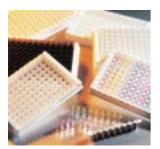
Corning<sup>®</sup> High Binding plates have a binding capacity of approximately 500 ng of Mouse IgG/cm<sup>2</sup>. The nontreated plates have a binding capacity of approximately 250 ng of Mouse IgG/cm<sup>2</sup>. Corning tests its EIA/RIA plates on a lot-to-lot basis and the certification results for each lot are made available upon request by contacting your local Corning Life Sciences office. In addition, five ELISA Technical Bulletins are available at **www.corning.com/lifesciences**.

## 96 Well EIA/RIA Clear Polystyrene Microplates

- Standard well volumes: flat bottom 360 µL; round bottom 330 µL; Easy-Wash™ bottom 360 µL; recommended working volumes of 75 to 200 µL
- Lids available where indicated. (Information on lids and other microplate accessories can be found beginning on page 64.)

#### 96 Well EIA/RIA Clear Polystyrene Microplate Ordering Information

Plate Format	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
Standard Plate	Round	Not Treated	No	25	100
Standard Plate	Round	High Bind	No	25	100
Standard Plate	Easy Wash	Not Treated	No	25	100
Standard Plate	Easy Wash	High Bind	No	25	100
Standard Plate	Flat	Not Treated	No	1	50
Standard Plate	Flat	Not Treated	No	25	100
Standard Plate, with Lid	Flat	High Bind	Yes	20	100
Standard Plate	Flat	High Bind	No	1	100
Standard Plate	Flat	High Bind	No	25	100
	Standard Plate Standard Plate Standard Plate Standard Plate Standard Plate Standard Plate Standard Plate Standard Plate, with Lid Standard Plate	Plate FormatBottomStandard PlateRoundStandard PlateRoundStandard PlateEasy WashStandard PlateEasy WashStandard PlateFlatStandard PlateFlatStandard Plate, with LidFlatStandard PlateFlat	Plate FormatBottomTreatmentStandard PlateRoundNot TreatedStandard PlateRoundHigh BindStandard PlateEasy WashNot TreatedStandard PlateEasy WashHigh BindStandard PlateFlatNot TreatedStandard PlateFlatNot TreatedStandard PlateFlatNot TreatedStandard PlateFlatHigh BindStandard PlateFlatHigh BindStandard Plate, with LidFlatHigh BindStandard PlateFlatHigh Bind	Plate FormatBottomTreatmentSterileStandard PlateRoundNot TreatedNoStandard PlateRoundHigh BindNoStandard PlateEasy WashNot TreatedNoStandard PlateEasy WashHigh BindNoStandard PlateFlatNot TreatedNoStandard PlateFlatNot TreatedNoStandard PlateFlatNot TreatedNoStandard PlateFlatNot TreatedNoStandard PlateFlatNot TreatedNoStandard Plate, with LidFlatHigh BindYesStandard PlateFlatHigh BindNo	Plate FormatBottomTreatmentSterileQty/PkStandard PlateRoundNot TreatedNo25Standard PlateRoundHigh BindNo25Standard PlateEasy WashNot TreatedNo25Standard PlateEasy WashNot TreatedNo25Standard PlateEasy WashHigh BindNo25Standard PlateFlatNot TreatedNo1Standard PlateFlatNot TreatedNo25Standard PlateFlatNot TreatedNo25Standard PlateFlatNot TreatedNo25Standard PlateFlatNot TreatedNo25Standard PlateFlatHigh BindYes20Standard PlateFlatHigh BindNo1



Stripwell Microplates



Standard vs. Low Volume

## Stripwell Low Volume Microplates

#### **Big Cost Savings!**

- Save 70% or more on antibody costs
- ▶ Save 50% or more on reagent costs

#### Features

- Total well volume: 190 μL
- Recommended working volume: 75 to 125 µL
- Same height/path length as a standard strip
- Standard 96 well centerto-center spacing

#### **Custom Stripwell Microplate Colors**



## **96 Well Polystyrene Stripwell<sup>™</sup> Microplates**

Corning® Stripwell plates are designed for in vitro diagnostic assays. The flat bottom strips are designed to easily break apart and are pre-assembled in an "egg-crate" style strip holder that allows each individual well to be positioned back into the plate once broken.

- > Stripwell plates have 96 well flat bottom polystyrene format
- **)** Low volume and standard Stripwell microplates have well volumes of 190 μL and 360 μL, respectively
- 1 x 8 strips are designed to fit only one way into the strip holder, eliminating the chance of misorientation
- Accessories can be found beginning on page 64.

#### Stripwell Microplates Ordering Information

Stripwell Low Volume Microplates

Cat. No.	Color	<b>Binding Property</b>	Qty/Pk	Qty/Cs
2480	Clear	Medium	25	100
2481	Clear	High	25	100
2482	Black	Medium	25	100
2483	Black	High	25	100
2484	White	Medium	25	100
2485	White	High	25	100

#### Standard Stripwell Microplates

Cat. No.	Color	<b>Binding Property</b>	Qty/Pk	Qty/Cs
2592*	Clear	High	25	100
2593*	Clear	Medium	25	100
2580**	Clear	High	200	800
9102***	Clear	TC-Treated, Sterile	1	50
3913	White	Medium	25	100
3923	White	High	25	100
3914	Black	Medium	25	100
3924	Black	High	25	100

Product has a certified surface chemistrv \*\*Individual 1 x 8 Strips without frame, bulk packed

\*\*\*Microplates individually packaged with lid

Surface Modified Stripwell Microplates, Clear

Cat. No.	Description	Surface Chemistry	Well Volume	Qty/Pk	Qty/Cs
2388	Amine	Amine	360 μL	1	50
2504	Universal-BIND <sup>™</sup> Surface	Universal	360 μL	1	50
2506	DNA-BIND <sup>™</sup> Surface	N-oxysuccinimide	360 μL	1	50
2508	Carbo-BIND <sup>™</sup> Surface	Hydrazide	360 µL	1	50
2510	Sulfhydryl-BIND <sup>™</sup> Surface	Maleimide	360 μL	1	50
Strip Acce	essories				
Cat. No.	Description	Sterile	Qty/	Pk	Qty/Cs
2572	Strip Holder "egg crat	te" No	5		20
2578	96 Well Strip Ejecto	r No	5		5

#### **Color Coding**

Corning offers customers the ability to color code their Stripwell microplates. Currently there are 14 colors available from which to choose on both our certified high and medium binding Stripwell plates. In addition to the clear strip, two other colors can be applied to the same plate. Color-coded Stripwell microplates are made to order and minimum order requirements do apply. If interested, please contact your local Corning representative.

## **4** 96 WELL POLYPROPYLENE STORAGE MICROPLATES AND CLUSTER TUBES

### 96 Well Polypropylene Microplates and Storage Blocks

Corning polypropylene microplates offer both small volume and large volume (blocks) well formats to meet assay and storage requirements.

- Flat, round or V-shaped well bottom
- Feature uniform skirt heights for greater robotic gripping surface
- Solvent resistant polypropylene provides compatibility with many common organic solvents (e.g., DMSO, ethanol, methanol)
- Certified DNase- and RNase-free
- Available sterile or nonsterile
- Refer to the Microplate Accessories section for information about microplate accessory products including sealing tapes and mats.

#### 96 Well Polypropylene Microplate Dimensions and Well Volumes

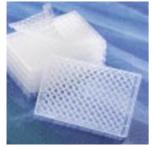
Well Shape	Total Well Volume (µL)	Well Depth (mm)	Well Diameter (mm)	Plate Dimensions (L x W x H) (mm)
96 Well Flat Bottom	360	10.67	6.86	127.76 x 85.48 x 14.22
96 Well Round Bottom	360	11.3	6.86	127.76 x 85.48 x 14.22
96 Well V-bottom	320	11.13	6.86	127.76 x 85.48 x 14.22
96 Well V-bottom, expanded volume	450	12.43	8.50	127.76 x 85.48 x 14.35
96 Well 0.5 mL Block	500	25.3	6.86	127.76 x 85.48 x 27.18
96 Well 1 mL Block	1000	39.9	6.86	127.76 x 85.09 x 41.66
96 Well 2 mL Block	2000	42.04	8.13 (width)	128.27 x 85.85 x 43.94

### 96 Well Polypropylene Microplate Ordering Information

Cat. No.	Plate Format	Color	Well Bottom	Sterile	Qty/Pk	Qty/Cs
3357	Standard Plate	Clear	V	Yes	25	100
3363	Standard Plate	Clear	V	No	25	100
3364	Standard Plate	Clear	Flat	No	25	100
> 3344	Expanded Volume Plate	Clear	V	Yes	10	50
3343	Expanded Volume Plate	Clear	V	No	10	50
3359	Standard Plate	Clear	Round	Yes	25	100
3365	Standard Plate	Clear	Round	No	25	100
3371	Corning <sup>®</sup> ClearPro <sup>™</sup> Plate	Clear	Round	No	25	100
3356	Standard Plate	Black	Round	No	25	100
3355	Standard Plate	White	Round	No	25	100

#### 96 Well Polypropylene Storage Block Ordering Information

Cat. No.	Plate Format	Well Volume	Well Bottom	Sterile	Qty/Pk	Qty/Cs
3956	0.5 mL Round Well Block	0.5 mL	V	Yes	10	50
3957	0.5 mL Round Well Block	0.5 mL	V	No	100	100
3958	1 mL Round Well Block	1 mL	Round	Yes	5	25
3959	1 mL Round Well Block	1 mL	Round	No	5	100
3960	2 mL Square Well Block	2 mL	V	Yes	5	25
3961	2 mL Square Well Block	2 mL	V	No	5	100



Corning ClearPro Microplate (Cat. No. 3371) has higher clarity than standard polypropylene plates and allows users to visually inspect their samples in each well.



96 Well Polypropylene Storage Blocks with Storage Mat



Cluster Tube Systems

## 96 Well Cluster Tubes

- Composed of 96 polypropylene tubes in a standard microplate format
- Feature 1.2 mL tubes that are available individually or in strips of eight tubes
- Polyethylene tube caps are available in 8-cap strips

## 96 Well Cluster Tube Ordering Information

Cat. No.	Format	Sterile	Rack	Qty/Pk	Qty/Cs
4401	Individual	No	No	960/Bag	960
4408	8-Tube Strip	No	No	120/Bag	120
4410	Individual	No	Yes	96/Rack	960
4411	Individual	Yes	Yes	96/Rack	960
4412	8-Tube Strip	No	Yes	12/Rack	120
4413	8-Tube Strip	Yes	Yes	12/Rack	120
4418	8-Cap Strip	Yes	No	12/Bag	120

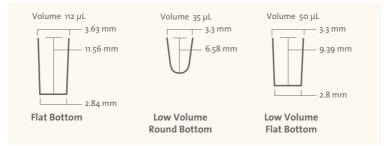
## 384 Well Microplates

Corning offers a variety of 384 well microplates for high throughput assays and storage. Microplates are grouped by application into three key areas:

- 1 General assays Not treated, NBS<sup>™</sup>, high binding, and UV microplates
- 2 Cell culture and cell-based assays Tissue culture treated, Corning<sup>®</sup> CellBIND<sup>®</sup> Surface, and poly-D-lysine coated polystyrene microplates
- **3** Storage Polypropylene microplates

This selection guide does not include 384 well microplates for PCR and genomics. Please refer to the Corning Genomics Selection Guide or web site (**www.corning.com/lifesciences**) for additional information on these products.

#### 384 Well Geometry and Dimensions



- Recommended working volume of 384 well standard plates is 20 to 80 µL
- $\blacktriangleright$  Recommended working volume of 384 well low volume solid plates is 5 to 20  $\mu L.$  (5 to 15  $\mu L$  with NBS treatment)
- ) Recommended working volume of 384 well low volume black clear bottom plates is up to 40  $\mu L$
- Corning 384 well polystyrene microplates have plate dimensions (length x width x height) of 127.76 x 85.48 x 14.22 mm that meet proposed industry standards

For additional microplate information, refer to *Selecting the Best Corning Microplate for Your Application* in the Overview section of this guide.

## **1** 384 WELL GENERAL ASSAY MICROPLATES

## 384 Well Clear Polystyrene Microplates

- Standard well volume of 112 μL; working well volumes of 20 to 80 μL
- Universal Optics NBS plate is manufactured using an advanced polymer with high clarity and improved chemical resistant properties
- Lids available as indicated. (Information on lids and other microplate accessories can be found beginning on page 64.)

### 384 Well Clear Polystyrene Microplate Ordering Information

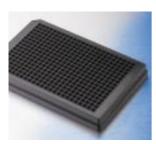
Cat. N	Io. Plate Format I	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
3702	Standard Plate	Flat	Not Treated	No	25	100
3680	Standard Plate, with Lid	Flat	Not Treated	Yes	20	100
3640	Standard Plate	Flat	NBS	No	25	100
3700	Standard Plate	Flat	High Bind	No	25	100
3723	Universal Optics Plate (Standard)	Flat	NBS	No	25	100



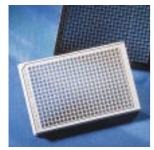
Low Volume 384 Well Solid Black and White Microplates

Unique well design for optimal assay performance

- Raised well bottom for higher sensitivity
- Raised rim for decreased wicking and contamination
- Round bottom for better Z factor and minimized trapped air
- Conical well molded in the shape of a light cone for efficiency
- NBS surface treatment for improved signal/ noise ratio and reduced bubbles



384 Well Solid Black Microplates



384 Well Clear Bottom Black and White Microplates

## 384 Well Solid Black and White Polystyrene Microplates

- Designed to reduce well-to-well crosstalk during fluorescent and luminescent assays
- Standard well volume of 112 μL; recommended working volumes of 20 to 80 μL
- **)** Low Volume microplate has well volume of 35 μL; working volumes of 2 to 20 μL
- Lids are available separately. (Information on lids and other microplate accessories can be found beginning on page 64.)

### 384 Well Solid Black and White Polystyrene Microplate Ordering Information

Cat. No.	Plate Format	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
Black Poly	styrene Microplates					
3710	Standard Plate	Flat	Not Treated	No	25	100
3654	Standard Plate	Flat	NBS <sup>TM</sup>	No	25	100
3708	Standard Plate	Flat	High Bind	No	25	100
3677	Low Volume Plate	Round	Not Treated	No	25	100
3676	Low Volume Plate	Round	NBS	No	25	100
3678	Low Volume Plate	Round	High Bind	No	25	100
White Pol	lystyrene Microplates					
3705	Standard Plate	Flat	Not Treated	No	25	100
3652	Standard Plate	Flat	NBS	No	25	100
3703	Standard Plate	Flat	High Bind	No	25	100
3674	Low Volume Plate	Round	Not Treated	No	25	100
3673	Low Volume Plate	Round	NBS	No	25	100

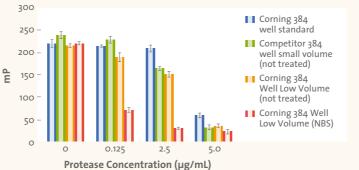
## 384 Well Clear Bottom Black and White Polystyrene Microplates

- > Suited for fluorescent and luminescent assays using either top or bottom detection plate readers
- $\blacktriangleright$  Standard well volume of 112  $\mu L;$  recommended working volumes of 20 to 80  $\mu L$
- ) Low volume plate has well volume of 50  $\mu L;$  working volume of up to 40  $\mu L$
- Lids are available separately. (Information on lids and other microplate accessories can be found beginning on page 64.)

#### 384 Well Clear Bottom Black and White Microplate Ordering Information

Cat. No.	Plate Format	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
Black Clear	· Bottom Microplates					
3711	Standard Plate	Flat	Not Treated	No	25	100
3540	Low Volume	Flat	Not Treated	No	10	50
3655	Standard Plate	Flat	NBS	No	25	100
White Clea	r Bottom Microplates					
3706	Standard Plate	Flat	Not Treated	No	25	100
3653	Standard Plate	Flat	NBS	No	25	100

Fluorescence-based Assay Performance with Corning® NBS Low Volume Microplates



Higher Sensitivity for Fluorescence Polarization Assays with 384 Well NBS Low Volume Microplates

Data demonstrates *Streptomyces griseus* protease activity on BODIPY fluorescent labeled (FL) casein substrate. Protease activity is measured as a reduction in millipolarization (mP) units. A significant reduction in fluorescence polarization was observed at the lowest concentration of enzyme in a 10 µL volume. Reduced Nonspecific Protein Binding with Corning® NBS™ Microplates



NBS Surface Significantly Reduces Nonspecific Binding of a BODIPY FL Casein Substrate to Corning Microplates Dilutions of BODIPY FL casein in digestion buffer were incubated for 30 min at room temperature in black Corning untreated and NBS microplates. Control wells contained digestion buffer only. Microplates were washed 3 times with PBS, pH 7.4, and 200  $\mu$ L/well of digestion buffer alone was added to the wells. Fluorescence intensity was measured.

## 384 Well UV Microplate

- Offers certified performance at 260 nm and 280 nm
- Provides consistently low background and well to well uniformity
- Performance approaches that of quartz cuvettes. Certified DNase- and RNase-free.

#### 384 Well UV Microplate Ordering Information

Cat. No.	Plate Format	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
3675	Standard Plate	Flat	Not Treated	No	5	25

## **2** 384 WELL CELL CULTURE MICROPLATES

Corning 384 well microplates for cell culture include the tissue culture treated, Corning CellBIND<sup>®</sup> Surface, and poly-D-lysine coated microplates. The tissue culture treated microplates have the same surface treatment used on other Corning cell culture vessels while the poly-D-lysine treatment improves attachment of anchorage-dependent cells. The new Corning CellBIND Surface treatment can provide improved consistency and even cell attachment.

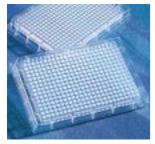
## 384 Well Cell Culture Polystyrene Microplates

These cell culture plates are designed for general cell culture assays requiring clear plates.

- Standard well volume of 112 μL; working volumes of 20 to 80 μL
- **)** Low volume plate has well volume of 50 μL; working volume of up to 40 μL
- The new optical imaging plate is designed for fixed or whole cell imaging and has superior well flatness for improved throughput
- Sterilized by gamma radiation and certified nonpyrogenic

#### 384 Well Cell Culture Microplate Ordering Information

	Cat. No.	Plate Format	Surface Treatment	Well Bottom	Sterile	Qty/ Pk	Qty/ Cs
(	Clear C	ell Culture Microplates					
-	3701	Clear Plate, with Lid	TC-Treated	Flat	Yes	20	100
	3662	Clear Plate, with Lid	Poly-D-Lysine	Flat	Yes*	25	100
1	Black a	nd White Cell Culture Microplates					
	3709	Solid Black Plate, with Lid	TC-Treated	Flat	Yes	20	100
-	3704	Solid White Plate, with Lid	TC-Treated	Flat	Yes	20	100
1	Black a	nd White Clear Bottom Cell Culture Microplates					
	3542	Low Volume Black plate with Clear Bottom, with Lid	TC-Treated	Flat	Yes	10	50
	3712	Black plate with Clear Bottom, with Lid	TC-Treated	Flat	Yes	20	100
	3683	Black plate with Clear Bottom, with Lid	Corning CellBIND Surface	Flat	Yes	10	50
-	3664	Black plate with Clear Bottom, with Lid	Poly-D-Lysine	Flat	Yes*	25	100
> 3	3985	Black Optical Imaging Plate with Clear Bottom and Lid	TC-Treated	Flat	Yes	20	100
	3707	White plate with Clear Bottom, with Lid	TC-Treated	Flat	Yes	20	100
	3663	White plate with Clear Bottom, with Lid	Poly-D-Lysine	Flat	Yes*	25	100
*	*Aeseptic	ally manufactured	· •				

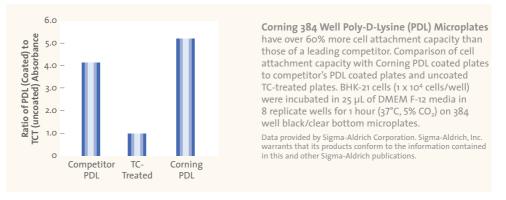


384 Well UV Microplates



384 Well Low Volume Black Clear Bottom Microplates

Performance of Corning® 384 Well Poly-D-Lysine Microplates



## **3** 384 WELL POLYPROPYLENE STORAGE MICROPLATES

Corning polypropylene microplates offer both small volume and large volume (blocks) well formats to meet assay and storage requirements.

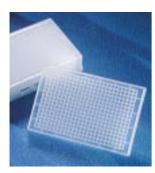
#### 384 Well Polypropylene Microplate Dimensions and Well Volumes

Well Shape	Total Well Volume (µL)	Well Depth (mm)	Well Diameter (mm)	Plate Dimensions (L x W x H) (mm)
384 Well Low Volume Low Profile Plate	20	6.30	3.30	127.76 x 85.48 x 10.00
384 Well Round Bottom Plate	95	11.56	3.63	127.76 x 85.48 x 14.22
384 Well Round Bottom Block	180	25.11	3.63	127.76 x 85.48 x 27.81
384 Well V-Bottom Block	240	22.31	3.30	127.76 x 85.48 x 24.73

- Resistant to many common organic solvents (e.g., DMSO, ethanol, methanol)
- Black polypropylene microplate (Cat. No. 3658) is ideal for fluorescent assays requiring solvent resistance
- Certified DNase- and RNase-free
- Available sterile or nonsterile
- Refer to the Microplate Accessories section for information about microplate accessory products including sealing tapes and mats.

#### 384 Well Polypropylene Microplate Ordering Information

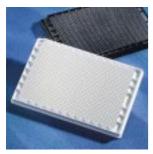
Cat. N	o. Plate Format	Well Bottom	Well Volume (µL)	Sterile	Qty/Pk	Qty/Cs
Polypro	pylene Microplates					
3658	Standard Plate, Black	Round	95	No	25	100
3656	Standard Plate, Clear	Round	95	Yes	25	100
3657	Standard Plate, Clear	Round	95	No	25	100
> 3672	Low Volume, Low Profile, Clear	Conical	20	No	10	50
Polypro	pylene Blocks					
3964	384 Well Block, Clear	Round	180	Yes	5	25
3965	384 Well Block, Clear	Round	180	No	5	100
> 3342	384 Well Block, Clear	V	240	Yes	5	50
> 3347	384 Well Block, Clear	V	240	No	5	50



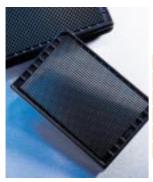
384 Well Polypropylene Storage Microplates

Ne

## 1536 Well Microplates



1536 Well Solid Round Bottom Microplates



1536 Well Black Clear Bottom Microplates

Corning® 1536 well microplates are the highest density microplates available for high throughput screening. The microplates conform to standard microplate footprint and dimensions. The 2  $\mu$ L well microplate is a thinner plate and represents leading edge technology in assay miniaturization, with the length and width dimensions and microplate footprint meeting industry standards.

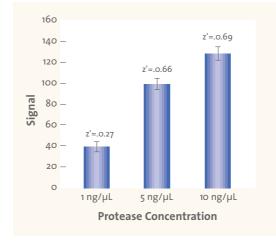
## **1536 Well Polystyrene Microplates**

- For fluorescent and luminescent assays
- ) Total well volume of 10  $\mu$ L for round well plates and 12.8  $\mu$ L for flat bottom plates
- Recommended working volume of up to 8 μL
- Round well bottoms for reduced air entrapment and improved CVs and Z factor
- Raised well bottoms for higher sensitivity
- > Flood reservoir on four sides to reduce instrument contamination
- Lids are available separately. (Information on lids and other microplate accessories can be found beginning on page 64.)

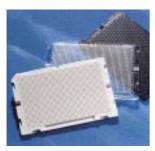
#### 1536 Well Polystyrene Microplate Ordering Information

Cat. No.	Plate Format	Color	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
Solid Bla	ick and White Microplates						
3937	Standard Plate	White	Round	Not Treated	No	10	50
3936	Standard Plate	Black	Round	Not Treated	No	10	50
3724	Standard Plate, nontreated	Black	Flat	Not Treated	No	10	50
3726	Standard Plate, with Lid	Black	Flat	TC-Treated	Yes	10	50
3728	Standard Plate	Black	Flat	NBS <sup>™</sup> Surface	No	10	50
3725	Standard Plate	White	Flat	Not Treated	No	10	50
3727	Standard Plate, with Lid	White	Flat	TC-Treated	Yes	10	50
3729	Standard Plate	White	Flat	NBS Surface	No	10	50
Black Cl	ear Bottom Microplates						
3891	Clear bottom	Black	Flat	Not Treated	No	10	50
3893	Clear bottom, with Lid	Black	Flat	TC-Treated	Yes	10	50
3895	Clear bottom	Black	Flat	NBS Surface	No	10	50

#### Performance of Corning 1536 Well 10 µL Round Well Microplates



Fluorescent Polarization Assay on Corning 1536 to  $\mu$ L Assay Microplate 10 ng/ $\mu$ L, 5 ng/ $\mu$ L and 1 ng/ $\mu$ L of Streptomyces griseus protease were incubated with 2.0 ng/ $\mu$ L of BODIPY FL casein substrate in 5  $\mu$ L volumes for 10 minutes at room temperature. (Corning 1536 Well 10  $\mu$ L black microplate, untreated, Cat. No. 3936).



1536 Well 2 µL Polystyrene Microplates

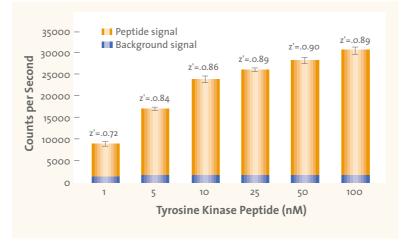
## 1536 Well 2 µL Polystyrene Microplates

- A variety of assays, including enzyme assays, receptor-ligand assays, and cell-based assays have been effectively performed in these plates.
- $\blacktriangleright$  Recommended working volume of up to 1.5  $\mu L$
- The plates are demarcated in a 8 x 12 array with each square containing 16 wells
- Eight extra wells on both the left and right sides of the plate that can be used to run controls
- Series of notches that allow stacked plates to be easily separated from one another
- Lids are not available for these microplates. (Information on lids and other microplate accessories can be found beginning on page 64.)

#### 1536 Well 2 µL Polystyrene Microplate Ordering Information

Cat. No.	Plate Format	Color	Well Bottom	Surface Treatment	Sterile	Qty/Pk	Qty/Cs
3851	Low Volume Plate	Black	Round	Not Treated	No	20	100
3854	Low Volume Plate	Black	Round	TC-Treated	Yes	20	100
3850	Low Volume Plate	Clear	Round	Not Treated	No	20	100
3853	Low Volume Plate	Clear	Round	TC-Treated	Yes	20	100
3858	Low Volume Plate	Clear	Round	High Bind	No	20	100
3852	Low Volume Plate	White	Round	Not Treated	No	20	100
3855	Low Volume Plate	White	Round	TC-Treated	Yes	20	100
3857	Low Volume Plate	White	Round	High Bind	No	20	100

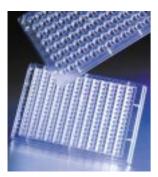
#### Performance of Corning 1536 Well 10 µL Round Well Microplates



#### Model TR-FRET Tyrosine Kinase Assay

Using a range of concentrations of biotinylated, phosphorylated, tyrosine kinase peptide with 2 nM Eu-PT66 antiphosphotyrosine antibody as the energy donor and 75 nM APC-SA as the energy acceptor. Signals were detected from 5  $\mu$ L total volumes in a model TR-FRET tyrosine kinase assay in a Corning 1536 Well 10  $\mu$ L white assay plate, untreated (Cat. No. 3937). The contribution of the background signal to the total signal is shown.

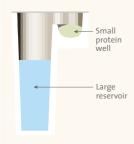
## Protein Crystallization Microplates



96 and 384 Well Protein Crystallization Microplates

## High Performance Well Design

Corning 96 and 384 Well Crystallization Microplates have unique well designs for sitting-drop crystallization.





96 Well Crystallization Microplate with Universal Optical Sealing Tape

- Corning<sup>®</sup> 96 and 384 well crystallization microplates are used for high-throughput protein crystal growth and screening.
- Designed for sitting-drop crystallization
- Meet 96 and 384 well microplate standards for automation
- Manufactured from an advanced polymer with high resistance to commonly used solvents, including acetone, acetic acid, butanone, ethanol, isopropanol, methanol, DMSO, nitric acid (65%), sulfuric acid (40%), hydrochloric acid (36%), and ammonia solution (33%)
- Polymer exhibits low background polarization and provides high optical clarity allowing protein crystals to be easily viewed under polarized light with minimal background interference
- Low water absorption of the polymer prevents loss of protein drop volume

## 96 Well Crystallization Microplate

- Features 96 large reservoir (reagent) wells and 96 corresponding protein wells
- Conical bottom protein wells provide better centering of the protein drop
- ) 210  $\mu$ L well volume for the reservoir well and 10  $\mu$ L for the protein well
- Compatible with manual pipettors and automation
- Novel merged well design provides efficient vapor space for protein crystallization

## 384 Well Crystallization Microplate

- The only microplate designed for full automation in crystal screening, built to meet industry standards for 384 well microplate footprint and well locations
- Features 192 reservoir wells and 192 corresponding protein wells
- Flat bottom protein wells
- ) 105  $\mu$ L well volume for the reservoir well and 4  $\mu$ L for the protein well
- Reservoir wells and protein wells are positioned to be compatible with multihead dispensing equipment (up to 96 well heads)

## Universal Optical Sealing Tape for 96 and 384 Well Crystallization Microplates

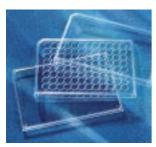
- > This high optical quality, pressure-sensitive tape ensures tight sealing to minimize evaporation.
- Ideal for microscopic observation of protein crystals
- ▶ Suitable for use between -70° and 100°C
- > Compatible with commonly used aqueous solutions and organic solvents

## Crystallization Microplate and Sealing Tape Ordering Information

Cat. No.	Plate Format	Reservoir Well Volume (µL)	Protein Well Volume (µL)	Sterile	Qty/ Pk	Qty/ Cs
3773	96 Well Plate, conical bottom	210	10	No	10	50
3785*	96 Well Plate, conical flat bottom, treated	210	7	No	10	50
3775	384 Well Plat, flat bottom	100	3.4	No	10	50
6575	Universal Optical Sealing Tape	N/A	N/A	No	100	100

\*Surface processed for hydrophilicity

## **Microplate Accessories**



Lids

Optimizing Sealing Conditions on Corning Polypropylene Microplates

Corning offers an application note (Corning Literature No. ALSP-AN-011) describing effective sealing with the ABgene<sup>®</sup> ALPS-100 automated plate sealer.



Corning Storage Mat Applicator

## Lids

- All lids are made of rigid polystyrene except where indicated
- All lids have a corner notch on the A1 corner (except where indicated) to correspond to the corner notches found on all Corning<sup>®</sup> microplates
- The Universal Lid without a corner notch (Cat. No. 3098) does not need to be oriented in any particular direction to be placed on Corning plates. The lid also has a shorter skirt than standard lids
- > The black Universal Lid (Cat. No. 3935) is suitable for fluorescent and other light-sensitive assays
- The DMSO-resistant cyclic-olefin lid (Cat. No. 3085) is tinted amber in color for light-sensitive assays and is 100% DMSO-resistant

## Microplate Lid Ordering Information

Cat. No.	Description	Plate Compatibility	Sterile	Qty/ Pk	Qty/ Cs
3930	Lid with corner notch and condensation rings	96 well microplates only (not 2 mL block)	Yes	1	100
3931	Lid with corner notch and condensation rings	96 well microplates only (not 2 mL block)	Yes	25	50
3098	Universal Lid without corner notch	All microplates	Yes	25	100
3099	Universal Lid with corner notch	All microplates	Yes	25	50
3935	Black Universal Lid with corner notch	All microplates	Yes	25	50
3085	DMSO-resistant Cyclic-olefin Lid without corner notch	All microplates	No	25	50
3849	1536 Well 2 µL Lid	2 µL 1536 Well Microplates only	Yes	20	100

## **Storage Mats and Accessories**

- Fits our 96 well plates and blocks
- Storage Mats Cat. Nos. 3080 and 3083 are manufactured from EVA (ethyl vinyl acetate), and polymer is compatible with DMSO
- Storage Mats Cat. Nos. 3346 and 3341 are chemical resistant
- Certified DNase- and RNase-free
- Can be applied manually or with our Storage Mat Applicator

#### Storage Mats and Accessories Ordering Information

	Cat. No.	Description	Sterile	Qty/Pk	Qty/Cs
	3080	Round well Storage Mat for 96 well plates and blocks	No	25	100
	3083	Square well Storage Mat for Corning 2 mL square blocks	No	1	50
W	3346	Storage Mat for Expanded Volume 96 Well Microplates	No	10	50
W	3341	Storage Mat for 384 Well V-Bottom Blocks	No	10	50
	3081	Storage Mat Applicator	N/A	1	1



96 and 384 Well Robolids

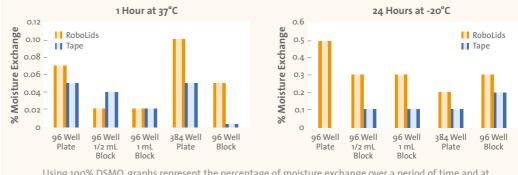
## Robolids

- Combines the sealing ability of a storage mat with the rigidity of a plastic lid
- Designed for repeated application and removal by automation and to prevent short-term evaporation
- > Silicone sealing plugs for organic solvent resistance and low extractables
- Can be used manually or with automation

### **Robolid Ordering Information**

Cat. No.	Description	Sterile	Qty/ Pack	Qty/ Case
3090	96 Well Robolid with corner notch	No	25	50
3089	384 Well Robolid with corner notch	No	25	50

#### Moisture Exchange with Corning® Robolids



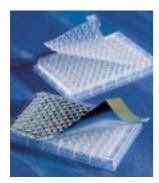
Using 100% DSMO, graphs represent the percentage of moisture exchange over a period of time and at various temperatures using aluminum sealing foil and the Robolid. Results show the 96 and 384 well Robolid having comparable results with the aluminum foil. Robolids validated for low percentage of moisture exchange similar to that of foil; the product is not recommended to be used in applications requiring an integral seal.

## **Sealing Tapes**

- Easy application and removal for short- and long-term storage
- Provide tight seal to minimize evaporation and condensation
- Acetate Sealing Tape (Cat. No. 3095) is suitable for use between -16°C and 38°C, is transparent, and is not pierceable
- Aluminum Sealing Tape (Cat. No. 6569, 6570) is suitable for use between -80°C and 150°C, is not transparent, and is pierceable
- Breathable Sealing Tape (Cat. No. 3345) allows gas exchange across the surface
- Universal Optical Sealing Tape (Cat. No. 6575) is suitable for use between -70°C and 100°C, and is transparent

### Sealing Tape Ordering Information

Cat. No.	Description	Sterile	Qty/Pk	Qty/Cs
3095	Acetate Sealing Tape for all microplates	No	100	100
6570	Aluminum Sealing Tape for 96 well microplates	No	100	100
6569	Aluminum Sealing Tape for 384 well microplates	No	100	100
3345	Breathable Sealing Tape	Yes	50	500
6575	Universal Optical Sealing Tape	No	100	100



Sealing Mats and Tapes

## **Technical Appendix**

## **Properties of Some Thermoplastics**

		Polystyrene	Polyvinylchloride	Polypropylene
Physical Characteristics	Basic Properties	Biologically inert, rigid, excellent optical qualities	Biologically inert, and flexible	Biologically inert, high chemical resistance, exceptional toughness
	Clarity	Clear	Clear	Translucent
	Autoclave Compatibility	No	Yes	Withstand several cycles
	Heat Distortion Point	147-175°F 64-80°C		275°F 135°C
	Burning Rate	Slow	Slow	Slow
Effects of	Weak Acids	None	None	None
Laboratory	Strong Acids	Oxidizing acids attack	Oxidizing acids attack	Oxidizing acids attack
Reagents	Weak Alkalis	None		None
	Strong Alkalis	None		None
	Organic Solvents	Soluble in aromatic chlorinated hydrocarbons		Resistant below 80°C

Portions of this table courtesy of Modern Plastics Encyclopedia. Most data are from tests by A.S.T.M. methods. Tables show averages or ranges. Many properties vary with manufacturer, formulation, testing laboratory, and specific operating conditions.

## **Corning Surface Technologies Properties and Applications**

Surface	Applications/Assays	Binding Interaction	Sample Properties	Performance Criteria
Untreated Polystyrene	<ul><li>General assays</li><li>Immunoassays (EIA/RIA)</li></ul>	Hydrophobic	High molecular weight (>20 kD). Large or abundant hydrophobic regions.	Well to well CV ≤5%. Average high and low wells from the mean ≤15%.
NBS <sup>TM</sup>	<ul> <li>Homogeneous assays (e.g., luminescent and fluorescent assays)</li> <li>Enhances signal to noise ratio</li> </ul>	Non-ionic hydrophilic	Ability to reduce significantly (<2 ng/cm <sup>2</sup> ) protein and nucleic acid binding to polymers, maintain enzyme activity, and inhibit adhesion of a number of cell lines.	At least 95% reduction of nonspecific binding of protein compared to untreated polystyrene.
Higb Binding	<ul><li>General assays</li><li>Immunoassays (EIA/RIA)</li></ul>	Hydrophobic and ionic	Medium to high molecular weight. Positively charged. +/- hydrophobic regions.	Well to well CV ≤3%. Average high and low wells from the mean ≤8%.
Tissue Culture	▶ Cell culture	Hydrophilic	Negative charged (carboxyl groups) for cell attachment.	
Poly-D- Lysine	<ul> <li>Cell-based assays</li> <li>Enhancing cell attachment, growth, and differentiation</li> <li>Numerous cell lines have been cultured on PDL coated surfaces including HEK-293, NIH3T3, L929, 3T3, and PC12</li> </ul>	Hydrophilic and ionic	Coated with PDL (70 to 150 kDa). Uniform net positive charge.	
Corning® CellBIND® Surface	<ul> <li>Cell-based assays</li> <li>Improved consistency and even cell attachment</li> </ul>	Hydrophilic and ionic	Negative charged for cell attachment	

## **Selected Corning Technical Literature**

All literature is available in PDF file format at www.corning.com/lifesciences.

#### **Assay Microplates**

Binding Comparison of Polymer Surfaces: Introducing Non-Binding Surface Microplates Corning<sup>®</sup> 96-well NBS<sup>™</sup> microplates are ideal for homogeneous assays in high throughput screening. Studies of protein and nucleic acid binding to the NBS, when compared to polystyrene and polypropylene surfaces, demonstrate significant reduction in nonspecific binding.

#### Chemiluminescent HRP-Based Assay Using Corning White Microplate

A comparison of the performance of white microplates from several microplate manufacturers to that of Corning 96 well white microplate using a model HRP based luminescent assay system.

#### Corning Non-Binding Surface Microplates for Fluorescent HTS Assays

This 4-page technical note evaluates the efficacy of the Corning NBS microplate for use in a homogeneous fluorescence polarization protease assay.

#### Corning Non-Binding Surface Treatment to Reduce Non-Specific Binding To Microplates

This 2-page technical note evaluates Corning NBS microplates for Scintillation Proximity Assays.

### Corning 384 Well Low Volume Microplate Performance in Miniaturized Assays

This technical note describes the performance of Low Volume microplates using a homogeneous fluorescence polarization assay at low volumes.

#### Design and Performance of the Corning 2 µL 1536 Well Plate

This 2-page technical note describes the design features and performance criteria for Corning 2  $\mu$ L 1536 well microplates.

### Fluorescent Polarization Kinase Assay Miniaturization in Corning 96 Well Half Area and 384 Well Microplates

This 4-page technical note examines assay miniaturization in Corning 96 well, 96 well Half Area, and 384 well microplates using fluorescence polarization tyrosine kinase assays.

### **Cell Culture Microplates**

### Helpful Hints to Manage Edge Effects

of Cultured Cells for High Throughput Screening This technical note is a compendium of techniques, collected from Corning Cell Culture facilities and customers, to reduce the occurrence of irregular patterns of cell adhesion or "edge effect" in microplates.

#### Poly-D-Lysine Coated Microplates

This 2-page application report describes binding and performance characteristics, and provides operating protocols for Corning's poly-D-lysine microplates.

#### **Immunoassay Microplates**

Corning offers five ELISA Technical Bulletins:

- Immobilization Principles Selecting the Surface
- Optimizing the Immobilization of Protein and other Biomolecules
- Effective Blocking Procedures
- Optimizing the Separation Step on 96 Well Plates
- Selecting the Detection System Colorimetric, Fluorescent, Luminescent

#### **Storage Applications**

Corning ClearPro<sup>™</sup> 96 Well Polypropylene Microplates

This 4-page technical note describes the heat sealing and storage performance characteristics for Corning ClearPro microplates.

#### New Storage Mat Applicator System Meets Customers' Strict Storage Requirements

This 2-page application note describes the performance characteristics of the Corning Storage Mat Applicator and the Corning products with which it is compatible.

Recommendations for Heat Sealing Corning Polypropylene Storage Products Using the ABgene® Automated Laboratory Plate Sealer

This 3-page application note describes the critical parameters for sealing Corning microplates with the ABgene Automated Laboratory Plate Sealer.



## Genomics

<b>OVERVIEW</b>
COLONY PICKING, BACTERIAL GROWTH, AND STORAGE
PURIFICATION
QUANTITATION AND DETECTION
DNA AMPLIFICATION
BAR CODE CUSTOMIZATION

## Overview

## FROM START TO FINISH – MEETING THE NEEDS OF THE GENOMICS LABORATORY

Corning's dedication to quality and technology has produced this comprehensive line of products for the genomics laboratory. Whatever aspect of research you are involved in – from culturing cells or microorganisms to printing and hybridizing DNA arrays, Corning's quality and breadth of line delivers reliable results. All of Corning's products are manufactured under stringent quality guidelines as an assurance of consistent performance from device to device and lot to lot. Featured in this brochure are our newest products for the high throughput genomics laboratory:

- ) Thermowell® Gold PCR reaction vessels for conventional and real-time PCR, and cycle sequencing
- > 96 well half area UV plates for nucleic acid quantitation
- Low profile BioAssay dishes that are robotic friendly and maximize incubator and storage space

#### THE EQUIPMENT COMPATIBILITY PROGRAM

The increasing use of automated laboratory equipment demands laboratory disposables whose fit and function have been qualified. Our microplates are designed with automation compatibility in mind and they meet industry standards for plate dimensions. In addition, Corning Life Sciences maintains a comprehensive equipment compatibility program in which leading equipment manufacturers certify the compatibility of our products with their instruments. This information is continually updated with our new products as well as new instruments. For the most current information, visit our website: **www. corning.com/lifesciences**.

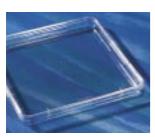
### LIFE SCIENCES EARLY ACCESS TO DEVELOPMENT - THE L.E.A.D. PROGRAM

Corning is committed to meeting the rapidly evolving needs of the life sciences laboratory. We are continually developing innovative new products that are compatible with the latest advances in technology and instrumentation. Our L.E.A.D. program gives researchers access to these products and special pricing prior to their full market release. Contact your local Corning Life Sciences office or representative for more information about the products currently available through this program.

## EXPERT ASSISTANCE IS JUST A TELEPHONE CALL OR E-MAIL AWAY

Customer service and technical representatives are available to answer any question – from pricing and product availability to protocols and applications advice. Our offices around the world are able to respond promptly to your inquiry regardless of your location. Contact us at your local office (listed on the back cover).

## Colony Picking, Bacterial Growth, and Storage



<sup>2</sup>45 mm Square BioAssay Dish

## 245 mm Square BioAssay Dishes

Square bioassay dishes are made from polystyrene and are certified nonpyrogenic. They are packed with lids and are designed with a stacking bead so that they will stack securely without slipping. The dishes are compatible with automated colony picking instruments.

Cat. No.	Description	Automation Compatibility	Qty/Pk	Qty/Cs
431111	245 mm x 245 mm, Square, 18 mm Deep Nontreated Dish, Sterile	PBA Flexys <sup>™</sup> and the Genetix "Q" Bot <sup>®</sup> automated colony picking and gridding robots	4	16
431272	245 mm x 245 mm, Square, 18 mm Deep Nontreated Dish, Sterile	AutoGen AutoGenesys, BioRobotics BioPick, BioGrid, TAS and MicroGrid II high volume automated colony picking systems	4	16
431301	245 mm x 245 mm, Low Profile, Sterile, Nontreated Dish	PBA Flexys, Genetix "Q" Bot, BioRobotics, BioPick	5	20

## 96 and 384 Well Polypropylene Blocks for Growth and Storage

These 96 and 384 well deep well blocks feature well designs for optimal liquid handling and meet industry standards for dimensions to facilitate automated handling. They are certified DNase-and RNase-free. For storage mats and accessories, see page 64.

Cat. No.	Description	Well Shape	Sterile	Well Volume	Qty/Pk	Qty/Cs
3956	96 Well	Round V	Yes	0.5 mL	10	50
3957	96 Well	Round V	No	0.5 mL	100	100
3958	96 Well	Round	Yes	1 mL	5	25
3959	96 Well	Round	No	1 mL	5	100
3960	96 Well	V-Bottom	Yes	2 mL	5	25
3961	96 Well	V-Bottom	No	2 mL	5	100
3964	384 Well	Square-Round	Yes	180 µL	5	25
3965	384 Well	Square-Round	No	180 µL	5	100
3342	384 Well	Square V	Yes	240 μL	5	50
3347	384 Well	Square V	No	240 μL	5	50

## **Disposable Culture Flasks**

Disposable plastic Erlenmeyer flasks are made from optically clear polycarbonate and feature a wide, easy access mouth. The polycarbonate construction also delivers mechanical strength for shaker culture applications. Each flask is individually packaged and radiation sterilized. The polypropylene plug seal caps offer two positions: open to allow gas exchange or closed for a liquid-tight seal. The vent caps allow free gas exchange while offering a liquid-tight, contamination-free seal.

Cat. No.	Capacity (mL)	Graduations (mL)	Neck Diameter (mm)	Cap Style	Sterile	Qty/Pk	Qty/Cs
430421	125	25	26	Plug Seal	Y	1	50
431143	125	25	26	Vent Cap	Y	1	50
430183	250	25	31	Plug Seal	Y	1	50
431144	250	25	31	Vent Cap	Y	1	50
430422	500	50	43	Plug Seal	Y	1	25
431145	500	50	43	Vent Cap	Y	1	25
431146	1000	50	43	Plug Seal	Y	1	25
431147	1000	50	43	Vent Cap	Y	1	25



384 Well Polypropylene Blocks

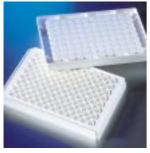


Disposable Plastic Erlenmeyer Flasks

## Purification



384 FiltrEX Filter Plates



96 FiltrEX Filter Plates



Volume Adapter

## Filtr*EX*<sup>™</sup> 96 and 384 Well Filter Plates

Corning<sup>®</sup> Filtr*EX* filter plates meet the industry standards for plate dimensions. The rigid side walls make the plate ideal for automation and the wide skirt accepts bar codes. Individual filter disks are encapsulated in the plate by a patented<sup>\*</sup> process that ensures 100% integrity of each well. The design of the nozzle prevents sample cross-contamination and wicking. Glass fiber filter plates can be used for a variety of applications, such as plasmid isolation, DNA purification, PCR<sup>†</sup> clean-up or receptor/ligand binding assays. They are a cost-saving alternative to expensive DNA prep kits. Use the low-binding hydrophilic PVDF membrane for lysate clarification, protein kinase assays, or bead- or resin-based separation assays. Visit the Technical Information Center at our web site for additional application information.

## 384 Well FiltrEX Filter Plates

Cat. No.	Membrane	Pigment	Sterile	Well Volume (µL)	Qty/Pk	Qty/Cs
3531	0.45 μm PVDF	White	No	180	5	25
3533	0.66 mm Glass Fiber	White	No	180	5	25

**XX7 11** 

## 96 Well FiltrEX Filter Plates

Cat. No.	Description	Sterile	Well Volume (µL)	Otv/Pk	Otv/Cs
3504	0.2 μm PVDF Membrane, Hydrophilic	No	350	10	50
3505	0.2 μm PVDF Membrane, Hydrophilic	Yes	350	10	50
3510	0.25 mm Glass Fiber Filter	No	350	10	50
3511	0.66 mm Glass Fiber Filter	No	350	10	50
New514	Fluid Guard for FiltrEX 96 Well Filter Plates	No	_	100	100

Please contact us for customized membranes. \*U.S. Patent No. 6,391,241

<sup>†</sup>PCR is covered by patents owned by Hoffman-LaRoche Inc., Nutley, NJ. Use of the PCR process requires a license.

## **Volume Adapter and Applicator**

A volume adapter allows larger volumes (up to 1 mL) to be applied to the 96 well filter plates. The applicator easily assembles and disassembles the filter plate and adapter, and ensures a perfect, leak-free fit.

Cat. No.	Description	Qty/Pk	Qty/Cs
3584	Volume Adapter, Nonsterile	10	50
3507	Applicator	1	1

## **Collection Microplates**

Filtr*EX* 96 and 384 well filter plates meet industry standards for plate dimensions and can be used with a broad range of collection plates. Polystyrene and polypropylene plates are available with a variety of well geometries. Commonly used collection plates are listed below. For information about other compatible collection plates, please contact us.

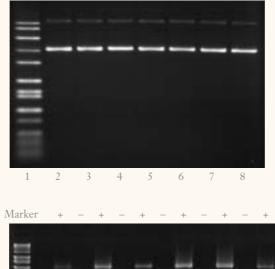
Cat. No.	Description	Well Volume (µL)	Otv/Pk	Qty/Cs
3371	96 Well Round Bottom Polypropylene ClearPro <sup>™</sup> Plat	St. /	25	100
3795	96 Well Round Bottom Polystyrene Plate	360	25	100
3897	96 Well V-Bottom Polystyrene Plate	320	25	100
3657	384 Well Polypropylene Plate	95	25	100
3965	384 Well Polypropylene Block	180	5	100
3702	384 Well Polystyrene Plate	125	25	100

#### FiltrEX<sup>™</sup> 96 and 384 Well Filter Plate Construction



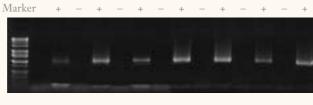
The proprietary nozzle design and individual, integrally-sealed filter disks prevent filtrate cross contamination and wicking. The rigid construction and wide skirt allow for robotic handling and bar coding.

## FiltrEX Filter Plate Performance

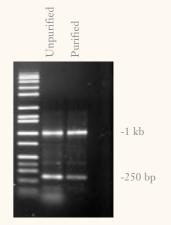


#### Agarose gel electrophoresis of Plasmid DNA prepared using Corning<sup>®</sup> FiltrEX 384 well filter plates.

Plasmid DNA samples isolated with glass fiber filter plates were separated in a 1% agarose gel in 1X TAE buffer. Lane 1 contains 10 µL of Hi-Lo™ markers (total DNA =  $1 \mu g$ ). Lanes 2-8 contain plasmid preparations isolated using 7 different wells of the filter plate. Plasmid DNA was recovered in approximately 55 µL total volume. Two microliters (2 µL) of recovered plasmid were loaded in each lane of the gel.



Integrally sealed wells eliminate sample cross contamination. Alternating wells of negative control (-) or plasmid DNA (+) filtered through FiltrEX 384 well Filter Plates were analyzed for cross-contamination by PCR. PCR products were not detected in the negative control wells, indicating the absence of contaminating DNA.



PCR Clean-Up PCR products were purified using a FiltrEX 384 well glass fiber filter plate. Primer dimers were efficiently removed with good recovery of the PCR products.



Spin-X Centrifuge Tube Filters

### Spin-X<sup>®</sup> Centrifuge Tube Filters

Spin-X centrifuge tube filters consist of a membrane-containing filter unit within a centrifuge tube. They filter by centrifugation for bacteria removal, particle removal, HPLC sample preparation, removal of cells from media and DNA removal from agarose or acrylamide gels. Maximum RCF<sup>\*\*</sup> is 16,000 x g.

Cat. No.	Membrane	Well Volume (working µL)	Pore Size (µm)	Tube Size (mL)	Qty/Cs
8160	CA	500	0.22	2.0	96
8161*	CA	500	0.22	2.0	100
8162	CA	500	0.45	2.0	96
8163*	CA	500	0.45	2.0	100
8169*	NY	500	0.22	2.0	200
8170*	NY	500	0.45	2.0	200

CA = Cellulose Acetate, NY = Nylon

\*Indicates that the product is nonsterile and certified nonpyrogenic.

\*\*RCF = Relative Centrifugal Force.

#### Spin-X Tube Purification of DNA from Agarose Gels

#### Introduction

Purification of DNA from an agarose gel with the Spin-X tube is quick and efficient, unlike the electroelution, dialysis, and "freeze-squeeze" methods. The Spin-X method consists of two simple steps: excision of the band from the gel and centrifugation in the Spin-X tube. Yields range from 30 to 80%.

#### Protocol\*

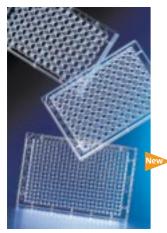
- 1. Electrophorese DNA in an agarose gel containing ethidium bromide.
- 2. After electrophoresis, illuminate the gel under long wavelength UV light, then, using a sharp instrument, carefully excise the band of interest (30-15,000 bp).
- 3. Place the gel slice into the filter cup of the Spin-X tube (Cat. No's. 8160, 8161, 8162, 8163) and mix with 100 to 200 μL of distilled water or Tris-EDTA.
- 4. Spin the tube at about 13,000 x g for 5 to 20 minutes at room temperature.
- 5. Collect the DNA from the microcentrifuge tube; the agarose gel will be retained on the Spin-X membrane. If needed, ethanol precipitate the DNA to remove any EDTA present.

#### Note: DNA yield may increase with the incorporation of one or all of the following steps:

- 1. Macerate the gel slice prior to placement in the Spin-X tube.
- 2. Prior to centrifugation in step #4, freeze the gel slice at -70°C in a separate tube, then allow to thaw.
- 3. After the initial centrifugation, add an additional 200  $\mu L$  of buffer to the Spin-X tube and centrifuge again.
- 4. Spin for a longer period of time.

\*Schwarz, Herbert and Whitton, J. Lindsay, 1992. A Rapid, Inexpensive Method for Eluting DNA from Agarose or Acrylamide Gel Slices Without Using Toxic or Chaotropic Materials. Vol. 13, No. 2, Biotechniques.

## **Quantitation and Detection**

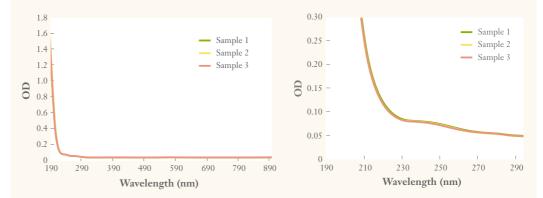


96 Well Half Area, 96 and 384 Well UV Microplates

## 96 and 384 Well UV Microplates

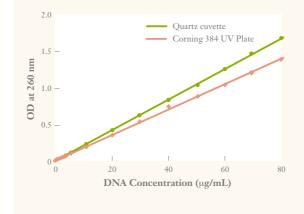
These plates have a unique UV-transparent bottom; ideal for determining protein and/or nucleic acid concentrations. The UV-transparent bottom is molded to the top without adhesives for greater strength and maximum leak resistance. Plates are certified for low background and consistent performance at 260 and 280 nm. Their broad linear detection range allows reliable detection of high and low concentrations of biomolecules.

	Well						
Cat. No.	Format	Bottom	Volume (µL)	Qty/Pk	Qty/Cs		
3635	96 Well	Flat	370	25	50		
3675	384 Well	Flat	125	5	25		
3679	96 Well Half Area	Flat	205	25	50		



#### 384 Well UV Microplate Performance

**Background absorbance of three samples of the Corning 384 well UV plate bottom material.** This material features consistently low absorbance over a broad wavelength range, including well into the UV. The three samples showed negligible background absorbance across the entire visible spectrum (left panel) and very low background in the UV range (right panel).



Comparison of DNA detection with the Corning 384 well UV plate to individual samples read in a quartz cuvette. For each indicated DNA concentration, triplicate 100 µL samples were read in a quartz cuvette with a Beckman DU® spectrophotometer. Six samples (90 µL) were read in a Corning 384 well UV plate at each concentration with a Tecan ULTRA<sup>™</sup> reader. These sample volumes were chosen in order to maintain a 1 cm path length (smaller volume samples can be read in the UV plate). The Corning UV plate demonstrates a broad linear range enabling the reliable detection of high and low concentrations as well as good sample to sample consistency (CV's of <2% at 50 µg/mL DNA).



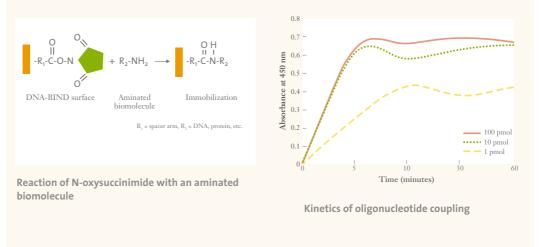
DNA-BIND Assay Microplates

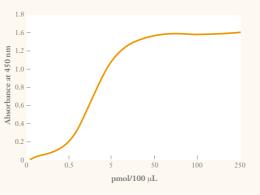
### **DNA-BIND®** Assay Microplates

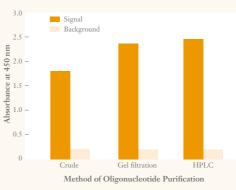
DNA-BIND surface covalently couples to amine groups, providing a convenient method to immobilize aminated single-stranded DNA by either the 5' or 3' end for hybridization, amplification, or other DNA-based assays. 96 well plates and 1 x 8 Stripwell<sup>™</sup> plates come without lids. Protocols and application information are available on our web site: www.corning.com/lifesciences.

Cat. No.	Format	Well Shape	Qty/Pk	Qty/Cs
2497	1 x 8 Stripwell Plate, White	Flat	1	50
2498	96 Well Plate, Solid Black	Flat	1	50
2499	96 Well Plate, Solid White	Flat	1	50
2505	96 Well Plate, Clear	Flat	1	50
2506	1 x 8 Stripwell Plate, Clear	Flat	1	50
2525	96 Well Plate, Clear	Flat	1	10

#### **DNA-BIND Surface Performance**



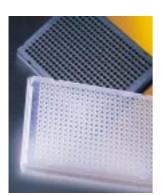




Detection of hybridization at increasing oligonucleotide concentrations

Effect of post-synthetic purification method on signal strength and background

## **DNA Amplification**



Thermowell GOLD 384 Well PCR Microplates



Thermowell GOLD 96 Well Polypropylene PCR Microplates

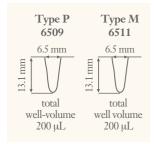


Plate Well Dimensions

## Thermowell<sup>®</sup> GOLD PCR<sup>†</sup> Reaction Vessels from Corning

Thermowell GOLD PCR reaction vessels exemplify Corning's commitment to innovation: to develop superior quality, reliable, and versatile products to complement today's dynamic changes in technology. The wide variety of options offered by Thermowell GOLD provides researchers the choices necessary for complete compatibility with laboratory equipment. Look to Thermowell GOLD for PCR, sequencing, and real-time PCR.

## Thermowell GOLD 384 Well Polypropylene PCR Microplates and Accessories

Thermowell GOLD 384 well PCR microplates feature exceptional dimensional stability following thermocycling, and are fully compatible with automation, commonly used thermal cyclers, and Applied Biosystems<sup>®</sup> sequencing adapters (see compatibility table).

Cat. No.	Description	Qty/Pk	Qty/Cs
3757	384 Well Polypropylene PCR Microplate, clear	10	50
3756	384 Well Polypropylene PCR Microplate, black	10	50
3699ª	Silicone Rubber Sealing Mat – 384 Well Microplates	1	25
6569	Aluminum Sealing Tape-384 Well Microplates	100	100
6575	Universal Optical Sealing Tape	100	100
6575		100	)

<sup>a</sup>Thermowell Sealing Mats, available for 384 Well PCR Plates, are easy to apply and remove, fully autoclavable and reusable (at least five times). These silicone rubber mats offer a cost effective alternative to other sealing methods and provide 100% sealing when used in conjunction with clamp or screw-down heated lid thermal cyclers.

## Thermowell GOLD and Thermowell 96 Well Polypropylene PCR Microplates and Accessories

Thermowell GOLD 96 well PCR microplates are offered in five formats to ensure maximum flexibility and a perfect match for your applications. The original Thermowell 96 well PCR microplates are universal fit and can be cut into 3 x 8 well segments.

Description	Qty/Pk	Qty/Cs
96 Well Microplate, Clear – Thermowell	25	25
96 Well Microplate, Full Skirt, Clear – Thermowell GOLD	10	50
96 Well Microplate, Full Skirt, Black – Thermowell GOLD	10	50
96 Well Microplate, Half Skirt, Clear – Thermowell GOLD	10	50
96 Well Microplate, Half Skirt, Black – Thermowell GOLD	10	50
96 Well Microplate, Elevated Skirt, Clear – Thermowell GOLD	10	50
	<ul> <li>96 Well Microplate, Clear – Thermowell</li> <li>96 Well Microplate, Full Skirt, Clear – Thermowell GOLD</li> <li>96 Well Microplate, Full Skirt, Black – Thermowell GOLD</li> <li>96 Well Microplate, Half Skirt, Clear – Thermowell GOLD</li> <li>96 Well Microplate, Half Skirt, Black – Thermowell GOLD</li> </ul>	96 Well Microplate, Clear – Thermowell2596 Well Microplate, Full Skirt, Clear – Thermowell GOLD1096 Well Microplate, Full Skirt, Black – Thermowell GOLD1096 Well Microplate, Half Skirt, Clear – Thermowell GOLD1096 Well Microplate, Half Skirt, Black – Thermowell GOLD1096 Well Microplate, Half Skirt, Black – Thermowell GOLD10

<sup>b</sup>Fully compatible with ABI 3700 and 3730.

## **Polycarbonate PCR Microplates**

Cat. No.	Format	Model Name	Well Volume (µL)	Qty/Pk	Qty/Cs
6509	96 Well	Model P	200	1	25
6511	96 Well	Model M	200	1	25

## Thermal Cycler Compatibility Guide for Polycarbonate PCR Microplates

Cat. No.	Name	Compatible Thermal Cyclers
6509	Model P	Applied Biosystems GeneAmp® PCR System 9600 <sup>c</sup> , Barnstead Thermolyne Amplitron II®, Techne® Cyclogene, and Gene E with 96 x 0.2 mL block
6511	Model M	MJ Research PTC-100-96V, PTC-200 DNA Engine <sup>™</sup> , Biometra Uno - Thermoblocker <sup>™</sup> , Coy Corporation Temp Cycler II, Corbett Research FTS-960, Hybaid OmniGene with Microblock, Quatro BioSystems T-C-40

<sup>c</sup>Requires the use of the Spacer Block and Frame (Cat. No. 6527). <sup>†</sup>PCR is covered by patents owned by Hoffman-LaRoche Inc., Nutley, NJ. Use of the PCR process requires a license.

## 96 Well Polycarbonate PCR Microplates with DNA-BIND<sup>®</sup> Surface

DNA-BIND Thermowell<sup>®</sup> M PCR plates can be used in solid phase applications such as DNA synthesis, conventional PCR reactions, mRNA isolation and RT-PCR, and standard DNA hybridization assays.

Cat. No.	Format	Model Name	Well Volume (µL)	Qty/Pk	Qty/Cs
6573	96 Well	Model M	200	1	25

## PCR Sealing Tape and Sealing Mats

Sealing tapes prevent evaporation and enable oil-free operation when used with thermal cyclers with heated lids. The universal optical sealing tape can be used in detection coupled with PCR systems (real-time PCR).

Cat. No.	Description	Qty/Pk	Qty/Cs
6524	Polyethylene Sealing Tape-96 Well Microplates	100	100
6569	Aluminum Sealing Tape-384 Well Microplates	100	100
6570	Aluminum Sealing Tape-96 Well Microplates	100	100
6575	Universal Optical Sealing Tape for Real Time PCR	100	100
6555	Thermowell™ Sealing Mat-96 Well Microplates	1	25
3699	Thermowell Sealing Mat-384 Well Microplates	1	25
3087	Silicone Rubber Septa Mat	10	50

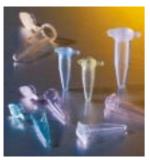
### **Thermowell GOLD and Thermowell PCR Tubes**

Individual PCR tubes are made of thin wall polypropylene and designed for precise fit in heat blocks to optimize heat transfer. Tubes are tested and certified to be free of DNase and RNase, are autoclavable at 121°C and withstand centrifugation to 10,000 x g.

Cat. No.	Volume (mL)	Cap Style	Color	Qty/Pk	Qty/Cs
Individual H	Polypropylene PCR Ti	bes – Thermowell (	GOLD		
3745	0.2	Flat	Clear	500	1,000
3744	0.2	Flat	Assorted	500	1,000
3747	0.2	Dome	Clear	500	1,000
3746	0.2	Dome	Assorted	500	1,000
3750	0.5	Flat	Clear	500	1,000
3749	0.5	Flat	Assorted	500	1,000
Individual I	Polypropylene PCR Ta	vbes – Thermowell			
6530	0.5	Flat	Clear	250	1,000
6531	0.2	Dome	Clear	96	960
6571	0.2	Flat	Clear	96	960



Sealing Tape, Sealing Mats, and Cap Strips for PCR



Thermowell GOLD PCR Tubes



Thermowell GOLD 8 Well PCR Tube Strips

## Thermowell<sup>®</sup> GOLD 8 Well PCR Tube Strips

Tube strips consist of eight 0.2 mL thin wall polypropylene tubes connected together. Dual connectors between adjacent tubes eliminate inadvertent breakage during sample handling. Tube strips are designed for precise fit in thermal cyclers to optimize heat transfer. Thermowell GOLD cap strips are sold separately from Thermowell GOLD tube strips. Original Thermowell tube strips and cap strips are packaged together. Tube strips are tested and certified to be free of DNase/RNase contamination and are autoclavable at 121°C.

Cat. No.	Description	Qty/ Pk	Qty/ Cs
3741	0.2 mL 1 x 8 Tube Strips, Clear – Thermowell GOLD	125	1,250
3740	0.2 mL 1 x 8 Tube Strips, Assorted Colors - Thermowell GOLD	125	1,250
6542	0.2 mL 1 x 8 Tube Strips, Clear – Thermowell	60	300
6547*	0.2 mL 1 x 8 Tube Strips, Assorted – Thermowell	60*	300
3743	1 x 8 Cap Strips, Domed, Clear – Thermowell GOLD	125	1,250
3748	1 x 8 Cap Strips, Domed, Assorted Colors – Thermowell GOLD	125	1,250
3742	1 x 8 Optically Clear Flat Cap Strips, for RT-PCR** – Thermowell GOLD	125	1,250

\*60 of each color per bag; 1 bag of each color per case. \*\*Optically Clear Flat Cap Strips are designed for real-time PCR. Suitable for use with Thermowell GOLD 0.2 mL 1 x 8 PCR tube strips and 96 well microplates.

See page 80 for Compatibility Guide and Volume Reference table.

## Compatibility Guide for Thermocyclers, Sequencers, and Real Time PCR

Thermowell GOLD Microplates



	-		Well GOLD Mile	
		96 Well	96 Well Full Skirt	384
		Half Skirt	Full Skirt	Well
Thermal Cyclers Applied BioSystems®	GeneAmp® 9600 GeneAmp 9700	:		
Biometra®	Uno <sup>®</sup> Uno II <sup>®</sup> T1 Thermocycler <sup>®</sup> Tgradient <sup>®</sup> Trobot <sup>®</sup>			:
Bio-Rad®	iCycler™			
Eppendorf	MasterCycler®			
Ericomp	SingleBlock® TwinBlock® Deltacycler I®	:		
Flexi	Gene Genius			-
ThermoHybaid	PCR Sprint® PCR Express® MultiBlock System Touchdown® Omnigene® Omn-E®			:
MJ Research™	PTC 200 DNA Engine <sup>™</sup> PTC 225 DNA Tetrad <sup>®</sup> PTC 100 <sup>®</sup>			:
$MWG^{TM}$	Primus 96® Primus 384®	-	•	
Stratagene®	Robocycler®			
TaKaRa	TP 240® TP 3000®		:	
Techne®	Touchgene X®			
RT-PCR Thermal Cycler	rs -			
Applied BioSystems	ABI PRISM® 7000 ABI PRISM 7700 ABI PRISM 7900 HT	-	•	1
Bio-Rad	iCycler®			
Stratagene®	Mx 4000®			
Sequencers				
Applied BioSystems	ABI PRISM 3100 ABI PRISM 3700 ABI PRISM 3730			1
Amersham Biosciences	MegaBACE™ 500 MegaBACE 1000 Mark II MegaBACE 4000			
MJ Research™	BaseStation <sup>®</sup> Transgenomic			

## Thermowell GOLD PCR Microplates Volume Reference Table

Format	Total Volume	Working Volume
384 Well PCR Microplates	55 µL	50 µL
96 Well PCR Microplates, Full Skirt	240 μL	200 µL
96 Well PCR Microplates, Half Skirt	340 μL	300 μL
96 Well PCR Microplates, Elevated Skirt	340 μL	300 μL

## **Bar Code Customization**



## **Dependable Durability**

Bar codes have been quality tested for optimal readability, chemical resistance and temperature variation.

## What is a Bar Code\*?

The same kind of bar codes you see in stores and supermarkets can be very useful to your lab. Consisting of a series of black bars and light spaces representing letters and/or numerals, a bar code is an easy-to-use vehicle for data collection. The specific arrangement of these bars and spaces follows strict rules known as a "symbology."

## How Does a Bar Code Work?

Bar codes reflect spots of light into a scanner in varying amounts. These differences in reflection are translated into electrical signals by a light detector inside the scanner. The signals are converted into binary ones and zeros, which are used in various combinations to stand for specific numbers and letters.

### **Common Characteristics of a Bar Code**

#### The Quiet Zones

The areas immediately adjacent to the beginning and the end of the bar code symbol. These zones define the parameters of the code. As a rule of thumb, zones should be 0.25" or larger to prevent misreads.

#### Start and Stop Characters

Found at the beginning and end of the bar code symbol. They tell the scanner from which direction information is being received.

#### Interpretation Line

Appears above or beneath a bar code where human readable information appears.

### Corning, Beyond the Common Bar Code

- ▶ 2.75" x 0.25" label size
- Linear (1-D) bar codes: Code 128, Code 3 of 9, Interleaved 2 of 5
- ▶ 10 Mil Narrow Bar Element (X-dimension = 0.010")
- Multiple bar code labels on a single plate
- Label placement on any side of a Corning microplate
- Customer sequence is electronically stored and can be maintained even if plates or projects change.

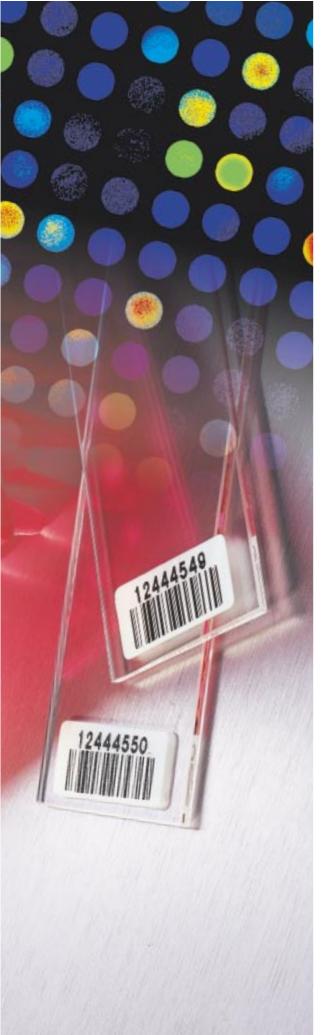
#### **Custom Designed Bar Codes**

Corning will assist in designing and implementing a bar code label to meet your exact specifications. We will provide bar code label test samples at the front end of a project, to confirm decodability and ensure flawless performance in your end-use process. Our other customization features include:

- Flexible bar code and corresponding human readable layout/orientation on the bar code label, for compatibility with the internal bar code scanner inside your automated instruments
- Color coding
- Superior print quality and resolution
- Flexible bar code label positioning
- Resistant to most commonly used organic solvents

#### **Expert Advice**

Most Corning genomics products are suitable for bar code customization. Contact Corning Life Sciences or your local representative for more information. \*Information provided by Computype, Inc.



## Microarray

OVERVIEW
SLIDE SELECTION CHART
MICROARRAY PRINTING
Epoxide Coated Slides
UltraGAPS™ Coated Slides
GAPS™ II Coated Slides88
Pronto!™ Universal Spotting Solution89
Pronto! Epoxide Spotting Solution
384 Well Microarray Printing Plates
Microarray Slide Mailers/Storage Boxes
Microarray Storage Pouches
MICROARRAY PROCESSING
Pronto! <i>Plus</i> Microarray System92
Pronto! Universal Hybridization Kits
Pronto! Background Reduction Kit95
Hybridization Chambers
Corning <sup>®</sup> Cover Glass 96

## Overview

The quality and reliability of microarray results largely depend on the quality and consistency of both the glass substrate and the reagents used to manufacture and process the arrays. Corning has a history rich in science and technology, with expertise in glass and surface modification, optics, biochemistry and molecular biology, which has led to many innovations for life science research. Using this broad-based knowledge, Corning provides complete solutions to customers' complex problems and enables the achievement of breakthrough discoveries.

#### TOOLS FOR EVERY STEP IN THE PROCESS

- Premium glass substrates for printing microarrays
- Optimized reagents for the highest possible performance and control throughout the microarray process
- > Storage products to facilitate the process and preserve sample content

### SUPERIOR TECHNICAL AND APPLICATIONS INFORMATION

- Protocols included with every case of product, optimized from Corning's vast research experience
- On-line tools to verify cDNA labeling efficiency at www.prontosystems.com
- Expert assistance that is just an e-mail or phone call away
- > Field Applications support with a direct link to our Applications Group

### UNPARALLELED MANUFACTURING PROCESSES

Corning<sup>®</sup> glass slides are manufactured using a proprietary coating process in a Class 100 cleanroom and undergo numerous quality control tests. Every slide is meticulously inspected for the presence of contaminating particulates, scratches and other defects before and after coating, ensuring a substrate of unmatched cleanliness, consistency, reliability and integrity.

The reagents in the Pronto!<sup>™</sup> Microarray Kits and Pronto! *Plus* Microarray System are quality controlled to deliver consistency at every step in the process. They are optimized for use with Corning microarray slides, allowing the highest possible level of performance, standardization, and control.

## Slide Selection Chart

Slide Surface	Recommended Printed Content	Binding Interaction	Recommended Hybridization Solutions
Epoxide Coated Slides	cDNA, long oligonucleotides (>50-mer)	Covalent	Pronto! cDNA/Long Oligo Hybridization Solution
	Short oligonucleotides (~30-mer) with or without amino modifications	Covalent	Pronto! Short Oligo Hybridization Solution
UltraGAPS <sup>™</sup> Coated Slides	cDNA, long oligonucleotides (>50-mer)	Ionic	Pronto! cDNA/Long Oligo Hybridization Solution
GAPS <sup>™</sup> II Coated Slides	cDNA	Ionic	Pronto! cDNA/Long Oligo Hybridization Solution
	Proteins	Ionic	Ligand-dependent



## **Microarray Printing**



### **Epoxide Coated Slides**

Versatility

Corning® Epoxide Coated Slides provide the optimal, uniform surface chemistry for covalent attachment of unmodified or amino-modifed short oligonucleotides (~30-mer), as well as long oligonucleotides (>50-mer) and cDNA. The Pronto!™ Epoxide Spotting Solution (see p. 90), when used in conjunction with Corning Epoxide Coated Slides, provides superior spot size control for printing high density arrays. Use Corning Epoxide Coated Slides with the Pronto! Universal Hybridization Kit (see p. 93) to achieve the highest possible level of overall microarray performance.

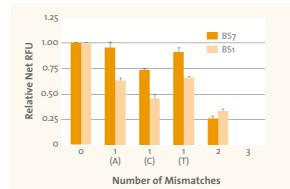
#### Ideal for short oligonucleotides, long oligonucleotides, and cDNA

- Print with unmodified or amino-modified oligonucleotides
- No UV crosslinking or baking step required for DNA coupling
- **Reproducibility** Interslide CVs below 10%

Sensitivity	Detect 1 pg RNA spiked into 4 µg of total RNA sample
Specificity	<ul> <li>Differentiate between 90% homologous oligos</li> <li>(3 mismatches in 30-mer oligonucleotides)</li> </ul>

#### **Epoxide Coated Slides Ordering Information**

Cat. No.	Description	Slides/Pk	Slides/Cs
40040	Epoxide Slide Starter Kit (10 Epoxide Coated Slides, 5 mL Epoxide Spotting Solution, 0.8 mL Short Oligo and 0.8 mL cDNA/Long Oligo Hybridization Solution)	5	10
40041	Epoxide Coated Slides with Bar Code	5	25
40042	Epoxide Coated Slides without Bar Code	5	25
40043	Epoxide Coated Slides with Bar Code, Bulk Pack	25	25
40044	Epoxide Coated Slides without Bar Code, Bulk Pack	25	25



#### Gene A Gene B Gene C Gene D Gene E Corning Competitor's Epoxide . Covalent Slides Slides

R

А R

## Differentiate Between 90% Homologous

Corning Epoxide Coated Slides and the reagents from Pronto! Universal Hybridization Kits perform together to differentiate between 90% homologous oligonucleotides (3 mismatches in 30-mer oligonucleotides). A study using mismatch oligonucleotides designed for two B. subtilis genes (BS7 and BS1) was performed. No mismatches (o), 1 mismatch (A, C, T) or multiple mismatches (2, 3) were tested for specificity of detection under identical processing conditions. As indicated in the above graph, there is a reduction in signal for each successive mismatch until no detectable signal is observed for 3 mismatches.

Oligonucleotides

#### Use Unmodified or Amino-Modified Oligonucleotides Oligonucleotides (30-mer) were printed onto

Corning Epoxide Coated Slides and a competitor's covalent slides, following recommended protocols. Oligonucelotides were either C6amino modified at the 5' end (A columns) or unmodified (B columns). Cy°5/Cy°3 ratios correlated strongly between modified and unmodified oligonucleotides for Corning Epoxide Slides, but the competitor's slides showed an absolute requirement for amino modification of the oligonucelotides.



### **UltraGAPS<sup>™</sup> Coated Slides**

The Gamma Amino Propyl Silane surface on UltraGAPS Coated Slides is ideal for printing long (>50-mer) oligonucleotides, as well as cDNA. UltraGAPS Coated Slides have a more hydrophobic surface than competitors' slides, resulting in smaller, more consistent spot size. Each lot is tested for consistent spot morphology, signal intensity, and low background in a hybridization assay. Some of the applications for which UltraGAPS Coated Slides are ideally suited include: gene expression analysis, genotyping, and CGH (comparative genomic hybridization).

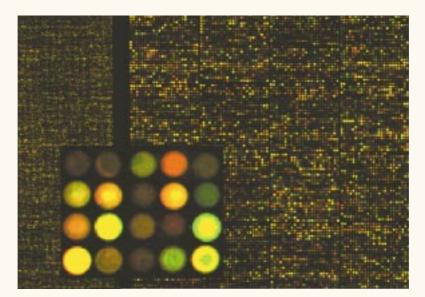
The Pronto!<sup>™</sup> Universal Spotting Solution (see p. 89) has been optimized for use with the UltraGAPS Coated Slides and provides excellent spot morphology for microarray printing. Use the Pronto! Universal Hybridization Kit (see p. 93) in conjunction with these slides to achieve the highest level of microarray performance.

- **Dynamic Range** Low background autofluorescence
- Manufacturing
   Consistent spot morphology

   Excellence
   Uniform surface treatment
  - Uniform surface treatmentHigher hydrophobicity
  - Inglier hydrophoblerty

## UltraGAPS Coated Slides Ordering Information

Cat. No.	Description	Slides/Pk	Slides/Cs
40015	UltraGAPS Coated Slides with Bar Code	5	25
40016	UltraGAPS Coated Slides without Bar Code	5	25
40017	UltraGAPS Coated Slides with Bar Code, Bulk Pack	25	25
40018	UltraGAPS Coated Slides without Bar Code, Bulk Pack	25	25
40019	UltraGAPS Slide Starter Kit (Includes 10 UltraGAPS Coated Slides, 5 mL Universal Spotting Solution)	5	10
40024	Pronto! Universal Validation Kit (Includes 10 UltraGAPS Coated Slides, 15 mL Universal Spotting Solution, Pronto! Hybridization Kit for 10 arrays)	5	10
40025	Pronto! Universal Printing Kit (Includes 25 UltraGAPS Coated Slides, 50 mL Universal Spotting Solution)	25	25



**27,000 Feature Array on UltraGAPS Coated Slides (three magnifications)** A 27,000 feature array was printed on UltraGAPS slides, processed and hybridized using the reagents in the Pronto! Universal Hybridization Kit. The inset shows a magnification to highlight the low background, uniform spot morphology, and signal intensity of a the array.

Data courtesy of A. Borg, Ph.D., Lund University, Sweden.



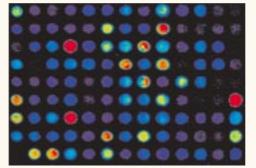
### **GAPS<sup>™</sup> II Coated Slides**

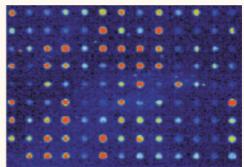
GAPS II Coated Slides are manufactured from a proprietary ultraflat glass that enhances microarray performance, enabling more accurate reading of microarrays by confocal laser scanners. GAPS II Coated Slides are manufactured using the same coating process and attachment chemistry as the original GAPS amino-silane coated slides, enabling researchers to use the same protocols that they optimized for GAPS slides. Use GAPS II Coated Slides with the Pronto!<sup>™</sup> Universal Hybridization Kit (see p. 93) to achieve maximum microarray performance.

- Flexibility
- Recommended for both DNA and protein arrays
- Binding Capacity High DNA retention for maximum signal strength
- Dynamic Range
- Low background autofluorescence

### **GAPS II Coated Slides Ordering Information**

Cat. No.	Description	Slides/Pk	Slides/Cs
40003	GAPS II Coated Slides with Bar Code	5	25
40004	GAPS II Coated Slides without Bar Code	5	25
40005	GAPS II Coated Slides with Bar Code, Bulk Pack	25	25
40006	GAPS II Coated Slides without Bar Code, Bulk Pack	25	25



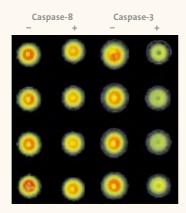


GAPS II Coated Slide

Ordinary Silane Coated Slide

#### Spot Morphology on GAPS II Coated Slides

Note uniform spot morphology, high signal strength, and ultra-low background with the GAPS II Coated Slide. *Images courtesy of Dr. John Quackenbush of the Institute for Genomic Research (TIGR), Rockville, MD.* 



#### **Functional Peptide Array on GAPS II Coated Slides**

The Caspase-3 substrate NH2-DEVDA-Biotin was suspended in Corning<sup>®</sup> Epoxide Spotting Solution and printed in quadruplicate onto anhydride-derivitized GAPS II Coated Slides. Peptide arrays were incubated with avidin-Cy<sup>®</sup>3 in the absence or presence of Caspase-8 or Caspase-3 (as indicated), and scanned at 532 nm. The printed DEVDA peptide retained function on the array, as indicated by the reduced fluorescence seen in the spots treated with Caspase-3, but not Caspase-8. Note: GAPS II Coated Slides have also been used successfully for protein arraying without derivitization.

Coleman et al., Proteomics 3 (11): 2101-07 (2003).



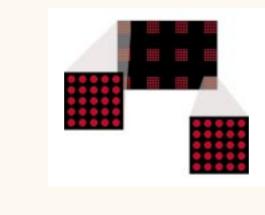
## **Pronto!™ Universal Spotting Solution**

Pronto! Universal Spotting Solution is optimized for both long oligonucleotides (>50-mer) and cDNA printed on UltraGAPS<sup>™</sup> Coated Slides. The proprietary formulation provides excellent spot morphology and has an extremely low evaporation rate. Pronto! Universal Spotting Solution is available in bulk as well as part of both the UltraGAPS Slide Starter Kit and Pronto! Universal Printing Kit.

- Low background autofluorescence
- Low evaporation rate
- Ensures consistent DNA printing concentration
- Eliminates need for volume adjustments
- Provides for even distribution of spotted DNA across entire array

# Pronto! Universal Spotting Solution Ordering Information Cat. No. Description Qty/Pk 40027 Pronto! Universal Spotting Solution, 250 mL 1

40027	Pronto! Universal Spotting Solution, 250 mL	1	1
Cat. No.	Description	Slides/Pk	Slides/Cs
40019	UltraGAPS Slide Starter Kit (Includes 10 UltraGAPS Coated Slides, 5 mL Universal Spotting Solution)	5	10
40025	Pronto! Universal Printing Kit (Includes 25 UltraGAPS Coated Slides and 50 mL Universal Spotting Solution)	25	25



#### Pronto! Universal Spotting Solution – Spot Uniformity

Qty/Cs

Quality control testing for Pronto! Universal Spotting Solution requires consistent spots when using 12 pins printed 25 times.



#### Pronto! Universal Spotting Solution – Low Evaporation Pronto! Universal Spotting Solution evaporative losses are <5% over 4 hours, as compared to evaporate losses of >25% with other commercial spotting solutions.



## **Pronto!™ Epoxide Spotting Solution**

Pronto! Epoxide Spotting Solution should be used for printing all types of DNA including short oligonucleotides (~30-mer), long oligonucleotides (>50-mer), and cDNA printed on Corning<sup>®</sup> Epoxide Coated Slides. When used with Corning Epoxide Coated Slides, this spotting solution provides spot size control for printing high density arrays without contributing to background fluorescence. Pronto! Epoxide Spotting Solution is available in bulk (250 mL) or as part of the Corning Epoxide Slide Starter Kit.

- Provides controlled spot size for high density arrays
- No significant contribution to background fluorescence of arrays
- ▶ Low evaporation rate
- Enhanced spot morphology

### Pronto! Epoxide Spotting Solution Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
40047	Pronto! Epoxide Spotting Solution, 250 mL	1	1
Cat. No.	Description	Slides/Pk	Slides/Cs
40040	Epoxide Slide Starter Kit (10 Corning Epoxide Coated Slides 5 mL Pronto! Epoxide Spotting Solution, 0.8 mL Short Olige Hybridization Solution)	, 5	10





## **384 Well Microarray Printing Plates**

Corning<sup>®</sup> 384 well polypropylene microplates are available in both low and full volume well formats to meet source plate requirements for printing DNA content onto microarray slides. The plates are manufactured from solvent resistant, virgin polypropylene that is compatible with many organic solvents including DMSO. The plates feature rigid, full length skirts for full compatibility with automation.

The 384 Well Low Volume Microarray Printing Plate (Cat. No. 3672), with a working volume of 2 to 20 µL, has a conical V-bottom, square well geometry that provides for maximum sample recovery. The 384 Well Full Volume Storage Plate (Cat. No. 3656) has a total well volume of 95 µL.

- Well design provides for maximum sample recovery
- Resistant to many organic solvents including DMSO
- Certified DNase- and RNase-free
- Automation compatible

#### 384 Well Microarray Printing Plates Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
3672	384 Well Microarray Printing Plate, Polypropylene, Low Volume	10	50
3656	384 Well Storage Plate, Polypropylene, Full Volume	25	100
6569	Aluminum Sealing Tape for 384 Well Microplates	100	100
3099	Universal Lid for 384 Well Microplates	25	50
3085	DMSO Resistant Lid for 384 Well Microplates	25	50



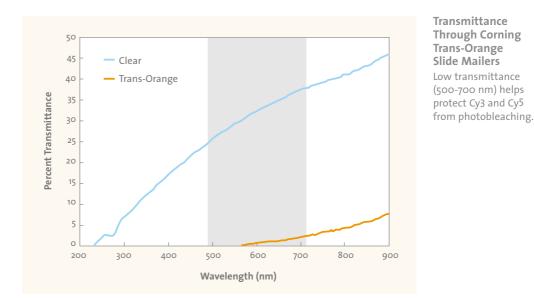
### **Microarray Slide Mailers/Storage Boxes**

The plastic containers in which UltraGAPS<sup>™</sup> Coated Slides are shipped also function as storage boxes for printed arrays. These containers are available as either 5 slide mailers or 25 slide storage boxes. The trans-orange plastic has low transmittance in the 500 to 700 nm wavelength range which helps protect Cy®3 and Cy®5 dyes from photobleaching. These rigid plastic containers do not shed particles or outgas volatile chemicals that may contaminate microarray slides.

The Corning<sup>®</sup> 25 Slide Storage Box has a lift off lid which is easy to open and close. The 5 Slide Mailer has a hinged lid that snaps closed tightly to prevent slides from accidentally falling out.

Microarry Slide Mailers/Storage Boxes Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
40082	5 Slide Mailer for Microarrays	50	50
40081	25 Slide Storage Box for Microarrays	10	20



### **Microarray Storage Pouches**

Corning<sup>®</sup> Microarray Storage Pouches are the same pouches in which Corning UltraGAPS<sup>™</sup> and Epoxide Coated Slides are shipped. These tear-resistant, laminated foil pouches can be used by customers for the storage of printed microarrays. They are available in two sizes for storing arrays in either 5 slide mailers (5 <sup>3</sup>/4" x 4 <sup>1</sup>/4" pouch) or 25 slide storage boxes (6" x 7 <sup>1</sup>/2" pouch).

When heat-sealed, the pouches provide microarrays with protection from light, humidity, and environmental contaminants. Each pouch comes affixed with a 3" x 4" white marking label.

Cat. No.	Description	Qty/Pk	Qty/Cs
40085	Microarray Storage Pouches for 5 Slide Mailers	50	50
40086	Microarray Storage Pouches for 25 Slide Mailers	50	50



# **Microarray Processing**



### Pronto!<sup>™</sup> Plus Microarray System

The Pronto! *Plus* Microarray System, jointly developed by Corning Incorporated and Promega Corporation, is a fully integrated solution that enables researchers to generate reliable, reproducible, and sensitive microarray data. The system combines the SV Total RNA Isolation System and ChipShot<sup>™</sup> Labeling System from Promega with the Pronto! Universal Printing Kit and Pronto! Universal Hybridization Kit from Corning. For additional information, visit **www.prontosystems.com**.

Use the Pronto! *Plus* System to isolate and purify total RNA, synthesize fluorescently labeled cDNA, and hybridize the labeled samples to DNA microarrays printed on Corning<sup>®</sup> Epoxide, UltraGAPS<sup>™</sup>, or GAPS<sup>™</sup> II Coated Slides.

Reproducibility	Interslide CVs below 10%
Sample Savings	• Optimized for 5 µg of unamplified total RNA per direct labeling reaction
Sensitivity	Detect 3 pg of spiked RNA in 5 µg total RNA sample
Low Background	• Reduce background autofluorescence by using presoak step
Convenience	• One system contains all reagents (except fluorescent dyes) for the complete processing of printed microarrays

The Pronto! *Plus* Microarray System is available in six different configurations to match all customer processes.

### Validation

Pronto! *Plus* Systems 1 and 2 are designed for core facilities or printing groups planning to validate their process from microarray manufacturing through hybridization (10 UltraGAPS<sup>™</sup> Coated Slides and 15 mL of Pronto! Universal Spotting Solution included).

### **RNA** Purification, Labeling, and Hybridization

Pronto! *Plus* Systems 3 and 5 are designed for microarray researchers who purify total RNA, generate labeled cDNA, and hybridize to microarrays printed on Corning Epoxide, UltraGAPS, or GAPS II Coated Slides.

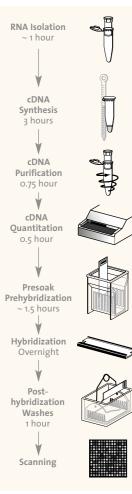
### Labeling and Hybridization

Pronto! *Plus* Systems 4 and 6 are configured for microarray researchers who obtain purified total RNA and need only to label cDNA and hybridize to microarrays printed on Corning Epoxide, UltraGAPS, or GAPS II Coated Slides.

### Pronto! Plus System Ordering Information

Cat. No.	Product	Reactions	UltraGAPS Slides	SV RNA Isolation	ChipShot™ Labeling	Pronto! Hybridization
40051	Pronto! Plus System 1	10				
40052	Pronto! Plus System 2	10			-	
40053	Pronto! Plus System 3	10			-	•
40054	Pronto! Plus System 4	10			-	-
40055	Pronto! Plus System 5	25			-	
40056	Pronto! Plus System 6	25				

#### **Process Flowchart**





### **Pronto!**<sup>™</sup> Universal Hybridization Kits

Pronto! Universal Hybridization Kits (Cat. Nos. 40026 and 40028) provide all of the reagents necessary to perform hybridizations of fluorescently labeled cDNA to microarrays printed on Corning<sup>®</sup> Epoxide, UltraGAPS<sup>™</sup>, or GAPS<sup>™</sup> II Coated Slides. The Pronto! Universal Validation Kit (Cat. No. 40024) contains all of the reagents from above as well as 10 UltraGAPS Coated Slides and 15 mL of Universal Spotting Solution.

<b>Pre-Soak Solution</b>	• Remove existing autofluorescence from printed microarrays
<b>Pre-Hybridization Solution</b>	Block background fluorescence during array hybridization
Hybridization Solutions	<ul> <li>Solutions compatible with cDNA, long oligonucleotide, and short oligonucleotide content</li> </ul>
	Ready to use (no dilution required)

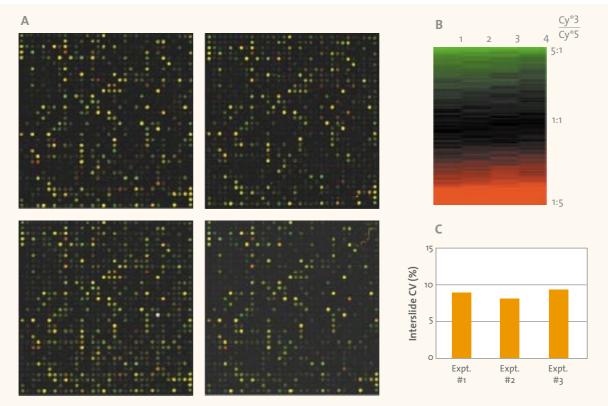
• Contain blockers to increase specificity

### Wash Solutions

• Quality tested to ensure manufacturing consistency

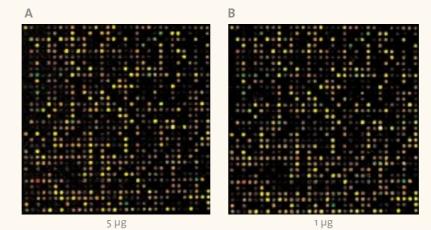
### Pronto! Universal Hybridization Kit Ordering Information

Cat No.	Product	Reactions	ChipShot™ Labeling	Pronto! Hybridization
40024	Pronto! Universal Validation Kit (Includes 10 UltraGAPS Coated Slide 15 mL Universal Spotting Solution)	10 s,		•
40028	Pronto! Universal Hybridization Kit	10		•
40026	Pronto! Universal Hybridization Kit	25		

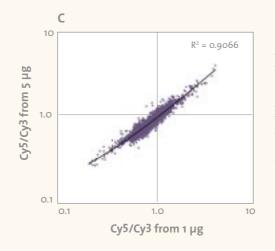


#### **Superior Reproducibility**

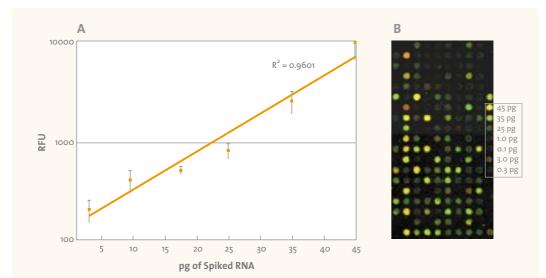
Four separate 4K arrays were processed using the Pronto!<sup>m</sup> Plus System to demonstrate reproducibility (A). Differential gene expression patterns as represented by ratios of normalized Cy<sup> $\circ$ </sup>3/Cy<sup> $\circ$ 5</sup> in the cluster diagram were found to be very consistent between the four arrays (B). Interslide CVs were shown to be <10% for each of 3 separate experiments performed (C).



Amount of Total RNA Template



**Use Less RNA for Labeling** Although the ChipShot<sup>™</sup> Labeling component of the Pronto!<sup>™</sup> *Plus* System is optimized for 5 µg of total RNA template (A), these figures demonstrate that as little as 1 µg of total RNA (B) can be used. The R<sup>2</sup> value of 0.9066 (C) shows a high correlation between data generated from 1 µg and 5 µg of total input RNA.



#### **Extreme Sensitivity**

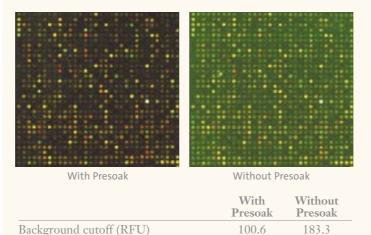
Known picogram quantities (indicated to the right of the array shown in [B]) of in vitro-transcribed, polyadenylated bacterial control RNAs were spiked into 5  $\mu$ g total RNA labeling reactions using the labeling protocol in the Pronto!" *Plus* System. Labeled cDNAs were purified and hybridized to custom 4K human cDNA arrays that included bacterial control spots printed on UltraGAPS<sup>®</sup> Coated Slides. The signal from 3 pg of spiked RNA in the 5  $\mu$ g labeling reaction was reproducibly detected above 2X background (see graph in [A] and representative array data in [B]).

### **Pronto!™ Background Reduction Kit**

The Pronto!<sup>™</sup> Background Reduction Kit is designed to eliminate background autofluorescence and prepare printed arrays for hybridization. It also can be used as the final step in the array fabrication process. The strong reducing effect of this treatment leads to increased sensitivity and specificity by removing autofluorescent background due to oxidation. The kit includes 10 Pre-Soak Tablets and 1 L of Pre-Soak Solution which provides enough reagents for the treatment of at least 50 arrays.

#### Pronto! Background Reduction Kit Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Case
40029	Pronto! Background Reduction Kit	1	1



#### Detect Low Expressing Genes

Use of the Pronto! Background Reduction Kit results in the increased detection of low expressing genes (see table). Reduction of background autofluorescence is evident when 4K human arrays were processed using the presoak reagents in the Pronto! Background Reduction Kit. Arrays that were processed with the presoak reagents (left image) had a lower background detection cutoff than those processed without presoak (right image).



### **Hybridization Chambers**

Number of features  $\geq$  2X background

Corning<sup>®</sup> Hybridization Chambers are designed to hold microarray slides (25 x 75 mm) at constant humidity during hybridization incubations. The O-ring and retaining clips ensure that the reusable chambers remain watertight when submerged in waterbaths and airtight in hybridization ovens. Wells in the base hold 10 to 15  $\mu$ L of water to maintain optimal interior humidity.

1221

891

The original Corning Hybridization Chamber (Cat. No. 2551) provides the ideal interior height and volume for use with one slide of the standard 1 mm thickness and a standard coverglass. The Corning Hybridization Chamber II (Cat. No. 40080) has an increased interior depth which not only allows for single slide hybridizations, but also allows the user to place two arrays face-to-face and hybridize using a single labeled target. This chamber can also be used with raised-edge coverslips (Erie Scientific M-Series Lifter Slips<sup>TM</sup>) that are thicker or taller than standard thin coverglass.

#### Hybridzation Chambers Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Case
2551	Hybridization Chamber	1	5
40080	Hybridization Chamber II with Increased Depth	1	5
40001	Replacement O-rings (fit both chambers)	5	5



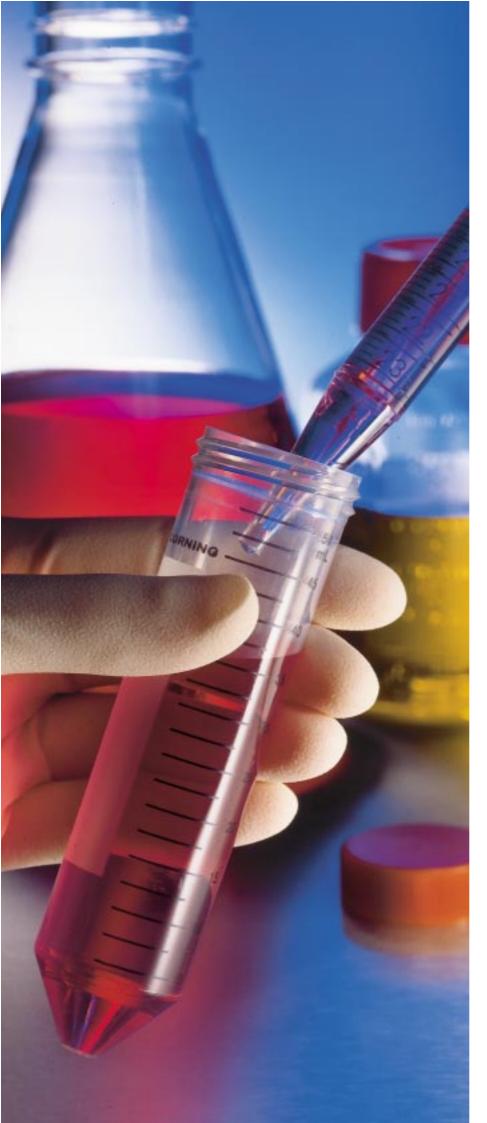
# **Corning® Cover Glass**

Corning Cover Glass is manufactured from special, optically clear glass. The cover glass is resistant to surface attack or weathering and will remain clear for extended periods of time. The flatness is controlled by a machine process resulting in a trouble-free fit to slides for a wettable and bubble-free mount.

The thickness of No. 1<sup>1</sup>/<sub>2</sub> cover glass is 0.16 to 0.19 mm. Cover glass is packaged in plastic boxes for protection and convenience. Cover glasses in sizes and thicknesses other than those listed are available.

### **Cover Glass Ordering Information**

Cat. No.	Description	Approx. Pcs/Oz	Qty/Case
2870-22	Corning Cover Glass, Square, 22 x 22 mm, No. 11/2	135	10 oz
2940-223	Corning Cover Glass, Rectangular, 22 x 30 mm, No. 11/2	97	10 oz
2940-224	Corning Cover Glass, Rectangular, 22 x 40 mm, No. 1 <sup>1</sup> /2	73	10 oz
2940-225	Corning Cover Glass, Rectangular, 22 x 50 mm, No. 11/2	58	10 oz
2940-243	Corning Cover Glass, Rectangular, 24 x 30 mm, No. 11/2	89	10 oz
2940-244	Corning Cover Glass, Rectangular, 24 x 40 mm, No. 1 <sup>1</sup> /2	67	10 oz
2940-245	Corning Cover Glass, Rectangular, 24 x 50 mm, No. 11/2	54	10 oz
2940-246	Corning Cover Glass, Rectangular, 24 x 60 mm, No. 11/2	45	10 oz



# Liquid Handling

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# Overview

### **DESIGNED FOR PERFORMANCE**

Corning Life Sciences offers a full line of liquid handling products that are manufactured under strict process controls guaranteeing consistent product performance. All Corning Life Sciences plastics manufacturing facilities are ISO 9002 registered. ISO registration is recognized worldwide as a standard of excellence for quality systems.

In addition, customers can now request a Certificate of Quality for any Corning® or Costar® liquid handling product. This certificate details lotspecific information on component materials, sterility testing and pyrogen testing. Also available are detailed product descriptions and drawings that highlight product dimensions and testing procedures. All are available simply by calling your local Corning Life Sciences office.

### NONPYROGENIC CERTIFICATION

Most Corning and Costar liquid handling products are certified nonpyrogenic with a documented endotoxin level of equal to or less than 0.1 EU/mL. Endotoxins have been shown to cause variability in cell culture. Nonpyrogenic certification is another way Corning helps ensure consistent cell culture results. Corning also offers a detailed technical bulletin on the effects of endotoxins in cell culture. This may be obtained by calling your local Corning Life Sciences office or by downloading the bulletin from the Corning web site **www.corning.com/lifesciences**.



# **Pipets**



Stripette Serological Pipets



Three packaging options



Exclusive Antidrip Tip

## Stripette<sup>®</sup> Serological Pipets

- Stripette pipets are sterile, nonpyrogenic, and DNase-/RNase-free.
- Exclusive antidrip tip assures accurate delivery.
- Color-coded magnifier stripes make volume reading easier.
- Bidirectional graduations provide choice of ascending and descending scales
- Negative graduations allow additional working volume.
- Four packaging options:
  - Individually wrapped, clear plastic
  - Individually wrapped, paper/plastic
  - Bulk packed for large-scale sterile and nonsterile liquid handling applications
  - Clean room packed; individually wrapped, paper/plastic, triple bagged

### **Stripette Pipets Ordering Information**

Cat. No.	Capacity (mL)	Graduations (mL)	Negative Grads. (mL)	Color Coded Stripe	Qty/Pk	Qty/Cs
Individually	Wrapped, Cl	ear Plastic Wrap				
4011	1	1/100	0.2	Yellow	100/bag	1,000
4012	1	1/100	0.2	Yellow	100/bag	200
4021	2	1/100	0.2	Green	100/bag	1,000
4051	5	1/10	2.5	Blue	50/bag	200
4101	10	1/10	3.0	Orange	50/bag	200
4492*	10	1/10	3.0	Orange	50/bag	200
4251	25	2/10	10.0	Red	50/bag	200
4501	50	1/2	10.0	Purple	25/bag	100
4484	100	1	N/A	Aqua	10/bag	100
Individually	Wrapped, Pa	per/Plastic Wrap				
4485	1	1/100	0.2	Yellow	50/bag	1,000
4486	2	1/100	0.2	Green	50/bag	1,000
4487	5	1/10	2.5	Blue	50/bag	200
4488	10	1/10	3.0	Orange	50/bag	200
4489	25	2/10	10.0	Red	25/bag	200
4490	50	1/2	10.0	Purple	25/bag	100
4491	100	1/1	N/A	Aqua	10/bag	100
Bulk Packed	in Bags					
4010	1	1/100	0.2	Yellow	50/bag	1,000
4020	2	1/100	0.2	Green	50/bag	1,000
4050	5	1/10	2.5	Blue	50/bag	500
4100	10	1/10	3.0	Orange	50/bag	500
4250	25	2/10	10.0	Red	25/bag	200
4500	50	1/2	10.0	Purple	25/bag	100
Clean Room	Pack, Individ	lually Wrapped, P	aper/Plastic, Triple	Bagged		
7015	10	1/10	3.0	Orange	50/bag	200
7016	25	2/10	10.0	Red	25/bag	200
7017	50	1/2	10.0	Purple	25/bag	100
7000	100	1/1	N/A	Aqua	10/bag	100

\*Cat. No. 4492 features a wide tip for handling viscous fluids.



**Aspirating Pipets** 

# **Pipetting Aids**



Stripettor Pipetting Aid

## **Aspirating Pipets**

Aspirating pipets are sterile, ungraduated and unplugged polystyrene pipets for aspirating liquid using vacuum suction.

### Aspirating Pipets Ordering Information

Cat. No.	Volume (mL)	Qty/Pk	Qty/Cs
4975	1	50	1,000
9186	2	Individual	1,000
9099	5	Individual	200

### **Stripettor Pipetting Aids**

- > Lightweight, adjustable speed control, and designed for use with all serological pipets
- ) Nose cones are autoclavable and have a replaceable 0.2 µm hydrophobic sterilizing filter
- Operates on a rechargeable 9V nickel hydride battery and features an LED light on the handle that lets the user know when to recharge
- Unit is fully operational while recharging

#### Stripettor Pipetting Aid Ordering Information

Cat. No.	Product Description	Qty/Cs
4910	Stripettor with sterile filter, rechargeable battery and recharger/adapter	1
4911	Grommet replacement (silicone pipet holder)	1
4922	0.2 μm hydrophobic replacement filter	4
4923	0.2 μm hydrophobic replacement filter	25
4914	Recharger/adapter for 4910	1

# **Pipettors**



Lambda Single Channel Pipettor

### Lambda<sup>®</sup> Single Channel Pipettor

- Corning<sup>®</sup> Lambda pipettors have a contoured handgrip and hook-style hand rest for greater comfort and less fatigue during prolonged use
- Quick-turn volume adjustment knob and easy-to-read digital volume display make volume selection easier
- $\bullet$  Volume ranges include 0.1 to 2  $\mu L,$  0.5 to 10  $\mu L,$  2 to 20  $\mu L,$  10 to 100  $\mu L,$  20 to 200  $\mu L,$  and 100 to 1000  $\mu L$
- Lower unit is autoclavable
- Backed by a three-year warranty

### Lambda Single Channel Pipettor Ordering Information

Cat. No.	Volume Range (µL)	Qty/Cs	
4959	0.1-2.0	1	
4960	0.5-10	1	
4961	2-20	1	
4962	10-100	1	
4963	20-200	1	
4964	100-1,000	1	
4958	Pipettor Stand	1	



8 and 12-Pette Multichannel Pipettors



Octapette Multichannel Pipettors

# Pipet Tips



Universal Fit Pipet Tips

### 8-Pette<sup>®</sup> and 12-Pette<sup>®</sup> Multichannel Pipettors

- Costar<sup>®</sup> 8-Pette and 12-Pette multichannel pipettors feature a unique, ergonomic trigger-style aspiration and dispense control mechanism designed to reduce thumb fatigue during repetitive pipetting
- Volume range is 20 to 200 μL
- Volume is adjusted with a vernier-scale spindle
- > Pipettors are entirely autoclavable

### 8-Pette and 12-Pette Multichannel Pipettors Ordering Information

Cat. No.	Volume Range (µL)	Channels	Qty/Cs
4880	20-200	12	1
4888	20-200	8	1

### **Octapette® Multichannel Pipettors**

- Costar<sup>®</sup> Octapette pipettors have 8 fixed-volume channels
- Available in 25, 50, 100, and 200 µL dispensing volumes

### Octapette Multichannel Pipettors Ordering Information

Cat. No.	Volume (µL)	Channels	Color Code	Qty/Cs
4825	25	1-8	Yellow	1
4850	50	1-8	Green	1
4800	100	1-8	Orange	1
4820	200	1-8	Blue	1

### Universal Fit 200 and 1000 µL Pipet Tips

- Corning<sup>®</sup> universal fit tips are designed to provide a reliable fit with all major brand pipettors. (A Pipet Tip Compatibility Guide can be requested or downloaded from the Corning website.)
- Beveled orifice helps ensure accurate fluid delivery
- ) 1-200 µL universal fit tips are graduated at the 10, 50, and 100 µL volumes
- Select from three packaging options:
  - Racked tips are certified RNase-/DNase-free and nonpyrogenic
- Stack rack tips feature a stack of five racks, each containing 96 tips, for a total of 480 tips in a space-saving design
- Bulk packed tips are nonsterile and very economical

#### Universal Fit 200 and 1,000 µL Pipet Tips Ordering Information

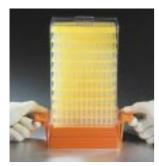
Cat. No.	Volume Range (μL)	Format	Color	Sterile	Racks/ Cs	Tips/ Cs
Racked Tip.	S					
4860	1-200	96 Tips/Rack	Yellow	Yes	10	960
4863	1-200	96 Tips/Rack	Natural	No	10	960
4864	1-200	96 Tips/Rack	Natural	Yes	10	960
4865	1-200	96 Tips/Rack	Yellow	No	10	960
4956	1-300	96 Tips/Rack	Natural	Yes	10	960
4867	100-1,000	100 Tips/Rack	Blue	No	10	1,000
9032	100-1,000	100 Tips/Rack	Blue	Yes	10	1,000



Universal Fit Pipet Tips



Smart Rack Pipet Tip Refill System



Pipet Tip Loading System

### Universal Fit 200 and 1000 µL Pipet Tips (Continued)

Universal Fit 200 and 1,000 µL Pipet Tips Ordering Information

Cat. No.	Volume Range (µL)	Format	Color	Sterile	Racks/ Cs	Tips/ Cs
Stack Rack	Tips					
4803	1-200	480 Tips/Stack Rack	Natural	No	10	4,800
4804	1-200	480 Tips/Stack Rack	Natural	Yes	10	4,800
4806	1-200	480 Tips/Stack Rack	Natural	No	2	960
Bulk Packed	d Tips					
4844	1-200	Bulk Pack	Natural	No	1,000	10,000
4845	1-200	Bulk Pack	Yellow	No	1,000	10,000
4862	1-200	Bulk Pack	Natural	No	1,000	1,000
4866	1-200	Bulk Pack	Yellow	No	1,000	1,000
4846	100-1,000	Bulk Pack	Blue	No	1,000	10,000
4868	100-1,000	Bulk Pack	Blue	No	1,000	1,000

### Smart Rack Pipet Tip Refill System

- Corning<sup>®</sup> Smart Rack makes refilling pipet tip racks easier than ever
- Tips are contained on an autoclavable plastic reload card and transferred to a rack with a disposable reloading device (included)
- Compatible with many popular brand 200 µL 96-tip racks
- Two configurations are available 94-tip and 96-tip. In the 94-tip configuration, each reload card contains 94 tips and two corner anchoring pins that secure the card to the rack
- The 96-tip configuration does not include the corner anchoring pins.
- Smart Rack tips are nonsterile, autoclavable, RNase-/DNase-free, nonpyrogenic, and DNA-free

### Smart Rack Pipet Tip Refill System Ordering Information

Cat. No.	Tip Volume (µL)	Color	Tips/Pack	Packs/Cs	Tips/Cs
4786	200	Natural	940	5	4,700
4787	200	Natural	960	5	4,800

### **Pipet Tip Loading System**

- > The Corning pipet tip loading system makes reloading racks economical and effortless
- The system consists of a one-piece base that attaches to a "magazine" consisting of 10 layers of 96 tips
- Simply place the loader and magazine over an empty rack, lower the magazine, and "click" the rack is loaded and ready for use

#### Pipet Tip Loading System Ordering Information

Cat. No.	Description			
4780	Starter Kit, natural 1-200 μL tips; includes 1 tip loader, 1 magazine with 960 tips and 10 empty racks			
4781	Starter Kit, yellow 1-200 µL tips; includes 1 tip loader, 1 magazine with 960 tips and 10 empty racks			

### **Pipet Tip Loading System Refill Magazines**

• Tip loading system refills consist of magazines containing 10 layers of 96 tips

• Each magazine refills 10 racks

#### Pipet Tip Loading System Refill Magazines Ordering Information

Cat. No.	Tip Volume (µL)	Color	Tips/Magazine	Magazines/Cs	Tips/Cs
4783	1-200	Natural	960	5	4,800
4785	1-200	Yellow	960	5	4,800



Isotip Filtered Pipet Tips



Gel-Loading Pipet Tips and Microvolume Gel-Loading Pipet Tips

### IsoTip<sup>™</sup> Filtered Pipet Tips

- IsoTip filtered pipet tips feature an inert, hydrophobic barrier that prevents aerosolized contaminants from coming in contact with pipettor shafts
- Ideal for applications where avoiding cross contamination is critical, such as DNA amplification and radioisotope handling
- Packaged sterile
- Certified RNase-/DNase-free and nonpyrogenic
- The IsoTip plus tips (Cat. No. 4810) are designed for use with 2 to 20  $\mu$ L, 10 to100  $\mu$ L, and 20 to 200  $\mu$ L pipettors, eliminating the need to stock three different filter tips
- A Pipet Tip Compatibility Guide can be requested or downloaded from the Corning website.

### IsoTip Filtered Pipet Tips Ordering Information

Cat. No.	Volume Range (μL)	Precise Fit	Tips/ Rack	Racks/ Cs	Tips/ Cs
4801	0.1-2.0	Gilson® and other popular ultra-micropipettors	96	10	960
4807	0.2-10	Gilson and other popular ultra-micropipettors	96	10	960
4808	0.5-10	Eppendorf <sup>®</sup> and other popular ultra-micropipettors	96	10	960
4821	1-30	All popular research-grade pipettors	96	10	960
4823	1-200	All popular research-grade pipettors	96	10	960
4810	1-200	All popular research-grade pipettors	96	10	960
4809	100-1,000	All popular research-grade pipettors	100	10	1,000

### 1 to 200 µL Gel-Loading Pipet Tips

- Corning<sup>®</sup> gel-loading pipet tips feature a capillary end that allows easy access into vertical and horizontal electrophoresis gels
- Total capacity of 200 μL
- Certified RNase-/DNase-free and nonpyrogenic
- Tips are 83 mm in length

### 1 to 200 µL Gel-Loading Pipet Tips Ordering Information

Cat. No.	Tip Shape	End Thickness (mm)	Sterile	Tips/ Rack	Racks/ Cs	Tips/ Cs
4853	Round	0.5	No	200	2	400
4854	Flat	0.4	No	200	2	400
4884	Flat	0.2	No	200	2	400

### **Microvolume Gel-Loading Pipet Tips**

- Corning microvolume gel-loading tips feature a capillary end for gel-loading and are designed for use with Gilson and other popular ultra-micropipettors
- Working volume of 0.2 to 10 μL
- Certified RNase-/DNase-free and nonpyrogenic

#### Microvolume Gel-Loading Pipet Tips Ordering Information

Cat. No.	Tip Shape	End Thickness (mm)	Sterile	Tips/ Rack	Racks/ Cs	Tips/ Cs
4815	Flat	0.2	No	200	2	400



**Microvolume Pipet Tips** 

### **Microvolume Pipet Tips**

- ) Microvolume tips provide accurate, reliable performance in the 0.1-10  $\mu L$  range for major brand ultra-micropipettors
- All racked tips are certified RNase-/DNase-free and nonpyrogenic

#### Microvolume Pipet Tips Ordering Information

Cat. No.	Volume Range (µL)	Fit	Sterile	Qty/Pk	Tips/ Cs
4826	0.1-10	Gilson <sup>®</sup> and other popular ultra-micropipettors	No	96/rack	960
4894	0.1-10	Gilson and other popular ultra-micropipettors	Yes	96/rack	960
4840	0.1-10	Gilson and other popular ultra-micropipettors	No	1,000/bag	10,000
4830	0.5-10	Eppendorf <sup>®</sup> and other popular ultra-micropipettors	Yes	96/rack	960
4834	0.5-10	Eppendorf and other popular ultra-micropipettors	No	96/rack	960
4901	0.5-10	Eppendorf and other popular ultra-micropipettors	No	1,000/bag	10,000

# **Reagent Reservoirs**



**4870 and 4871** 50 mL Reagent Reservoir



**4872 and 4873** 100 mL Reagent Reservoir

Costar® Reagent Reservoirs are ideal for repetitively filling multichannel pipettors

- Manufactured from modified polystyrene
- Sterile
- Disposable

### **Reagent Reservoirs Ordering Information**

Cat No.	Volume (mL)	Color	Qty/Pk	Qty/Cs
4870	50	Natural	5/bag	200
4871	50	Natural	1/bag	100
4872	100	White	5/bag	200
4873	100	White	1/bag	100

# Transtar-96<sup>®</sup> Well Liquid Transfer System



Transtar-96 System



Transtar Disposable Cartridge

- The Costar Transtar-96 System is a portable, autoclavable liquid handling device for use with 96 well plates
- A sterile 96 tip disposable cartridge, which loads into the Transtar system, enables liquids to be aspirated, transferred and dispensed over a volume range of 25 to 200  $\mu$ L in 5  $\mu$ L increments
- The Transtar-96 System is ideal for changing cell culture media and screening monoclonal antibodies
- ) Transtar-96 System accuracy is rated at  $\pm 5\%$  at all volume levels

### Transtar-96 Well Liquid Transfer System Ordering Information

Cat. No.	Description	Sterile	Qty/Pk	Qty/Cs
7605	Transtar-96, adjustable-volume pipettor	N/A	1	1
7606	Transtar elevator	N/A	1	1
7610	Transtar disposable cartridges	Yes	1	24
4876	Transtar disposable reservoir liner, open	Yes	1	100
4877	Transtar disposable reservoir liner, 12-channel	Yes	1	100
4878	Transtar disposable reservoir liner, 8-channel	Yes	1	100

# Aspirator



Aspirator

The Costar® aspirator is an aspirating device for safe liquid removal/disposal from a variety of laboratory vessels using standard disposable pipet tips

### Aspirator Ordering Information

Cat. No.	Description
4930	Aspirator device (includes hand piece, grommet for accessory attachment, and single-channel adapter for use with disposable pipet tips)
4931	8-channel adapter for use with disposable pipet tips

# Vacuum Filters

Corning offers a variety of filter systems, membranes, pore sizes, and materials. For help in selecting the best filter combination for your research, please refer to the Technical Appendix for *Selecting the Best Filter for Your Application* on page 117.

### 115 mL Vacuum Filters

- ▶ 60 mm diameter membrane
- Low center of gravity and wide base for stability
- > Separate pour spout to remove filtered sample which minimizes contamination
- Individually packaged, sterile, certified nonpyrogenic

### 115 mL Vacuum Filters Ordering Information

Cat. No.	Membrane	Volume (mL)	Pore Size (µm)	Qty/Cs
430944	CA	115	0.22	24
430945	CA	115	0.45	24
430945	CA	115	0.45	

Vacuum Filter



Tube Top Vacuum Filter

CA = Cellulose Acetate

### 150 mL Tube Top Vacuum Filters

- ▶ 50 mm diameter membrane
- Minimizes unnecessary transfers by filtering directly into 50 mL centrifuge tube
- Includes two centrifuge tube stands with each case
- Each polypropylene centrifuge tube is supplied with an individually wrapped cap for storage
- Individually packaged, sterile, certified nonpyrogenic

### 150 mL Tube Top Vacuum Filters Ordering Information

Cat. No.	Membrane	Funnel Size/ Tube Size (mL)	Pore Size (µm)	Qty/Cs
430314	CA	150/50	0.45	12
430320	CA	150/50	0.22	12

CA = Cellulose Acetate



Vacuum Filter Systems

### **Vacuum Filter Systems**

- Four sizes: 150 mL; 250 mL, 500 mL, and 1 L
- Adapters are color coded by membrane type for easy product identification
- Angled hose connector simplifies vacuum line attachment
- Receiver bottles feature easy grip sides for improved handling
- Individually packaged, sterile, certified nonpyrogenic
- Caps for receiver bottles are sterile and individually packaged
- Extra plastic storage bottles are available, see page 109

### Vacuum Filter Systems Ordering Information

Cat. No.	Membrane	Funnel/Bottle Volume (mL)	Pore Size (µm)	Color-Coded Adapter	Qty/Cs
150 mL Cap	acity, 50 mm Diam	eter Membrane			
431153	PES	150/150	0.22	Yellow	12
431154	CA	150/150	0.22	Orange	12
431155	CA	150/150	0.45	Orange	12
250 mL Cap	acity, 50 mm Diam	eter Membrane			
430756	CN	250/250	0.2	Blue	12
430767	CA	250/250	0.22	Orange	12
430768	CA	250/250	0.45	Orange	12
430771	NY	250/250	0.2	Red	12
431096	PES	250/250	0.22	Yellow	12
500 mL Cap	acity, 70 mm Diam	eter Membrane			
430758	CN	500/500	0.2	Blue	12
430769	CA	500/500	0.22	Orange	12
430770	CA	500/500	0.45	Orange	12
430773	NY	500/500	0.2	Red	12
431097	PES	500/500	0.22	Yellow	12
1,000 mL C	apacity, 90 mm Dia	meter Membrane			
430186	CN	1,000/1,000	0.2	Blue	12
430515	NY	1,000/1,000	0.2	Red	12
430516	CA	1,000/1,000	0.45	Orange	12
430517	CA	1,000/1,000	0.22	Orange	12
431098	PES	1,000/1,000	0.22	Yellow	12
431205*	CA	500*/1,000	0.22	Orange	12
431206*	CA	500*/1,000	0.45	Orange	12
				-	

\*500 mL Funnel with 70 mm membrane.

PES = Polyethersulfone, CA = Cellulose Acetate, CN = Cellulose Nitrate, NY = Nylon.



Bottle Top Vacuum Filters

### **Bottle Top Vacuum Filters**

- Available in 33 mm and 45 mm neck sizes to fit most glass and plastic media storage bottles
- ▶ 45 mm neck sizes fit on Corning<sup>®</sup> plastic storage bottles, see page 109
- Adaptors are color coded by membrane type
- Individually packaged, sterile and certified nonpyrogenic

### **Bottle Top Vacuum Filters Ordering Information**

Cat. No.	Membrane	Volume (mL)	Neck Size (mm)	Pore Size (µm)	Color-Coded Adapter	Qty/Cs
150 mL Cat	pacity, 50 mm Dia	meter Membra	ne			
430624	CA	150	33	0.22	Orange	48
430625	CA	150	33	0.45	Orange	48
430626	CA	150	45	0.22	Orange	48
430627	CA	150	45	0.45	Orange	48
431160	PES	150	33	0.22	Yellow	48
431161	PES	150	45	0.22	Yellow	48
500 mL Caț	pacity, 70 mm Dia	meter Membra	me			
430049	NY	500	45	0.2	Red	12
430512	CA	500	33	0.45	Orange	12
430513	CA	500	45	0.22	Orange	12
430514	CA	500	45	0.45	Orange	12
430521	CA	500	33	0.22	Orange	12
431117	PES	500	33	0.22	Yellow	12
431118	PES	500	45	0.22	Yellow	12
1,000 mL C	apacity, 90 mm D	)iameter Memb	rane			
430015	CA	1,000	45	0.22	Orange	12
431174	PES	1,000	45	0.22	Yellow	12

PES = Polyethersulfone, CA = Cellulose Acetate, CN = Cellulose Nitrate, NY = Nylon.

# Syringe Filters



### **µStar<sup>®</sup> Syringe Filters**

- Costar<sup>®</sup> µStar syringe filters have a bidirectional flow pattern that eliminates the priming and air lock effects of conventional syringe tip filters
- Cellulose acetate membrane in a polyvinyl chloride (PVC) housing
- Utilizes all of the membrane surface area for a working volume up to 100 mL while minimizing fluid retention to less than 30 µL with an air purge
- Integrity tested with a maximum operating pressure of 100 psi, the µStar filter, a Class II medical device, is designed for sterilization and clarification of aqueous solutions including: media additives, serum, antibiotics, biological fluids, radioactive tracers, and virus suspensions
- Sterile, certified nonpyrogenic

### µStar Syringe Filters Ordering Information

Cat. No.	Membrane	Color	Pore Size (µm)	Qty/Cs
8110	CA	Blue	0.22	50
8112	CA	Clear	0.45	50

CA = Cellulose Acetate



Syringe Filters

### **Syringe Filters**

- Corning<sup>®</sup> syringe filters are 100% integrity tested, are certified nonpyrogenic and noncytotoxic, and are manufactured in accordance with ISO 9002 standards
- A variety of membranes are available to meet your needs: PES for low protein binding and faster flow rates; surfactant-free cellulose acetate (SFCA) for the lowest protein binding; PTFE for chemical resistance; and regenerated cellulose (RC), the best choice for DMSO compatibility

### Syringe Filters Ordering Information

Cat. No.	Diameter (mm)	Pore Size (µm)	Membrane Material	Housing Material	Sterile	Inlet/ Outlet	Packaging	Qty/ Cs
431212	4	0.2	RC	PP	Yes	LL/LS	Ind	50
431215	15	0.2	RC	PP	Yes	LL/LS	Ind	50
431218	26	0.2	SFCA-PF	AC	Yes	LL/LS	Ind	50
431219	26	0.2	SFCA	AC	Yes	LL/LS	Ind	50
431220	26	0.45	SFCA	AC	Yes	LL/LS	Ind	50
431221	26	0.8	SFCA	AC	Yes	LL/LS	Ind	50
431222	25	0.2	RC	PP	Yes	LL/LS	Ind	50
431224	25	0.2	NY	PP	Yes	LL/LS	Ind	50
431225	25	0.45	NY	PP	Yes	LL/LS	Ind	50
431227*	50	0.2	PTFE	PP	Yes	HB/HB	Ind	12
431229	26	0.2	PES	AC	Yes	LL/LS	Ind	50
431231	25	0.45	PTFE	PP	No	LL/LS	Bulk	50

PP = Polypropylene, AC = Acrylic Copolymer, LL = Luer Lock/Female, LS = Luer Slip/Male, HB = Hose Barb, NY = Nylon, PES = Polyethersulfone, PTFE = Teflon, RC = Regenerated Cellulose, SFCA = Surfactant Free Cellulose Acetate, SFCA-PF = Surfactant Free Cellulose Acetate with Prefilter.

\*Recommended as in-line air filter.

# Spin-X<sup>®</sup> Centrifuge Tube Filters



Spin-X Centrifuge Tube Filters

- Costar<sup>®</sup> Spin-X centrifuge tube filters consist of a membrane-containing filter unit within a centrifuge tube.
- Uses:
  - Removing bacteria, cells and particles from liquids
  - HPLC sample preparation
  - DNA removal from agarose or acrylamide gels. Maximum RCF (Relative Centrifugal Force [x g]) is 16,000

#### Spin-X Centrifuge Tube Filters Ordering Information

Cat. No.	Membrane Material	Working Volume (µL)	Pore Size (µm)	Sterile	Tube Size (mL)	Qty/Cs
8160	CA	500	0.22	Yes	2.0	96
8161	CA	500	0.22	No	2.0	100
8162	CA	500	0.45	Yes	2.0	96
8163	CA	500	0.45	No	2.0	100
8169	NY	500	0.22	No	2.0	200
8170	NY	500	0.45	No	2.0	200

CA = Cellulose Acetate, NY = Nylon.

# **Storage Bottles**



- Disposable polystyrene bottles for storage of media, buffers and other aqueous solutionsTwo styles:
- Low profile, easy grip style has sides that facilitate handling
- Traditional style has smooth sides
- Plug seal caps (45 mm) provide an airtight seal and help minimize the risk of contamination.
- Bottles can be used with Corning<sup>®</sup> Vacuum Filter Systems
- Sterile, certified nonpyrogenic

### Corning® Easy Grip Style Storage Bottles Ordering Information

Cat. No.	Volume (mL)	Neck Size (mm)	Qty/Pk	Qty/Cs
431175	150	45	2	24
430281	250	45	2	24
430282	500	45	2	24
430518	1,000	45	2	24

### Costar® Traditional Style Storage Bottles Ordering Information

Cat. No.	Volume (mL)	Neck Size (mm)	Qty/Pk	Qty/Cs
8388	125	45	1	24
8390	250	45	1	12
8393	500	45	1	12
8396	1,000	45	1	12

# Containers



- Flexible polypropylene bottom with snap-on polyethylene lid serves as a beaker or storage container.
- Graduated in both milliliters and ounces
- Certified nonpyrogenic

#### **Containers Ordering Information**

Cat. No.	Description	Sterile	Capacity (mL)	Qty/Pk	Qty/Cs
430179	Container and Lid	Yes	250	1	100
430180	Container Only	Yes	250	20	500
430181	Lid Only	Yes	n/a	20	500

# Cylinder



- Corning optically clear polystyrene graduated cylinder is designed for sterile, accurate dispensing of culture media or other biological fluids
- A polyethylene dust cover is included

#### **Cylinder Ordering Information**

Cat. No.	Capacity (mL)	Graduation (mL)	Sterile	Qty/Pk	Qty/Cs
430182	100	1	Yes	1	50

# Erlenmeyer Flasks



1L Erlenmeyer Flask

### Shaker Flask Application Tip

Corning recommends starting with a shaking rate of 75-125 RPM (orbital shaker) and a medium volume of 30-40% of the nominal flask capacity.



431255 2L Erlenmeyer Flask



**431252** 3L Fernbach Culture Flask

### **Polycarbonate Erlenmeyer Flasks**

- Made from optically clear polycarbonate
- Ideal for shaker culture applications
- Two-position polypropylene plug seal caps can be open for gas exchange or closed for liquid-tight seal
- Vent caps available for applications requiring sterile gas exchange
- Sterilized by gamma radiation
- Certified nonpyrogenic







Breathable two-position plug seal caps feature one-pieceVerlinerless construction with a flexible plug for a gas- andmeliquid-tight seal. In addition, the unique breathable capcordesign allows use in either an open or closed mode.mi

Vent caps contain a 0.2 µm nonwettable membrane sealed to the cap, providing consistent, sterile gas exchange while minimizing the risk of contamination.

### Polycarbonate Erlenmeyer Flasks Ordering Information

Cat. No.	Capacity (mL)	Graduation (mL)	Neck Diameter (mm)	Cap Style	Qty/Pk	Qty/Cs
430421	125	25	26	Plug Seal	1	50
431143	125	25	26	Vent Cap	1	50
430183	250	25	31	Plug Seal	1	50
431144	250	25	31	Vent Cap	1	50
430422	500	50	43	Plug Seal	1	25
431145	500	50	43	Vent Cap	1	25
431146	1,000	50	43	Plug Seal	1	25
431147	1,000	50	43	Vent Cap	1	25

### Polycarbonate 2L and 3L Flasks

- Made from optically clear polycarbonate
- Ideal for shaker and suspension culture applications
- > Flasks are available with or without baffled bottoms
- Vent caps are available and feature a hydrophobic membrane for applications requiring sterile gas exchange
- Sterilized by gamma radiation
- Certified nonpyrogenic

### Polycarbonate 2L and 3L Flasks Ordering Information

Cat. No.	Description	Sterile	Qty/Cs
431255	Erlenmeyer Flask, 2L, Polycarbonate	Yes	6
431256	Erlenmeyer Flask, 2L, Polycarbonate, Baffled Bottom	Yes	6
431252	Fernbach Culture Flask, 3L, Polycarbonate	Yes	4
431253	Fernbach Culture Flask, 3L, Polycarbonate, Baffled Bottom	Yes	4
431339	Cap, Vented, 48 mm for 2L Flask	Yes	24
431340	Cap, Vented, 70 mm for 3L Flask	Yes	24

# Spatulas



Spatulas



Microspatulas

- Corning<sup>®</sup> spatulas are designed to save researcher's time and to provide them with contamination-free samples
- Each spatula is individually packaged, certified RNase-/DNase-free, nonpyrogenic, antistatic and sterile
- They are specifically targeted toward researchers interested in eliminating the recycling and resterilizing necessary with reusable spatulas
- > Spatulas are available in five different configurations
- Microspatulas are available in 2 configurations

### Spatulas Ordering Information

*	6	
Cat. No.	Description	Qty/Cs
3003	Spatula, Tapered Blade/Spoon	100
3004	Spatula, Small Spoon/Spoon	100
3005	Spatula, Round End/Spoon	100
3006	Spatula, V-Scoop/Spoon	100
3007	Spatula, Flat End/Spoon	100
3012	Microspatula, Tapered End/Scoop	50
3013	Microspatula, Rounded End/Scoop	50

# **Centrifuge Tubes**

### 15 mL Centrifuge Tubes

- Corning 15 mL centrifuge tubes feature black printed graduations and a large white marking spot
- Available with your choice of cap styles; the original plug seal or flat cap
- Available in racks or bulk packed in ziplock, resealable sleeves
- > Sterile, certified nonpyrogenic, and RNase-/DNase-free
- Foam racks also available separately

### **Centrifuge Tubes Ordering Information**

Cat. No.	Material	Cap Style	Max. RCF	Qty/Pk	Qty/Cs
430053	PET	Plug Seal	3,600	25/Sleeve	500
430055	PET	Plug Seal	3,600	50/Rack	500
430052	PP	Plug Seal	8,400	50/Rack	500
430766	PP	Plug Seal	8,400	25/Sleeve	500
430790	PP	Flat Top	8,400	50/Rack	500
430791	PP	Flat Top	8,400	25/Sleeve	500
431355	Foam Cent	rifuge Tube Rack, 15	mL		20

PP = Polypropylene, PET = Polyethylene Terephthalate, RCF = Relative Centrifugal Force (x g).



15 mL Centrifuge Tube



50 mL Centrifuge Tube

### **50 mL Centrifuge Tubes**

- Corning<sup>®</sup> 50 mL centrifuge tubes feature black printed graduations and a large white marking spot
- Available with your choice of cap styles; the original plug seal or flat cap
- Available in racks or bulk packed in ziplock, resealable sleeves
- > Sterile, certified nonpyrogenic, and RNase-/DNase-free
- Foam racks also available separately

### 50 mL Centrifuge Tubes Ordering Information

Cat. No.	Material	Cap Style	Max. RCF	Qty/Pk	Qty/Cs
430290	PP	Plug Seal	9,400	25/Rack	500
430291	PP	Plug Seal	9,400	25/Sleeve	500
430304	PET	Plug Seal	3,600	25/Rack	500
430828	PP	Flat Top	9,400	25/Rack	500
430829	PP	Flat Top	9,400	25/Sleeve	500
4558	PP	CentriStar™ Cap	15,500	25/Universal Rack*	300
4365	Foam Cer	ntrifuge Tube Rack, 50	mL	_	20

PP = Polypropylene, PET = Polyethylene Terephthalate, RCF = Relative Centrifugal Force (x g).

\*New innovative universal rack can hold 50 mL and 15 mL tubes securely, allowing researchers to work with and store both size tubes in the same rack, saving bench and storage space.

### Self-Standing 50 mL Centrifuge Tubes

- All Corning 50 mL centrifuge tubes feature black printed graduations and a large white marking spot
- Available with your choice of cap styles; the original plug seal or flat cap
- Tubes are bulk packed in ziplock, resealable sleeves
- > Sterile, certified nonpyrogenic, and RNase-/DNase-free

### Self-Standing 50 mL Centrifuge Tubes Ordering Information

Cat. No.	Material	Cap Style	Max. RCF	Qty/Pk	Qty/Cs
430897	PP	Plug Seal	3,000	25	500
430921	PP	Flat Top	3,000	25	500

PP = Polypropylene, RCF = Relative Centrifugal Force (x g).

### 250 mL and 500 mL Centrifuge Tubes and Support Cushions

- Corning 250 mL and 500 mL polypropylene tubes are ideal for applications requiring large-volume centrifugation
- Each case of tubes contains a rack to facilitate handling
- Support cushions must be used with this product unless the rotor has appropriately shaped V-bottom holders
- Tubes are sterile and certified nonpyrogenic

#### 250 mL and 500 mL Centrifuge Tubes Ordering Information

Cat. No.	Description	Material	Cap Style	Max RCF	Qty/Pk	Qty/Cs
430776	250 mL Tube	PP	Plug	6000	6	102
430236	250 mL Support Cushion	PEI	n/a	n/a	n/a	6
431123	500 mL Tube	PP	Plug	6000	6	36
431124	500 mL Support Cushion	PEI	n/a	n/a	n/a	6

PP = Polypropylene, PEI = Polyetherimide, RCF = Relative Centrifugal Force (x g).



Self Standing 50 mL Centrifuge Tube



500 and 250 mL Centrifuge Tubes

# Microcentrifuge Tubes

Corning offers two styles of microcentrifuge tubes: traditional snap cap tubes for quick access or screw cap tubes for greater sealing security.

### **Snap Cap Polypropylene Microcentrifuge Tubes**

- Costar® microcentrifuge tubes are certified RNase-/DNase-free
- Supplied nonsterile and are autoclavable
- > External graduations and frosted writing spot for easy sample identification
- Positive seal design allows for repeated opening and closing
- Flat cap surface for convenient labeling
- Withstands a maximum RCF of 17,000 x g
- Costar low binding microcentrifuge tubes feature a bonded polymer technology that reduces protein and nucleic acid binding, resulting in better sample recovery

### Snap Cap Polypropylene Microcentrifuge Tubes Ordering Information

Cat. No.	Volume (mL)	Color	Qty/Pk	Qty/Cs
Snap Cap Mi	icrocentrifuge Tubes			
3208	0.65	Natural	500	1,000
3209*	0.65	Rainbow*	200	1,000
3620	1.7	Natural	500	500
3621	1.7	Natural	500	5,000
3622*	1.7	Rainbow*	100	500
3213	2.0	Natural	500	1,000
Low Binding	Snap Cap Microcentrifug	ge Tubes Ordering Informa	ition	
3206	0.65	Natural	500	500
3207	1.7	Natural	250	250

\*Rainbow pack includes one bag each of blue, green, yellow, red, and orange tubes.

### Screw Cap Polypropylene Microcentrifuge Tubes

- Corning<sup>®</sup> polypropylene microcentrifuge tubes feature screw caps that provide a tight secure seal
- Choice of attached cap with silicone O-ring or unattached rim seal cap
- All tubes have a large white marking spot.
- Withstands a maximum RCF of 13,000 x g
- Sterile

Microcentrifuge Tubes



 Attached loop cap allows for optimum one-handed convenience. Silicone O-ring gasket provides a snug seal, safeguarding samples against leakage.



• Easy-to-use unattached rim seal cap design twists on or off in a single turn.

#### Screw Cap Polypropylene Microcentrifuge Tubes Ordering Information

Cat. No.	Volume (mL)	Cap Style	O-ring	Self Standing	Qty/Cs
430909	1.5	Attached	Yes	No	500
430915	2.0	Attached	Yes	Yes	500
430917	2.0	Unattached	No	Yes	500



Micrcoentrifuge Tubes

# **Cryogenic Vials and Accessories**



Internal Thread Cryogenic Vial

- Color-coded polypropylene cap inserts simplify vial identification.
   Available in variety packs of white, blue, green, red, and yellow. Silicone washers or rubber
- O-rings provide a secure seal. Easy-to-read black graduations
- for partial volumes Self-standing base, self-locking skirt

### **External Thread**

- Plug Seal Cap Sure-grip plug seal screw cap
- Inner cap ring
- assures a tight seal.



External Thread Cryogenic Vials

### **Cryogenic Vial** Safety Tip

Appropriate safety equipment (gloves, face shields, biological safety cabinets, hoods, etc.) should always be used to protect personnel when removing vials or ampules from cryogenic storage systems.

## **External Thread Cryogenic Vials**

Manufactured from polypropylene to withstand temperatures down to -196°C

H

Corning offers three styles of cryogenic vials as well as storage racks and boxes.

- Larger marking spot
- Black graduations
- Certified RNase-/DNase-free
- Vials have a silicone washer for a secure seal.
- Vials may be color coded with inserts (see page 116)
- > Self-standing vials have a special base design allowing them to be locked into cryogenic rack and tray (Cat. No. 430525 or 431131) for single-handed manipulation
- Sterilized by gamma radiation
- Certified nonpyrogenic
- Free foam rack with each case

### **External Thread Cryogenic Vials Ordering Information**

Cat. No.	Capacity (mL)	Style	Self-Standing	Qty/Pk	Qty/Cs
430658	1.2	Conical Bottom	Yes	50	500
430659	2.0	Round Bottom	Yes	50	500
430661	2.0	Round Bottom	No	50	500
430662	4.0	Round Bottom	Yes	50	500
430663	5.0	Round Bottom	Yes	50	500

Warning! Do not use cryogenic vials for storage in the liquid phase of liquid nitrogen. Only store vials in the vapor phase above the liquified gas. Always use appropriate safety equipment when removing vials from cryogenic storage.



Internal Thread Cryogenic Vials

### **Internal Thread Cryogenic Vials**

Manufactured from polypropylene to withstand temperatures down to -196°C

- Larger marking spot
- Black graduations
- Certified RNase-/DNase-free
- Vials have a silicone washer or rubber O-ring for a secure seal
- Vials may be color coded with inserts (see page 116)
- Self-standing vials have a special base design allowing them to be locked into cryogenic rack and tray (Cat. No. 430525 or 431131) for single-handed manipulation
- Sterilized by gamma radiation
- Certified nonpyrogenic
- Free foam rack with each case

### Internal Thread Cryogenic Vials Ordering Information

Capacity Cat. No.	(mL)	Style	Self- Standing	Seal Type	Qty/Pk	Qty/Cs
430487	1.2	Conical Bottom	Yes	Washer	50	500
2012	1.2	Conical Bottom	Yes	O-Ring	50	250
430488	2.0	Round Bottom	Yes	Washer	50	500
430489	2.0	Round Bottom	No	Washer	50	500
2027	2.0	Round Bottom	No	O-Ring	50	250
2028	2.0	Round Bottom	Yes	O-Ring	50	250
430490	4.0	Round Bottom	No	Washer	50	500
430491	4.0	Round Bottom	Yes	Washer	50	500
430492	5.0	Round Bottom	No	Washer	50	500
430656	5.0	Round Bottom	Yes	Washer	50	500
2051	5.0	Round Bottom	No	O-Ring	50	250

Warning! Do not use cryogenic vials for storage in the liquid phase of liquid nitrogen. Only store vials in the vapor phase above the liquified gas. Always use appropriate safety equipment when removing vials from cryogenic storage.

## **External Thread Cryogenic Vials with Plug Seal Cap**

- Manufactured from polypropylene to withstand temperatures down to -196°C
- Vials feature an external thread with a traditional plug seal cap design for a secure seal
- Cap does not accept color-coded inserts
- Sterilized by gamma radiation
- Certified nonpyrogenic

### External Thread Cryogenic Vials with Plug Seal Cap Ordering Information

Cat. No.	Capacity (mL)	Style	Self-Standing	Qty/Pk	Qty/Cs
430289	2.0	Round Bottom	No	50	500

Warning! Do not use cryogenic vials for storage in the liquid phase of liquid nitrogen. Only store vials in the vapor phase above the liquified gas. Always use appropriate safety equipment when removing vials from cryogenic storage.



External Thread Cryogenic Vials with Plug Seal Cap



Cap Inserts

### **Cap Inserts for Cryogenic Vials**

- Cap inserts provide color coding for easy sample identification
- Inserts are packaged in resealable bags
- Nonsterile
- Cap inserts fit all Corning<sup>®</sup> cryogenic vials except Cat. No. 430289

### Cryogenic Vials Cap Inserts Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
430499	Assorted colors, polypropylene cap inserts: 100 each of white, blue, red, green, and yellow	50	500
2015	White polypropylene cap inserts	50	500
2016	Blue polypropylene cap inserts	50	500
2017	Red polypropylene cap inserts	50	500
2018	Green polypropylene cap inserts	50	500
2019	Yellow polypropylene cap inserts	50	500

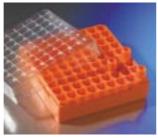
### **Cryogenic Vial Racks and Storage Boxes**

- Reusable racks are designed for use with most cryogenic vials
- Cat. No. 430525 has a locking feature for use with all Corning self-standing vials

### Cryogenic Vial Racks and Storage Boxes Ordering Information

Cat. No.	Description	Qty/Pk	Qty/Cs
430525	Polycarbonate rack and tray, holds 30 vials; self-locking design in ice/water bath	1	1
430526	Polycarbonate rack only, holds 30 vials; self-locking design	1	1
431131	Reusable orange polypropylene vial rack, holds 50 vials; self-locking design	2	2
431119	81 count (9 x 9 array) Cryogenic Box, for 1-2 mL vials	5	10
431120	81 count (9 x 9 array) Cryogenic Box, for 4-5 mL vials	5	10
431121*	100 count (10 x 10 array) Cryogenic Box, for 1-2 mL vials	5	10

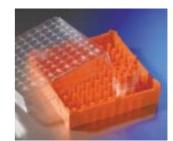
\*431121 accepts internally threaded cryogenic vials only.



431119 Cryogenic Storage Box



431120 Cryogenic Storage Box



431121 Cryogenic Storage Box



Cryogenic Vial Racks

# **Technical Appendix**

## SELECTING THE BEST FILTER FOR YOUR **APPLICATION**

Choosing a filter does not have to be complicated - Corning has simplified the process. Just follow these four easy steps:

Step 1: Match your application with the best pore size.

Step 2: Select the best membrane and housing material for your application.

Step 3: Select the correct membrane diameter to optimize flow rate and throughput.

Step 4: Choose the best filter design for your application.

### Step 1: Match Your Application with the Best Pore Size

The pore size is usually determined by your application or objective.

- Routine laboratory sterilization of most media, buffers, biological fluids and gases is usually done with 0.2 or 0.22 µm pore filter membranes
- Clarification and prefiltration of solutions and solvents is best accomplished with 0.45 µm or larger filter membranes
- Prefiltration to improve filter performance can also be accomplished by the use of glass fiber prefilters sold separately.

Use Table 1 to match your applications with a recommended membrane and pore size.

### Step 2: Select the Best Membrane and Housing **Material for Your Application**

Your filter unit must be fully compatible with the chemical characteristics of your sample.

- Some filter membranes contain nontoxic wetting agents that may interfere with some applications
- Other membranes may bind proteins or other macromolecules leading to premature filter clogging or loss of valuable samples

Therefore, it is very important to understand their characteristics and the potential effects filter membranes can have on the solutions they contact. The following four graphs (Figure 1)



### Figure 1. Important Performance Characteristics of **Corning® Filter Membranes**

compare the flow rates, levels of extractable materials, and relative amounts of protein binding of four of the most popular membranes used in Corning® filters. Combining this with the information from Tables 2 and 3 (page 118) will help you choose the best Corning membranes for your applications.

### **Corning Filter Membrane Materials**

Polyethersulfone (PES) membranes are the best for filtering cell culture media. PES has very low protein binding and extractables. PES also demonstrates faster flow rates than cellulose or nylon membranes.

SFCA\*, Glass Fiber Prefilters

Table 1. Selecting the Fore Size		
Application	Pore Size (µm)	Membrane Availability
Sterilization and Ultracleaning of Aqueous Solutions	0.20 to 0.22	All Membranes except Teflon™
Ultracleaning of Solvents (HPLC)	0.20 to 0.22	RC*, Teflon, Nylon
Clarification of Aqueous Solutions	0.45	All Membranes except Teflon
Clarification of Solvents (HPLC)	0.45	RC, Teflon, Nylon

0.8

### Table 1. Selecting the Pore Size

Coarse Particle Removal

\*RC = Regenerated Cellulose, SFCA = Surfactant-Free Cellulose Acetate.

PES = Polyethersulfone, CA = Cellulose Acetate, CN = Cellulose Nitrate, NY = Nylor

**Cellulose acetate** (CA) membranes have a very low binding affinity for most macromolecules and are especially recommended for applications requiring low protein binding, such as filtering culture media containing sera. However, both cellulose acetate and cellulose nitrate membranes are naturally hydrophobic and have small amounts (less than 1%) of nontoxic wetting agents added during manufacture to ensure proper wetting of the membrane. If desired, these agents can be easily removed prior to use by filtering a small amount of warm purified water through the membrane or filter unit. Surfactant free cellulose acetate membranes, with very low levels of extractables, are available on some Corning<sup>®</sup> syringe filters.

**Cellulose nitrate** (CN) membranes are recommended for filtering solutions where protein binding is not a concern. They are recommended for use in general laboratory applications such as buffer filtration. Corning's cellulose nitrate membranes are Triton X-100<sup>®</sup>-free and noncytotoxic.

**Nylon** membranes are naturally hydrophilic and are recommended for applications requiring very low extractables since they do not contain any wetting agents, detergents or surfactants. Their greater chemical resistance makes them better for filtering more aggressive solutions, such as alcohols and DMSO. However, like cellulose nitrate membranes, they may bind greater amounts of proteins and other macromolecules than do the cellulose acetate or PES membranes. They are recommended for filtering protein-free culture media.

**Regenerated cellulose** (RC) membranes are hydrophilic and have very good chemical resistance to solvents, including DMSO. They are used to ultraclean and de-gas solvents and mobile phases used in HPLC applications.

**Teflon**<sup>™</sup> (PTFE; polytetrafluoroethylene) membranes are naturally and permanently hydrophobic. They are ideal for filtering gases, including humidified air. The extreme chemical resistance of Teflon membranes makes them very useful for filtering solvents or other aggressive chemicals for which other membranes are unsuitable. Because of their hydrophobicity, Teflon membranes must be prewetted with a solvent, such as ethanol, before aqueous solutions can be filtered.

**Glass fiber filters** are used as depth filters for prefiltering solutions. They have very high particle loading capacity and are ideal for prefiltering dirty solutions and difficult to filter biological fluids such as sera.

### Table 2. Characteristics of Corning Filter Membranes

	Cellulose Nitrate	Cellulose Acetate	Nylon	Polyether- Sulfone	Regenerated Cellulose	Teflon (PTFE)
Flow rates for medium with 10% serum	Good	Very Good	Poor	Best	NA	NA
Wetting Agents	Yes	Yes	No, naturally hydrophilic	No	Yes	Does not wet
Protein Binding	Very high	Very low	Low to moderate	Very low	Low	NA
DNA Binding	High	Very low	Very high	Very low	Low	NA
Chemical Resistance	Low	Low	Moderate to high	Low	Very high	Very high

### Table 3. Chemical Resistance Guide for Corning Filters

This information has been developed from a combination of laboratory tests, technical publications, or material suppliers. It is believed to be reliable. Due to conditions outside of Corning's control, such as variability in temperatures, concentrations, duration of exposure and storage conditions, no warranty is given or is to be implied with respect to this information.

		Filter Membranes							Ho	ousing Ma	aterials		
Chemical Class	CN	CA	PC	NY	PES	RC	PTFE	PET	PS	PP	AC	PYR	PVC
Weak Acids	2	2	1	2	3	1	1	1	1	1	2	1	1
Strong Acids	3	2	3	3	3	3	1	3	2	1	3	2	1
Alcohols	3	1	1	1	1	1	1	1	2	1	3	1	1
Aldehydes	2	3	2	2	3	2	1	1	3	1	3	1	3
Aliphatic Amines	3	3	3	1	1	1	1	1	3	1	3	1	2
Aromatic Amines	3	3	3	2	3	1	1	2	3	1	3	1	3
Bases	3	3	3	2	3	2	1	3	1	1	2	2	1
Esters	3	3	2	1	3	1	1	1	3	2	2	1	3
Hydrocarbons	2	2	2	2	3	1	1	1	3	2	2	1	2
Ketones	3	3	2	2	3	1	1	1	3	2	3	1	3

Key: 1 = Recommended, 2 = May be suitable for some applications, a trial run is recommended, 3 = Not recommended, CN = Cellulose Nitrate, CA = Cellulose Acetate, NY = Nylon, PYR = PYREX Glass, PC = Polycarbonate, PES = Polyethersulfone, PET = Polyethylene Terephthalate, RC = Regenerated Cellulose, PS = Polystyrene, PTFE = Polytetrafluoroethylene (Teflon), PP = Polypropylene, PVC = Polyvinylchloride, AC = Acrylic Copolymer.

### **Corning® Filter Housing Materials**

The filter housing materials also must be compatible with the solutions being filtered.

**Polystyrene** (PS) is used in the filter funnels and storage bottles for all of the Corning plastic vacuum filters. This plastic polymer should only be used in filtering and storing nonaggressive aqueous solutions and biological fluids. Refer to Table 3 (page 118) for more chemical compatibility information.

Acrylic copolymer (AC) and Polyvinyl chloride (PVC) are used in some of the Corning syringe filter housings. These plastics should only be used in filtering less aggressive aqueous solutions and biological fluids. Refer to Table 3 for more chemical compatibility information.

**Polypropylene** (PP) is used in the Spin-X<sup>®</sup> centrifuge filters and some of the syringe and disc filter housings. This plastic polymer has very good resistance to many solvents. Refer to Table 3 for more chemical compatibility information.

### **Chemical Compatibility**

The mechanical strength, color, appearance, and dimensional stability of Corning filters are affected to varying degrees by the chemicals with which they come into contact. Specific operating conditions, especially temperature and length of exposure, will also affect their chemical resistance. Table 3 provides basic information on the chemical resistance of Corning filter membranes and housings.

# Step 3: Select the Correct Membrane Diameter to Optimize Flow Rate and Throughput

The third step is selecting a filter that will have enough volume capacity or throughput to process your entire sample quickly and efficiently. This is primarily determined by the effective surface area of the membrane. Table 4 shows the relationship between filter diameter, effective filtration surface area and expected throughput volumes. The lower values are typical of viscous or particle-laden solutions; the higher values are typical of buffers or serum-free medium.

# **Step 4: Choose the Best Filter Design for Your Application**

### **Disposable Plastic Vacuum Filters**

These sterile filters are available in four styles: complete filter/ storage systems, bottle top filters, centrifuge tube top filters, or one-piece filter systems. Four membranes are available to meet all of your filtration needs: cellulose acetate, cellulose nitrate, nylon, or polyethersulfone.

### **Disposable Syringe/Disc Filters**

The smaller conventional Corning syringe disc-type filters (4, 15, 25, and 26 mm diameter) are used with syringes which

### Table 4. Typical Expected Throughput Volumes

Filter Diameter and Description	Area (cm²) Throughput (mL)*	Effective Filter Expected
4 mm syringe/disc	0.07	0.05-3
15 mm syringe/disc	1.7	3-15
µStar <sup>®</sup> syringe filter	3.0	15-100
25 mm syringe/disc	4.8	15-100
26 mm syringe/disc	5.3	15-100
50 mm disc	19.6	100-750
50 mm vacuum system	16.6	100-750
60 mm vacuum system	24.6	200-1,000
70 mm vacuum system	38.5	300-1,500
90 mm vacuum system	58.1	500-2,000

\*These values assume an aqueous solution and a 0.2 µm membrane. Solutions containing sera or other proteinaceous materials will be at the lower end of the range. Use of prefilters may extend the throughput 50 to 100% above the values shown.

serves as both the fluid reservoir and the pressure source. The HPLC certified nonsterile syringe filters are available with nylon, regenerated cellulose or Teflon<sup>®</sup> (PTFE) membranes in polypropylene housing for extra chemical resistance. The sterile tissue culture tested syringe filters are available in PES, regenerated cellulose (ideal for use with DMSO-containing solutions) or surfactant-free cellulose acetate membranes in either polypropylene or acrylic copolymer housings.

The larger 50 mm diameter disc filter has a Teflon (PTFE) membrane and polypropylene housing with hose barb connectors. This product is ideal for filtering aggressive solvents or gases and applications requiring sterile venting of gases. Because they have a hydrophobic (will not pass aqueous solutions) membrane, they are also ideal for protecting vacuum lines and pumps.

### Spin-X<sup>®</sup> Disposable Centrifuge Tube Filters

Costar<sup>®</sup> Spin-X centrifuge tube filters consist of a membranecontaining (either cellulose acetate or nylon) filter unit within a polypropylene centrifuge tube. They filter small sample volumes by centrifugation for bacteria removal, particle removal, HPLC sample preparation, removal of cells from media, and purification of DNA from agarose and polyacrylamide gels. (See Corning Technical Bulletin: *Spin-X Purification of DNA from agarose gels* at **www.corning.com/lifesciences**.)

### Corning Filtr*EX*<sup>™</sup> 96 and 384 Well Filter Plates

Information on Corning Filtr*EX* 96 and 384 well filter plates can be found in the Corning Genomics Selection Guide or on the Corning Life Sciences web site **www.corning.com/lifesciences**.

### Table 5. Corning<sup>®</sup> Filter Designs

Design	Sterile	Filter Diameters (mm)	Available Membrane Materials	Pore Sizes (µm)	Special Features
Syringe Filters	Some	4, 15, 25, and 26,	RC, PES, SFCA, NY, and PTFE	0.2, 0.45, and 0.8	Ideal for small volume pressure filtration
µStar® Syringe Filters	Yes	Not applicable	CA and CN	0.22, 0.45, and 0.8	Ideal for sterilizing aqueous solutions and biological fluids
Disc Filters	Yes	50	PTFE	0.2	Ideal for filtering solvents and gases
Vacuum Filter Storage Systems	Yes	50, 70 and 90	PES, CA, CN, and Nylon	0.2, 0.22, and 0.45	Easy grip bottles for storing filtrate
Bottle Top Vacuum Filters	Yes	50, 70 and 90	PES, CA, CN, and Nylon	0.2, 0.22, and 0.45	2 neck widths to fit most glass bottles
Tube Top Vacuum Filters	Yes	50	CA	0.22 and 0.45	Minimizes unnecessary transfers by filtering into a 50mL centrifuge tube
115 One Piece Vacuum Filters	Yes	60	CA and CN	0.2 and 0.45	Very economical with separate pour spout
Spin-X <sup>®</sup> Centrifuge Filters	Some	7.7	CA and Nylon	0.22 and 0.45	Ideal for purifying DNA from agarose gels
Filtr <i>EX</i> <sup>™</sup> 96 and 384 Well Filter Plates	Some	6.4, 3.2	PVDF, GlassFiber, PES, NC, and UF	0.2, 0.45, 1.2 and others	Clear, opaque, or solvent resistant*

\*Call for specific details; several custom-made products available.

CN = Cellulose Nitrate, CA = Cellulose Acetate, PES = Polyethersulfone, RC = Regenerated Cellulose, PTFE = Polyetrafluoroethylene (Teflon), SFCA = Surfactant-Free Cellulose Acetate.

### CHARACTERISTICS OF CORNING PLASTICWARE

		Polystyrene	Polyethylene (High Density)	Polypropylene	Polycarbonate	Nylon	P.T.F.E. (Teflon®)
Physical Characteristics	Basic Properties	Biologically inert, hard, excellent optical qualities	Biologically inert, high chemical resistance	Biologically inert, high chemical resistance, exceptional toughness	Clear, very tough, inert, high temperature resistance	Tough, heat resistant, machinable, high moisture vapor transmission	Biologically and chemically inert, high resistant slippery surface
	Clarity	Clear	Opaque	Translucent	Clear	Opaque	Opaque
	Autoclave Results	Melts	May distort	Withstands several cycles	Withstands one cycle	OK	ОК
	Heat Distortion Point	147-175°F 64-80°C	250°F 121°C	275°F 135°C	280-290°F 138-143°C	300-356°F 150-180°C	250°F 121°C
	Burning Rate	Slow	Slow	Slow	Self- extinguishing	Self- extinguishing	None
Effects of	Weak Acids	None	None	None	None	None	None
Laboratory Reagents	Strong Acids	Oxidizing acids attack	Oxidizing acids attack	Oxidizing acids attack	May be attacked	Attacked	None
	Weak Alkalies	None	None	None	None	None	None
	Strong Alkalies	None	None	None	Slowly attacked	None	None
	Organic Solvents	Soluble in aromatic chlorinated hydrocarbons	Resistant below 80°C	Resistant below 80°C	Soluble in chlorinated hydrocarbons; partly soluble in aromatics	Resistant	Resistant
Gas Permeability	O <sub>2</sub>	Low	High	High	Very low	Very low	_
of Thin Wall Products <sup>*</sup>	$N_2$	Very low	Low	Low	Very low	Very low	_
11000003	CO <sub>2</sub>	High	Very high	Very high	Low	_	_

Portions of this table courtesy of Modern Plastics Encyclopedia. Most data are from tests by A.S.T.M. methods. Tables show averages or ranges. Many properties vary with manufacturer, formulation, testing laboratory, and the specific operating conditions. \*Obtained from a table which lists gas permeability in CC/100 sq. inches per 24 hrs./mil.

### CHEMICAL COMPATIBILITY OF CORNING PLASTICWARE

	PS	PP	PVC	CA	PC	CN	NY	MCE	PTFE	PET
Acids										
Hydrochloric acid (25%)	G	G	G	Ν	R	R	Ν	0	R	R
Hydrochloric acid (concentrated)	F	G	F	Ν	R	Ν	Ν	Ν	R	0
Nitric acid (concentrated)	Р	Р	Р	Ν	R	Ν	Ν	Ν	0	Ν
Nitric acid (25%)	Р	G	F	Ν	R	L	Ν	0	R	R
Alcohols										
Butanol	G	G	G	R	R	R	R	R	R	R
Ethanol	G	G	G	R	R	Ν	R	0	R	R
Methanol	G	G	G	R	R	Ν	R	0	R	R
Amines										
Aniline	G	G	Р	Ν	Ν	R	R	Ν	R	0
Dimethylformamide	Р	G	F	Ν	Ν	Ν	R	Ν	R	Ν
Bases										
Ammonium hydroxide (25%)	F	G	G	R	Ν	R	R	Ο	Ν	0
Ammonium hydroxide (1N)	F	G	G	Ν	Ν	R	R	0	Ν	Ν
Sodium hydroxide	G	G	G	Ν	Ν	Ν	R	Ν	R	Ν
Hydrocarbons										
Hexane	Р	G	F	R	R	R	R	R	R	R
Toluene	Р	G	Р	R	0	R	R	R	R	Ν
Xylene	Р	F	Р	R	R	R	R	R	R	Ν
Dioxane	Р	G	Р	Ν	Ν	Ν	R	Ν	R	R
Dimethylsulfoxide (DMSO)	Р	G	Р	Ν	Ν	Ν	R	Ν	R	0*
Halogenated Hydrocarbons										
Chloroform	Р	G	Р	Ν	Ν	R	R	Ν	R	R
Methylene chloride	Р	F	Р	Ν	Ν	R	R	Ν	R	Ν
Ketones										
Acetone	Р	G	Р	Ν	0	Ν	R	Ν	R	R
Methyl ethyl diketone	Р	G	Р	Ν	0	Ν	R	0	R	R

\*Can be used with aqueous solutions containing up to 20% DMSO.

R = Recommended, L = Limited Resistance, N = Not Recommended, O = Testing Advised, F = Fair, G = Good, P = Polyr PP = Polyropylene, PVC = Polyvinyl Chloride, CA = Cellulose Acetate, PC = Polycarbonate, PTFE = Polytetrafluoroethylene PS = Polystyrene, CN = Cellulose Nitrate, NY = Nylon, MCE = Mixed Cellulose Esters, PET = Polytethylene Terephthalate.

### CHARACTERISTICS OF CORNING<sup>®</sup> CENTRIFUGE TUBES

The following information is provided to serve as a general guideline for determining suitability of Corning centrifuge tubes for your applications. In addition, Corning recommends following the procedures outlined by the centrifuge manufacturer, as well as conducting a trial run to determine proper conditions before beginning any critical applications.

Corning centrifuge tubes are tested for leakage. They should not break or leak if used in a properly balanced rotor with suitable carriers, holders, and adapters that fully support the tubes when run in accordance with the guidelines in this section. These tubes are intended for one-time use only; reuse is not recommended as breakage or leakage may occur.

The recommended working temperature range for Corning centrifuge tubes is 0 to 40°C. The suitability of these tubes for storage below 0°C depends on both the solution and the

storage conditions. In general, the polypropylene and PET tubes are more resistant to stress at low temperatures than polystyrene. It is strongly recommended that a trial run be performed under actual conditions to test the suitability of the tubes for frozen storage.

### **Suggestions for Safe Centrifugation**

- *Caution*: When centrifuging pathogenic organisms, clinical specimens known or suspected of being infectious, or any other potentially biohazardous materials, approved safety containment systems should be used. Contact your centrifuge manufacturer for appropriate accessories or recommendations.
- Read protocols and instruction manuals carefully. Do not confuse speed or revolutions per minute (RPM) with relative centrifugal force (RCF). Instructions for centrifuging a sample at a given RPM and time are incomplete unless the rotor or radius is specified. Protocols should always state the time and RCF value for centrifuging a sample.

Proper balancing and distribution of the load in a centrifuge is critical for optimum performance and to prevent damage to the tubes or centrifuge. Opposing buckets or loads should always be balanced within the range specified by the manufacturer. Tubes should always be distributed in the buckets with respect to the center of rotation as well as the pivotal axis of the bucket. Failure to do this may prevent the bucket from achieving a horizontal position during the centrifugation run. Uneven separations or tube failure may result.

These centrifuge tubes are intended for use by persons knowledgeable in safe laboratory practices. Failure can result from surface damage, exceeding the specified RCF values, using unsuitable support systems, improper temperatures, or incompatible chemicals.

The RCF ratings for Corning<sup>®</sup> disposable centrifuge tubes have been established at room temperature using tubes filled to nominal capacity with water and spun in a horizontal rotor centrifuge for 5 minutes. The centrifuge must be equipped with the recommended carriers, adapters, and cushions that fully support the tubes. If an angle head rotor is used or proper support is not provided, RCF values will be lower. Use of liquid other than water may also lower RCF values. Please consult your centrifuge specifications and the nomogram table (page 123) to determine speeds at which maximum RCF is achieved.

### Chemical Compatibility of Disposable Plastic Centrifuge Tubes

The mechanical strength, flexibility, color, weight and dimensional stability of all plastic centrifuge tubes are affected to varying degrees by the chemicals with which they come in contact. Specific operating conditions, especially temperature, RCF, rotor type, carrier design, and run length will also affect tube performance.

### Physical Properties of Disposable Plastic Centrifuge Tubes

	Clear Polypropylene	Opaque Polypropylene	New Polyethylene Terephthalate
Recommended Working Temp*	0-40°	0-40°	0-40°
Heat Distortion Point	121°	121°	70°
Flexibility	Moderate	Moderate	Rigid
Transparency	Clear	Opaque	Clear
Maximum RCF: 15 mL Tube	8,400 x g	_	3,600 x g
50 mL Tube	9,400 x g	_	3,600 x g
250 mL Tube	_	6,000 x g	_
500 mL Tube	_	6,000 x g	—

\*At room temperature for 24 hours.

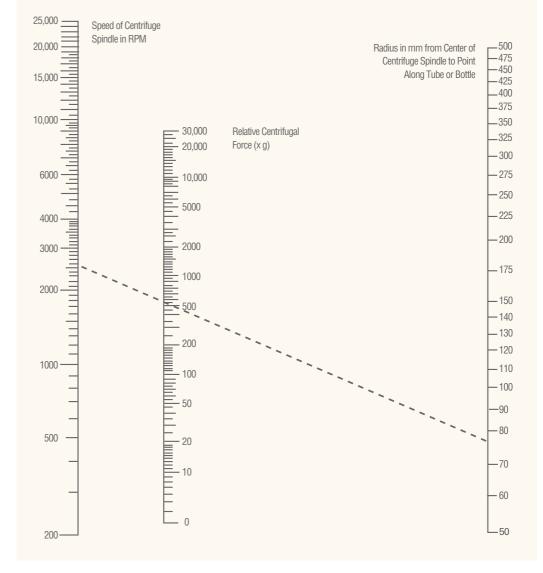
#### Chemical Resistance of Disposable Plastic Centrifuge Tubes\*

Chemical Class	Polyethylene Terephthalate	Polypropylene	Polyethylene Caps
Acids (weak)	1	1	1
Acids	3	1	1
Alcohols	1	1	1
Aldehydes	3ª	2ª	1
Bases	3	1	1
Esters	2	2	2
Hydrocarbons:			
Aliphatic	1	2	3
Aromatic	3	3 <sup>b</sup>	3
Halogenated	2	3	3
Ketones	2	2°	2

\*At room temperature for 24 hours.

1 = Recommended; 2 = Suitable for most applications. However, a trial run under specific operating conditions is recommended; 3 = Not recommended.

Note: a = Formaldehyde, rated 1; b = Phenol, rated 1; c = Acetone, rated 1.



#### NOMOGRAM FOR COMPUTING RELATIVE CENTRIFUGAL FORCE

To calculate the RCF value at any point along the tube or bottle, measure the radius, in mm, from the center of the centrifuge spindle to the particular point. Draw a line from the radius value on the right hand column to the appropriate centrifuge speed on the left-hand column. The RCF value is the point where the line crosses the center column. The nomogram is based on the formula:

 $RCF = (11.17 \text{ x } 10^{-7}) \text{ RN}^2$ 

where:

R = Radius in mm from centrifuge spindle to point in tube bottom N = Speed of spindle in RPM

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40080 93	402697 26	430521 107	431079 5	431256 28, 110
	402698 26	430525 33, 116	4310805	431272 71
40082	402699 26	430526 33, 116	4310816	431301 71
40085	402700 26	430588 8	431082 6	431306 5
40086 91	402711 26	4305898	431085 5	431328 5
400640-402720	402720 25	430591 8	431096 106	431329 18
TUUUTU-TU2/20		430597 8	431097 106	431339 28, 110
400640	430015-430945	4305997	431098 106	431340 28, 110
401392 25	430015 107	430624 107	4311107	431346 6
401637 26	430049 107	430625 107	431111 8, 71	431355 34, 111
401638	430052 34, 111	430626 107	431112	
	190092 97, 111		J1114/	

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## Culturefuge 100

Pilot plant separation system



A steam sterilizable, aseptic and contained Culturefuge 100 separation system. Its small size but high performance makes it ideal for pilot plants and small-scale production.

Many new biological products are derived from fragile organisms. Although relatively easy to separate the trick is accomplishing the separation in a gentle manner without destroying the shear sensitive cell wall membranes that isolate the comlex intracellular proteins from the extracellular liquid. If this can be avoided, downstream purification of the target proteins becomes much easier.

#### Unique hollow spindle design

Alfa Laval has worked for many years with machines that are bottom fed through a hollow spindle. Liquids entering the Culturefuge 100 are gradually accelerated as they move upwards through the spindle. The feed zone of the machine is completely filled with rotating liquid and there is no air/liquid interface. This smooth acceleration minimizes shear forces acting on the liquid and thus prevents cell lysis.

#### Hermetic outlet

Another feature of the Culturefuge 100 is the completely hermetic outlet. Clarified centrates are discharged via a sealed outlet that precludes any contact with air. This is particularly desirable when the liquids are prone to foam or where the products are susceptible to oxidation.

#### Hygienic design

Hygienic considerations were of the utmost importance in the design of the Culturefuge 100. It is fully steam sterilizable and has a cleaning-in-place capability. Pressure vessel designs according to ASME or PED are available. Cooling jackets surrounding the centrifuge bowl provide efficient temperature control and also contribute to a low noise level.

The "dosing ring" solids-ejecting system with its rapid, distinct discharge action ensures low product losses and drier solids. Flushing nozzles spray the outside of the centrifuge bowl, cyclone and the inside of the frame hood for maximum hygiene.

#### Complete system

The centrifuge is mounted on a fixed base frame, which in-cludes process piping for service liquids and process liquids entering and leaving the centrifuge. Typically, a steam sterilizable pump removes the solids phase. The built-in electrical system includes starter, PLC control system and pneumatic unit. An integral motor with built-in VFD is standard and this provides considerable space savings for a complete system.

#### Materials

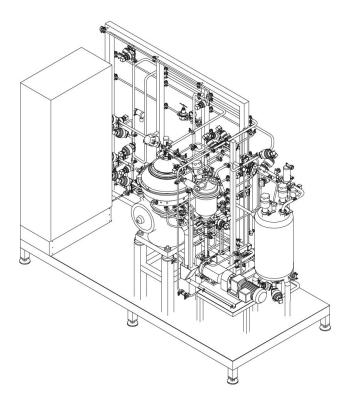
All product contact parts are made of high-grade stainless steel. Various grades of surface finish are available 1.2  $\mu$ m Ra, 0.8  $\mu$ m Ra or 0.5  $\mu$ m Ra with electropolish. Gaskets are made of FDA-approved EPDM elastomer.

#### Available configurations

The skid-mounted modular design can be delivered for open operation, contained running, steam sterilizable aseptic operation or steam decontamination-only operation.

#### Working principles

The feed is introduced to the rotating centrifuge bowl (see figure 1) from the bottom through a hollow spindle (1). It is accelerated in a distributor (2) before entering the disc stack (3), where the separation takes place. The separated liquid phase leaves through the liquid outlet (4) at the top of the bowl. The collected solids in the solid space (5) are intermittently discharged from the periphery of the bowl. During normal production the operating water keeps the sliding bowl bottom (6) closed against the bowl hood. During discharge the sliding bowl bottom drops for a short time (less than a second) and the solids are ejected through the discharge ports (7). The high velocity of the ejected solids is reduced in the cyclone.



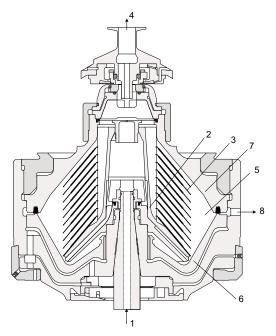


Fig. 1. Typical bowl for a hermetic solids-ejecting centrifuge. The details illustrated do not necessarily correspond to the centrifuge described.

#### Technical specifications

Max. hydraulic capacity	1.2 m³/h*
Max. G-force	12,200
Max. bowl speed	9,650 rpm
Installed motor power, control torque	7.5 kW
Sound pressure	74 ±3 dB(A)

\* Actual capacity depends on feed material and separation demands.

#### Main dimensions\*\*

2,140 mm
2,780 mm
1,270 mm

Can vary according to specific demands.

#### Shipping data (approximate)\*\*\*

Net weight	1,400 kg
Gross weight	1,760 kg
Volume	12 m <sup>3</sup>

\* Complete system with bowl and motor.

#### PPM00036EN 0304

Alfa Laval reserves the right to change specifications without prior notification.

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# sartorius stedim

## Standard Flexel<sup>®</sup> 3D Bioprocessing Bags for Drums



#### Description

Flexel®3D standard bags are designed for processing, storage and transport of large volume biopharmaceutical solutions in drums. They provide a single-use alternative to traditional stainless steel vessels in a large variety of applications.

#### Cost reduction and Risk reduction

Single-use Systems used in biopharmaceutical manufacturing improve process safety as they reduce the risk of cross contamination from batch-to-batch and product-to-product. Costly and time consuming CIP & SIP operations are minimized. This results not only in significant cost savings within the entire manufacturing process, but also in the optimization of capacity utilization.

#### Applications

The multi-layer film construction of different materials provides a strong structure with low gas permeability and high chemical resistance for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications such as:

- Buffers and Media filtration & storage
- Bulk harvest
- Product pooling
- Fraction collection
- Sample collection
- Bulk intermediate filtration & hold
- Final product storage and transport

#### Flexibility

Standard Flexel® bags for drums are available as stand-alone bags with Silicone tubing, stand-alone bags with C-Flex tubing and Filter & Bag assemblies incorporating a variety of filter and bag sizes allowing easy adoption to process volume and media. Multiple configurations that also integrate thermoweldable TPE tubing are provided for flexible incorporation into your process. Thus, sterile connection and disconnection devices like the BioWelder® and the BioSealer® can be used to allow safe connections and disconnections from and to another process step.

Female luer fittings with a needle free sampling port may be used for easy and convenient sampling, quick connects may be attached directly or adapted to a variety of connections and tri-clamps that are widely used in a production environment assure maximum flexibility.

#### Security of Supply

Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single-Use solutions combined with collaborative supplier management and customer demand planning assures a state of the art product supported by a robust supply chain that can cope with strong market growth.

Features	Benefits
Multiple manufacturing sites	High security of supply
All connections extensively qualified	Safe and robust
Full compliance with ISO11137	Highest sterility assurance level
Standard design	Most designs available from stock
Various bag & filter sizes	High flexibility

#### Specifications

#### Standard Flexel®3D for Drum

Bag Chamber:	Multiple layer film construction, including EVOH gas barrier layer, ULDPE Contact Layer
Tubing:	Silicone, TPE
Fittings:	MPX Couplings, Female Luer Lock, MPC Male Coupling, Triclamp, Needle free sampling port
Filters:	Sartopore <sup>®</sup> 2 Gamma Capsule
Volumes:	50L- 560L
Sterilization:	by Gamma Irradiation

#### Validation

Flexel® bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® with data representing the widest range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single use products with a sterility assurance level of 10<sup>-6</sup> over the shelf life.

#### **Quality Assurance**

Sartorius Stedim Biotech Quality Systems for Single Use Products follow applicable ISO and FDA regulations for Medical Devices. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements.

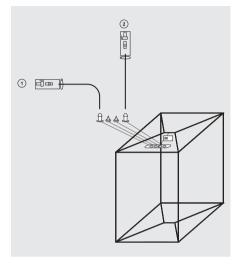
Flexel<sup>®</sup> 3D bags are tested for compliance to:

- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19 : Particulate
- ISO 11737 : Bioburden
- ISO 11137 : Sterilization of Medical devices

#### **Supply Chain**

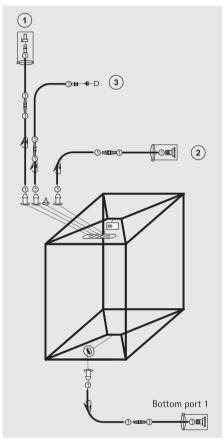
The majority of Standard Flexel<sup>®</sup> 3D bags for drum systems are available from stock.

#### 1. Standard Flexel<sup>®</sup> 3D bags for drum with silicone tubes



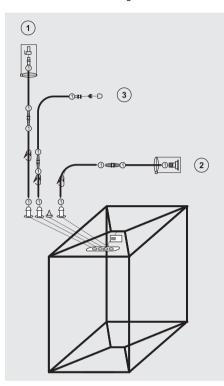
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Top Port 4	Qty/Box
FXB103162	Flexel <sup>®</sup> 50L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102464	Flexel <sup>®</sup> 100L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102465	Flexel <sup>®</sup> 200L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB103294	Flexel <sup>®</sup> 300L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB103367	Flexel <sup>®</sup> 370L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102167	Flexel <sup>®</sup> 560L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5
FXB102508	Flexel <sup>®</sup> 1,000L for Drum – Silicone	Silicone	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	1/2" × 11/16" × 0.5 m (20") 1/2" MPX male + sealing cap	Plug	Plug	5

- 2. Standard Flexel\* 3D bags for drum with silicone  $\mbox{\ensuremath{\&t}}$  TPE tubes
- 2.1. Standard Flexel<sup>®</sup> 3D bags for drum with silicone & TPE tubes with side bottom drain



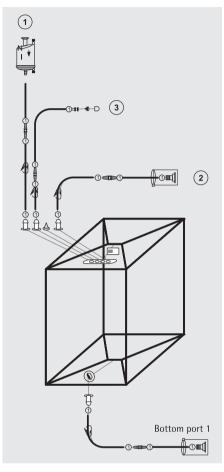
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110917	Flexel <sup>®</sup> 50L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110919	Flexel <sup>®</sup> 100L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110920	Flexel <sup>®</sup> 200L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m. (60") 1-1/2" Tri-Clamp	5
FXB111626	Flexel <sup>®</sup> 300L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB111631	Flexel <sup>®</sup> 370L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110921	Flexel <sup>®</sup> 560L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

#### 2.2. Standard Flexel<sup>®</sup> 3D bags for drum with silicone & TPE tubes



Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110922	Flexel <sup>®</sup> 50L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110923	Flexel <sup>®</sup> 100L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110924	Flexel <sup>®</sup> 200L for Drum – TPE	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 1/2" MPX male + sealing cap	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

- 3. Standard Flexel® 3D bags for drum with silicone & TPE tubes & Sartopore® 2 Gamma capsules
- 3.1. Standard Flexel® 3D bags for drum with silicone & TPE tubes with side bottom drain & Sartopore® 2 Gamma capsules



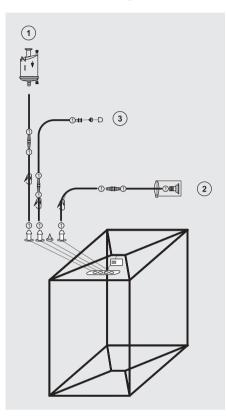
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110954	Flexel® 50L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441307H7G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.2 µm; filter inlet 1,5" sanitary flange 500 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110958	Flexel® 100L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441307H8G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.2 μm; filter inlet 1,5" sanitary flange 1000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110960	Flexel® 200L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441307H9G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.2 µm; filter inlet 1,5" sanitary flange 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5

#### 3. Standard Flexel® 3D bags for drum with silicone & TPE tubes & Sartopore® 2 Gamma capsules

3.1. Standard Flexel® 3D bags for drum with silicone & TPE tubes with side bottom drain & Sartopore® 2 Gamma capsules

Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB111629	Flexel® 300L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K9G-SM; filter inlet 1,5" sanitary flange Sartopore® 2 Gamma 0.2 μm, 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp a,	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111633	Flexel® 370L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K9G-SM; filter inlet 1,5" sanitary flange Sartopore® 2 Gamma 0.2 µm, 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp a,	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB110969	Flexel® 50L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K7G-SM; filter inlet 1,5" sanitary flange Sartopore® 2 Gamma 0.1 µm, 500 cm <sup>2</sup>	(60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110971	Flexel® 100L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K8G-SM; filter inlet 1,5" sanitary flange Sartopore <sup>®</sup> 2 Gamma 0.1 µm, 1000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp a,	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110973	Flexel® 200L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K9G-SM; filter inlet 1,5" sanitary flange Sartopore® 2 Gamma 0.1 µm, 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp a,	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB111630	Flexel® 300L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K9G-SM; filter inlet 1,5" sanitary flange Sartopore® 2 Gamma 0.1 µm, 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp a,	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2
FXB111634	Flexel® 370L for Drum – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K9G-SM; filter inlet 1,5" sanitary flange Sartopore <sup>®</sup> 2 Gamm: 0.1 μm, 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp a,	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	2

3.2. Standard Flexel® 3D bags for drum with silicone & TPE tubes & Sartopore® 2 Gamma capsules 0.2 µm (50L to 200L)

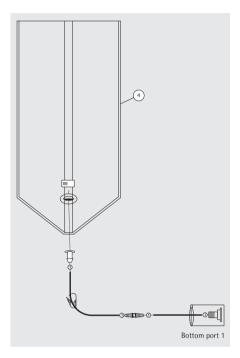


Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110955	Flexel® 50L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441307H7G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.2 μm; filter inlet 1,5" sanitary flange 500 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110959	Flexel® 100L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex <sup>®</sup> 374	$1/2" \times 3/4" \times 1.5 m$ (60") 5441307H8G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.2 µm; filter inlet 1,5" sanitary flange 1000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110961	Flexel® 200L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	$1/2" \times 3/4" \times 1.5 m$ (60") 5441307H9G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.2 µm; filter inlet 1,5" sanitary flange 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

#### 3.2. Standard Flexel® 3D bags for drum with silicone & TPE tubes & Sartopore® 2 Gamma capsules

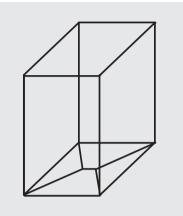
Part Number	Description	Tubing	Top Port 1	Top Port 2	Top Port 3	Bottom Port 1	Qty/Box
FXB110970	Flexel® 50L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K7G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.1 μm; filter inlet 1,5" sanitary flange 500 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110972	Flexel® 100L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K8G-SM, Sartopore <sup>®</sup> 2 Gamma, 0.1 μm; filter inlet 1,5" sanitary flange 1000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5
FXB110974	Flexel® 200L – TPE – Sartopore® 2 Gamma	Silicone + Clear C-Flex® 374	1/2" × 3/4" × 1.5 m (60") 5441358K9G-SM, Sartopore® 2 Gamma, 0.1 µm; filter inlet 1,5" sanitary flange 2000 cm <sup>2</sup>	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	1/8" × 1/4" × 1.1 m (40") LL female + needle free sampling port	No bottom drain	5

- 4. Standard Flexel<sup>®</sup> Tank Liners for drum
- 4.1. Standard Sterile Flexel<sup>®</sup> tank Liners for drum with side bottom drain



Part Number	Description	Tubing	Bottom Port 1	<b>Qty/Box</b>
FXB110931	Flexel <sup>®</sup> 30L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110934	Flexel <sup>®</sup> 50L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110936	Flexel <sup>®</sup> 100L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110937	Flexel <sup>®</sup> 200L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB111636	Flexel <sup>®</sup> 300L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB111637	Flexel <sup>®</sup> 370L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	10
FXB110939	Flexel <sup>®</sup> 560L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5
FXB110940	Flexel <sup>®</sup> 1,000L liner – TPE	Silicone + Clear C-Flex <sup>®</sup> 374	1/2" × 3/4" × 1.5 m (60") 1-1/2" Tri-Clamp	5

#### 4.2. Standard Flexel<sup>®</sup> tank Liners for drum



Part Number	Description	Sterility	Qty/Box
FXB102120	Flexel <sup>®</sup> 50L liner	Non sterile	20
FXB102116	Flexel <sup>®</sup> 100L liner	Non sterile	20
FXB102117	Flexel <sup>®</sup> 200L liner	Non sterile	20
FXB102119	Flexel <sup>®</sup> 300L liner	Non sterile	20
FXB103406	Flexel <sup>®</sup> 370L liner	Non sterile	20
FXB103357	Flexel <sup>®</sup> 560L liner	Non sterile	20
FXB111118	Flexel <sup>®</sup> 30L liner	Sterile	10
FXB103126	Flexel <sup>®</sup> 50L liner	Sterile	40
FXB103087	Flexel <sup>®</sup> 100L liner	Sterile	20
FXB102965	Flexel <sup>®</sup> 200L liner	Sterile	20
FXB103132	Flexel <sup>®</sup> 300L liner	Sterile	10
FXB103318	Flexel <sup>®</sup> 370L liner	Sterile	15
FXB103368	Flexel <sup>®</sup> 560L liner	Sterile	20

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Specifications subject to change without notice. Printed and copyrighted by Sartorius Stedim Biotech GmbH W · G Publication No.: SPT2010-e09113 Order No.: 85034-535-08 Ver. 11 | 2009 The TotalTreat<sup>®</sup> Continuous Neutralization System (NS) is a packaged system designed for continuous flow neutralization. The system includes reaction tanks with chemical injection pumps, pH meters and mixers and effluent clearwell. The system consists of a rectangular polypropylene tank with external steel reinforcement (polypropylene encased). Internally, the system consists of either two or three reaction chambers plus a final effluent clearwell. Standard system sizing is based on a 10-minute retention time in each chamber. Each chamber is a separate stirred tank reactor with

individual pH control. Gross chemical dosing pumps and effluent flow meters are available as options. The TotalTreat<sup>®</sup> NS can be used as a stand alone unit or integrated as part of a larger system. The system requires influent, effluent and a single power connection. The chemistry used in the TotalTreat® NS is

NS-100-2 Neutralization System

selected to provide optimum treatment for the waste.



Totaltreat<sup>®</sup> Continuous Neutralization System (NS)

# SIEMENS

#### **FEATURES**

- NEMA-4X electrical enclosure
- Compact design for small footprint
- Polypropylene construction for superior corrosion resistance
- No inter-chamber piping required
- TEFC mixer motors
- **Pre-piped**
- **Pre-wired**
- Factory tested
- Stand alone operation
- Integrate with other wastewater products

#### **AVAILABLE STANDARD OPTIONS**

- Effluent flow transmitter/sensor/recorder
- Dual pH transmitters/sensors
- Additional air operated (gross) dosing pumps

## Totaltreat<sup>®</sup> Continuous Neutralization System (NS)

	SPECIFICATIONS							
Model Number	NS-10-2	NS-30-2	NS-50-2	NS-100-2	NS-10-3	NS-30-3	NS-50-3	NS-75-3
Nominal Flow Rate	10 gpm 2.3 m <sup>3</sup> /hr	30 gpm 6.8 m <sup>3</sup> /hr	50 gpm 11.4 m <sup>3</sup> /hr	100 gpm 22.7 m <sup>3</sup> /hr	10 gpm 2.3 m <sup>3</sup> /hr	30 gpm 6.8 m <sup>3</sup> /hr	50 gpm 11.4 m <sup>3</sup> /hr	75 gpm 17.0 m <sup>3</sup> /hr
Design Temperature				40° to 120° F	/ 4° to 49° C		-	
Maximum Influent pH Range (S.U)	1 to 13	1 to 13	1 to 13	1 to 13	0.5 to 13.5	0.5 to 13.5	0.5 to 13.5	0.5 to 13.5
Reaction Chambers	Two	Two	Two	Two	Three	Three	Three	Three
Reaction Chamber Volume	125/105 gallons 0.5/0.4 m <sup>3</sup>	350/320 gallons 1.3/1.2 m <sup>3</sup>	570/500 gallons 2.2/1.9 m <sup>3</sup>	1,100/1,020 gallons 4.2/3.9 m <sup>3</sup>	120/120/105 gallons 0.5/0.5/0.4 m <sup>3</sup>	360/360/320 gallons 1.4/1.4/1.2 m <sup>3</sup>	570/570/500 gallons 2.2/2.2/1.9 m <sup>3</sup>	850/850/780 gallons 3.2/3.2/3.0 m <sup>3</sup>
Clearwell Volume	16 gallons 0.06 m <sup>3</sup>	40 gallons 0.15 m <sup>3</sup>	70 gallons 0.26 m <sup>3</sup>	85 gallons 0.32 m <sup>3</sup>	16 gallons 0.06 m <sup>3</sup>	40 gallons 0.15 m <sup>3</sup>	70 gallons 0.26 m <sup>3</sup>	70 gallons 0.26 m <sup>3</sup>
Effluent Connection	2" Sched. 80 PVC FNPT	3" Sched. 80 PVC FNPT	4" Sched. 80 PVC FNPT	6" Polypropylene Flange	2" Sched. 80 PVC FNPT	3" Sched. 80 PVC FNPT	4″ Sched. 80 PVC FNPT	4" Polypropylene Flange
Material of Construction				Polypropylene	/Carbon Steel		-	
Mixers		Ç	ty. 1 - Chamber Bra	awn, BD-33-350, 17	750 rpm, 0.33 HP, 3	16SS Shaft/Impelle	r	
Chemical Pumps				Qty. 2 - Chamber	LMI, PVC/Ceramic			
pH Instrumentation				Qty. 1 - Ch	amber GLI			
Effluent Chart Recorder				Qty. 1 – H	loneywell		_	
Dimensions	5'-1" x 3'-6"x 5'-1"	7'-1" x 4'-6" x 6'-10"	9'-2" x 4'-6" x 7'-10"	11'-1" x 5'-6" x 9'-0"	6'-11" x 3'-6" x 5'-1"	10'-1" x 4'-6" x 6'-10"	13'-2" x 4'-6" x 7'10"	13'-10" x 5'-6" x 9'-0"
$(L \times W \times H)$	1,549 x 1,067 x 1,549 mm	2,159 x 1,372 x 2,083 mm	2,794 x 1,372 x 2,388 mm	3,378 x 1,676 x 2,743 mm	2,108 x 1,067 x 1,549 mm	3,073 x 1,372 x 2,083 mm	4,013 x 1,372 x 2,388 mm	4,216 x 1,676 x 2,743 mm
Shipping Weight	550 lbs 250 kg	1,100 lbs 500 kg	2,000 lbs 900 kg	3,500 lbs 1,590 kg	700 lbs 320 kg	1,650 lbs 750 kg	3,000 lbs 1,360 kg	4,050 lbs 1,830 kg
Operating Weight	2,650 lbs 1,200 kg	6,950 lbs 3,150 kg	11,600 lbs 5,260 kg	21,900 lbs 9,930 kg	3,330 lbs 1,510 kg	10,500 lbs 4,760 kg	17,400 lbs 7,890 kg	25,350 lbs 11,500 kg
Power			208-VA	C, 3-Phase, 60-Hert	z, 30-Amps, 5-Wire	Service		
Compressed Air	5 cfm @ 100 psi 8.5 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor	5 cfm @ 100 psi 8.5 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor	10 cfm @ 100 psi 17 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor	10 cfm @ 100 psi 17 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor	5 cfm @ 100 psi 8.5 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor	10 cfm @ 100 psi 17 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor	20 cfm @ 100 psi 34 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor	20 cfm @ 100 psi 34 m <sup>3</sup> /hr @ 690 kPa, 10% duty factor

The information provided in this literature contains merely general descriptions or characteristics of performance which in actual case of use do not always apply as described or which may change as a result of further development of the products. An obligation to provide the respective characteristics shall only exist if expressly agreed in the terms of the contract.

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Siemens Water Technologies 2000 Marconi Drive Warrendale, PA 15086 866.525.0621 Toll Free 724.772.6520 Phone 724.772.6521 Fax

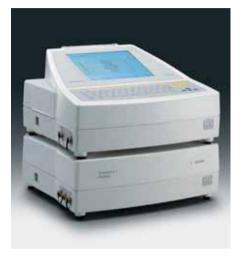
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## Sartocheck 4 MultiUnit

Next Generation of Filter Integrity Testing





#### Description

The Sartocheck 4 MultiUnit has been developed to enable parallel integrity testing of multiple filters in the biopharmaceutical industry. The MultiUnit is an identical copy of the Sartocheck 4, without the user interface and the data management system. Each MultiUnit connected to a Sartocheck 4 is operated and controlled by this Sartocheck 4 via a RS485 connection.

#### Efficiency

Up to 4 MultiUnits can be connected to one Sartocheck 4 allowing to integrity test up to 5 different filter systems in parallel including the testing capabilities of the Sartocheck 4 itself. Testing up to 5 filters in parallel allows to reduce the time required for filter integrity testing in bio-pharmaceutical production significantly and increases the efficiency of your production process.

#### Flexibility

There is no relevant distance limitation between the Sartocheck 4 and the connected MultiUnits. The MulitUnits can be placed all over your production facility and are centrally controlled and operated by the Sartocheck 4. A printout of the test results of the MultiUnit is made by the printer of the Sartocheck 4 and the test data can be transferred to a network for review and achiving.

#### Data transfer security

The Sartocheck 4 MultiUnit is an independent test unit with its own power supply, electronics and pneumatics. It will maintain the test results even if switched off or if the connection is lost until the handshake communication with the Sartocheck 4 confirms that the test results have been transferred successfully. If the MultiUnit is switched off during the test it will transfer a corresponding error message as soon as the communication has been automatically reestablished.

#### Traceability

The Sartocheck 4 test result printout contains the serial number of the MultiUnit, the user name (log-on identity), a unique file name and all the information that has been entered in the batch protocol. The included software, Sartocontrol, can be used to print the test results on an external printer in A4 format.

#### Patent pending thermal insulation

The Sartocheck 4 and its Multiunit feature a unique, patent pending separation of the electronic components and the temperature sensitive pneumatics in addition to the efficient vent fan. This superior solution avoids any thermal influence on the integrity test measurement from the unit itself.

#### Clean room venting adapter

The Sartocheck 4 and its MultiUnit can be equipped with an optional venting fan adapter that allows to contain the out coming air in order to avoid any dispersion of particles in a clean room.

#### Sartorius Validation Package

The MultiUnit is delivered with a comprehensive validation package including an IQ & OQ protocol that can be accomplished by qualified Sartorius personnel. Assistance for PQ can also be provided from the Sartorius Technical Support team.

#### **Technical specifications**

Power requirements	100–240 V AC 50/60 Hz
Maximum operating	9999 mbar
pressure	145 psi
Minimum inlet	4000 mbar
pressure	58 psi
Measuring ranges	
Test pressure	100–8000 mbar
	1.5–116 psi
Pressure drop	1–2000 mbar
	0.01–29 psi
System net volume	0000
- with internal ref. vessel	9000 ml
<ul> <li>with external ref. vessel</li> </ul>	100
Measuring accuracy	
Pressure	± 0.1% full scale
	± 9.5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4%
Diffusion	± 5%
Water intrusion	± 5%
Bubble point	± 50 mbar
	0.7 psi
Operating conditions	
Ambient temperature	+15 to + 35°C
Relative humidity	10-80%
Max distance between SC4 and multiunit (RS485)	

#### **Order information**

Order number

16288---TU

### Filter Integrity Testing

#### **Equipment supplied**

(country specific)

MultiUnit	16288TU
Tubing for compressed gas inlet	18104
Tubing for test gas	18103
Test certificate	
Calibration certificate	
Installation and operating instructions	
Validation package	16288VP
Mains lead	

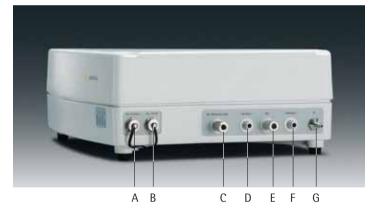
- 1. MultiUnit RS485 in out 2. MultiUnit
- RS485 in out 3. MultiUnit
- PLC in out 4. Sartocheck 4 PLC in out 5. Sartocheck 4
- RS485 in out



3 4 5 2

Accessories	
External pressure Transducer	1ZE0018
Valve kit for ext. venting (1 valve)	1ZE0025
Valve kit for WIT and   or external pressure sensor (3 valves)	1ZE0026
Cleaning kit	16288CK
Clean room venting adapter	1ZE0021

A. Ext. sensor B. Ext. valve C. Ext. reference tank D. Venting 1 E. Outlet (test gas) F. Venting 2 G. Inlet comp. gas



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www.sartorius.com USA +1.631.2544249 UK +44.1372.737100 France +33.1.69192100 Italy +39.055.634041 Spain +34.91.3586100 Japan +81.3.33293366

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## The µ-24 Bioreactor

A tool for massive testing, screening and optimisation studies



## Annlikon Bintechnolow

The U-24 Bioreactor

### Screening and testing of micro-organisms and cells

new strains • high productive strains • clone selection

### **Optimization studies**

medium • feed strategies • process parameters

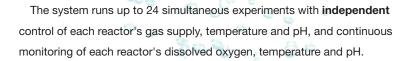
### Quick, accurate and massive

### **Optimal tool for Metabolic Engineering**

saving money e.g. in case of experiments when labelling with C14

### The µ-24 Bioreactor:

A fermentation and cell culture system using specialized single use 24-reactor cassettes providing individual control and monitoring of reactor conditions.

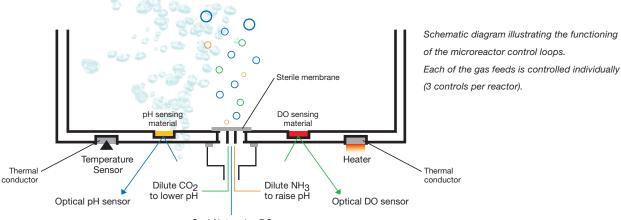


The 24 well cassettes are fitted with bottom membranes. The membranes form an aseptic and water tight seal between the control system and the reactors.

- Independent gas supplies: for Air / O2 / N2 and CO2 / NH3
- Temperature measurement and control per reactor
- pH measurement and control per reactor
- DO measurement and control per reactor
- Orbital shaker 0-800 rpm

### Demonstrated applications

• E. coli, Saccharomyces cerevisiae, Bacillus subtilis, lactobacillus • Shewanella oneidensis MR-1, Aspergillus nidulans • Aspergillus oryzae, Trichoderma reesi • CHO cells • Cell-free expression









#### Applikon Biotechnology

#### **Cassettes**

The reactor cassettes are conforming to the SBS standard for 24 well culture plates (128x86 mm). The total volume per well is 10ml with recommended working volume is 3ml. This in particular is relevant for demanding growth conditions (high air delivery and high agitation). Working volumes may be adjusted from one application to the next as determined empirically by the user (1-6ml).

(a) applikon®

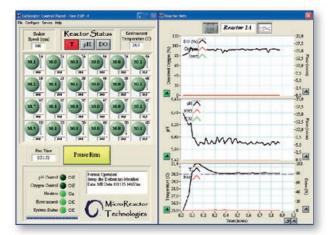
Cassettes are delivered gamma sterilized and sealed in a dark packaging. During experiments the wells can be sealed with help of commercially available sterile 'peel and stick' sealing, e.g. gas permeable adhesive seals. The alternative for seals are the individual caps with filter and airlock valve. These caps come in gamma irradiated packs of 6 x 24 caps.

#### **Control system**

The Microbioreactor system includes a pentiumbased laptop system running Windows XP and a software application to perform experimental control strategies as well as data acquisition.

#### The software control system will allow

- Entering and changing set points for temperature, pH and Dissolved Oxygen for each of the 24 wells (the software will allow the user to change set points during a run)
- · Entering and changing set points for shake table revs





- Real time monitoring of temperature, pH, Dissolved Oxygen, and gas fluxes in both tabular and graphic representations.
- Multiple system control capability
- · Logging of monitored data in exchangeable file formats

#### **Connections**

The instrument requires connection to a standard 230V AC power supply and pressurized gas supplies (air, nitrogen, carbon dioxide).

The instrument's electronics is connected to a laptop computer through a standard USB port.

#### Cables & auxiliary materials

#### The system comes with

- One 230V AC power cord for the instrument
- One 230V AC power supply adapter for the laptop computer
- · One USB cable to connect laptop and instrument
- Four gas lines and connectors

#### The μ-24 Bioreactor

MicroReacto	r System Specification	
Dissolved Oxygen	O2 supply	0 - 500 mmol/L/hr
	DO setpoint range	0 - 100% air saturation
рH	pH setpoint range	6.0 - 8.0
рп		+ 0.1
	pH sensitivity	
	pH control accuracy (standard conditions)	± 0.2 (at pH 7.0)
Temperature	T setpoint range	10°C - 50°C
	T sensing range	0 - 70°C
	T sensitivity	± 0.1°C
	T control accuracy	± 1.0°C (at 37°C)
	T differential between adjacent wells	Max 2°C
	· · · · · · · · · · · · · · · · · · ·	
System	Shaker	0-800 rpm, 5mm orbital
	Power requirements	230 V, 2A
	Air requirements	< 30L/min, 1/4" tubing
	Size	W x H x D = 48 x 25 x 43cm
Utility	Air	minimal 5.5 bar 8 bar maximal
requirements	Oxygen (optional)	minimal 1.5 bar 8 bar maximal
	Carbon Dioxide (optional)	minimal 1.5 bar 8 bar maximal
	Nitrogen (optional)	minimal 1.5 bar 8 bar maximal

Opplikoo

Ordering info	ormation
Z360002410	The Micro Bioreactor complete with: • cover for reactor chamber • power cord • USB cable • laptop computer • software + drivers • gas line installation kit
Z860002410	<b>6 incubation cassettes in a 6-pack.</b> Each cassette is packed sterile(gamma radiated). The 10ml format 24-well plates have a recommended working volume of 3ml (max 7ml).
Z860002450	6 sterile packs of 24 closure caps each.
Z862000010	Ammonia bubbler vessel. The 10L ammonia bubbler vessel comes equipped with 4mm line in and line out quick connects. Max pressure rating on the vessel is 10 bar.



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www.applikon.com

## Space-Saving, Stackable Incubator Shakers I 26 and Refrigerated I 26R

New Brunswick Scientific now offers two new spacesaving incubator shakers. Based on the design concepts of the industry leading Innova<sup>®</sup> Shaker Series, the new I 26 and refrigerated I 26R offer excellent performance, value priced.

These advanced shakers feature NBS' Innova Triple-Eccentric Drive for dependable operation under even the most extreme conditions. Each I 26 shaker is independently controlled, so you can vary temperature, speed and agitation. Heavy-duty construction ensures that units can be safely stacked without vibration.

#### **Features**

- Dynamic Speed and Temperature Range for culturing shear-sensitive cells as well as robust bacterial cultures. Temperature from 5°C above ambient to 60°C for I 26 and from 15°C below ambient for I 26R. Speed 25 to 400 RPM with a 1″ (2.5 cm) diameter orbit.
- Microprocessor Control to Regulate Speed, Temperature and Running Time. Timer can be set up to 99.9 hours or operate continuously.
- Audible and Visual Alarms alert user of setpoint deviations. Audible alarm may be muted.
- User-Friendly Keypad with Large Display. Easy to enter setpoints and view operating conditions. Display is clearly visible from all angles, across the room and in all lighting conditions.
- **Smooth and Quiet Running** for a more favorable work environment.
- **Cool-Running Brushless Motors** never require lubrication and provide years of long life.
- Large (18" x 30") Interchangeable Accessory Platforms slide out easily while accommodating a wide range of accessories and flasks up to 2.8 liters.
- **Powerful Fan and Heater** provide rapid heat up and temperature recovery after door opening.



NBS' I 26 Shakers can be stacked up to three units high in about the same space normally occupied by a single shaker! As configured above, two shakers on a medium-height base.

- RS232 Interface for Data Logging directly to your PC.
- **Sub Platform Protects Components** by deflecting liquid from accidental spills.
- **Comprehensive Warranty** Two years on parts and labor.
- c Us Certified Meets CSA, UL and CE standards.

### Accessories

- Platforms, Clamps and Racks sold separately.
- **Stacking Kit** Used to join two shakers. One kit required for two shakers. Two kits required for stacking three shakers.
- **Bases** Used to raise height for easier access. Short Base - recommended for three shakers. Medium Base - recommended for two shakers. Tall Base - recommended for one shaker.



### I 26 & I 26R Stackable Incubator Shaker Specifications\*

SHAKING	Range & Control <sup>§</sup>	25 to 400 rpm v ±1 rpm over en Acceleration cir	vith 1" (2.5 cm) strok tire speed range by cuit prevents sudde	e. 25 to 250 rpm v PI microprocessor n starts/stops	when stacking 3 ι control	ınit		
SHAKING	Indication	Digital LED ele	ectronic display in	1 rpm increments	. Character heig	ght: % <sub>16</sub> " (1.4 cm)		
	Timer	Programmable status light at	e shaking periods f end of period. Can	rom 0.1 hr. to 99. be deactivated f	.9 hrs. Triggers or continuous of	audible alarm an peration	d energizes	
	Range		I 26: 5°C above ambient to 60°C I 26R: Same, but from 15°C below ambient (minimum setpoint is 4°C)					
	Control		PI microprocessor feedback regulation, $\pm 0.1^{\circ}$ C in 30°C to 40°C range, and $\pm 0.5^{\circ}$ C for the remaining range					
TEMPERA- TURE	Uniformity	Nominally $\pm 0$ .	Nominally $\pm 0.25^{\circ}$ C at 37°C					
	Indication	Digital LED dis	splay in 0.1°C incre	ements. Characte	er height $\frac{9}{16}$ " (1.4	4 cm)		
	Heaters	Low-watt dens	ity, resistance-type	e heaters with hig	h-temperature s	afety thermostat	t cut off	
	Refrigeration	I 26R only: He	rmetically-sealed	compressor uses	CFC-free refrige	erant		
ALARMS			Audible <sup><math>\Diamond</math></sup> and visible signals indicate when speed deviates more than 5 rpm, temperature more than 1°C from setpoint, and when timer operation has expired					
LED DISPLAY	LED DISPLAY		Indicates speed, temperature, running time and alarm conditions					
COMMUNICAT	IONS	RS-232 for data logging						
DRIVE & DRIV	E MOTOR	Triple-eccentric counterbalanced drive in cast-iron housing with solid-state brushless D.C. motor						
SAFETY		Shaker stops when excess vibration is detected or when door is opened Heater shuts off when high-temperature limit is exceeded						
SETPOINT RET	TENTION	Setpoints and operating status retained in non-volatile memory. Automatic restart after power is restored (indicated by flashing display)						
DOOR		Large viewing window, 13.5" x 17.5" (34.3 x 44.5 cm) allows for easy viewing of cultures Door swings down and supports platform. Open door adds 19.5" (49.5 cm) to depth						
STACKING SHA	KERS	Up to 3 shake	rs can be stacked	using accessory	stacking kit(s). (	One kit for 2 units	s; two kits for 3 units	
ELECTRIC PO	WER	120V, 60 Hz. 15 Amp						
	Platform ‡	30" x 18" (76.2	x 45.72 cm). Quicl	k release design a	allows platform to	slide out for read	dy access	
	Chamber	34" Wide x 25"	Deep x 14" High a	bove platform (86	6.4 x 63.5 x 35.6	cm)		
DIMENSIONS	Overall:	Sin	gle Unit	Two U	nits	Three	Units <sup>ø</sup>	
	Wide	50"	127 cm	50"	127 cm	50"	127 cm	
	Deep †	30"	76.2 cm	30"	76.2 cm	30"	76.2 cm	
	High	27"	69 cm	52.25"	133 cm	77.5"	197 cm	
WEIGHT		I 26: Net: 370	bs. (168 kg) Gross	: 470 lbs. (213 kg	) I 26R: Net: 40	0 lbs. (182 kg) G	ross:500 lbs. (227 kg)	

(\*) Specifications subject to change without notice. (§) Based on shaking a typical workload. (◊) Audible alarm may be muted.
(‡) Shaker does not include platform or clamps which much be ordered separately. I 26/I 26R platforms are not interchangeable with other NBS platforms.
(†) With door open, add 19.5" (49.5 cm) to depth.

Ordering Information					
Description	Catalog No.	Description C	atalog No.		
I 26 Incubator Shaker, 120V 60 Hz	M1324-0000	Universal Platform (clamps sold separately)	M1324-9904		
I 26 Incubator Shaker, 230V 50 Hz	M1324-0002	Short Base - raises shaker 4"	M1324-0600		
I 26R Refrigerated Inc. Shaker, 120V 60 Hz	M1324-0004	Medium Base - raises shaker 13"	M1324-0800		
I 26R Refrigerated Inc. Shaker, 230V 50 Hz	M1324-0006	Tall Base - raises shaker 17"	M1324-0700		
Stacking Kit - joins two shakers	M1324-0500				

Flask Clamps for Universal Platforms			Dedicated Platforms with Clamps Included		
Clamp Description	Platform Capacity	Catalog No.	Platform Description	Clamps	Catalog No.
125 mL Erlenmeyer	39	M1190-9001	125 mL Dedicated Platform	60	M1324-9905
250 mL Erlenmeyer	30	M1190-9002	250 mL Dedicated Platform	40	M1324-9906
500 mL Erlenmeyer	24	M1190-9003	500 mL Dedicated Platform	24	M1324-9907
1 L Erlenmeyer	12	ACE-1000S	1 L Dedicated Platform	15	M1324-9908
2 L Erlenmeyer	8	ACE-2000S	2 L Dedicated Platform	12	M1324-9909
2.8 L Fernbach	6	ACE-2800S	2.8 L Dedicated Platform	6	M1324-9910

Test tube racks, microplate holders, sticky tape, sticky pad, and other size clamps available. Contact your New Brunswick Scientific rep for details.



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 - A culture of innovation

 USA Headquarters
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 • Fax: 1.732.287.4222
 • www.nbsc.com

## Corning<sup>®</sup> Polycarbonate Erlenmeyer and Fernbach Flasks

Corning baffled and plain Erlenmeyer and Fernbach culture flasks are ideal for shaker culture applications and storage. Like all Corning flasks, the Erlenmeyer flasks are certified nonpyrogenic and sterile.

#### **Features:**

#### More Robust

- Polycarbonate construction: USP Class VI material provides excellent optical clarity and mechanical strength
- Unlike PETG, flasks will not collapse when autoclaving media or sanitizing waste
- Unlike glass, flasks will not break when dropped

#### **More Options**

- Sizes range from 125 mL to 3L
- Baffled or plain bottom options in every size

#### More Reliable

- Molded-in graduations for accuracy
- Vent cap option for continuous gas exchange while ensuring sterility and preventing leakage
- Individually packaged and radiation sterilized for ease of use
- All flasks have the highest Sterility Assurance Level (SAL) of 10<sup>-6</sup>
- Certified nonpyrogenic

#### Corning Erlenmeyer Flasks – a complete line for your shaker culture, liquid handling and storage needs

Corning Erlenmeyer Flasks are sterile, disposable and are ideal for all shaker culture applications as well as liquid handling and storage. Corning Erlenmeyer flasks are available with baffled and plain bottoms in the 125 mL, 250 mL, 500 mL, 1L, 2L and 3L sizes. The 125 mL through 1L flasks are available with flat caps or filtered vent caps. The 2L and 3L flasks are available with vent caps.





Unique baffled design with a molded-in "1/3 Fill" line for customer convenience on all 125 mL, 250 mL, 500 mL, and 1L Baffled Erlenmeyer Flasks.

## CORNING

### **Corning® Polycarbonate Erlenmeyer Flasks and Caps Ordering Information**

#### **Baffled Bottom Erlenmeyer Flasks**

Cat. No.	Description	Sterile	Qty/Cs
431405	Erlenmeyer Flask, Baffled, 125 mL, Vent Cap	Yes	50
431404	Erlenmeyer Flask, Baffled, 125 mL, Flat Cap	Yes	50
431407	Erlenmeyer Flask, Baffled, 250 mL, Vent Cap	Yes	50
431406	Erlenmeyer Flask, Baffled, 250 mL, Flat Cap	Yes	50
431401	Erlenmeyer Flask, Baffled, 500 mL, Vent Cap	Yes	25
431408	Erlenmeyer Flask, Baffled, 500 mL, Flat Cap	Yes	25
431403	Erlenmeyer Flask, Baffled, 1L, Vent Cap	Yes	25
431402	Erlenmeyer Flask, Baffled, 1L, Flat Cap	Yes	25
431256	Erlenmeyer Flask, Baffled, 2L, Vent Cap	Yes	6
431253	Fernbach Culture Flask, Baffled, 3L, Vent Cap	Yes	4

#### **Plain Bottom Erlenmeyer Flasks**

	-		
Cat. No.	Description	Sterile	Qty/Cs
431143	Erlenmeyer Flask, 125 mL, Vent Cap	Yes	50
430421	Erlenmeyer Flask, 125 mL, Flat Cap	Yes	50
431144	Erlenmeyer Flask, 250 mL, Vent Cap	Yes	50
430183	Erlenmeyer Flask, 250 mL, Flat Cap	Yes	50
431145	Erlenmeyer Flask, 500 mL, Vent Cap	Yes	25
430422	Erlenmeyer Flask, 500 mL, Flat Cap	Yes	25
431147	Erlenmeyer Flask, 1L, Vent Cap	Yes	25
431146	Erlenmeyer Flask, 1L, Flat Cap	Yes	25
431255	Erlenmeyer Flask, 2L,Vent Cap	Yes	6
431252	Fernbach Culture Flask, 3L, Vent Cap	Yes	4

#### **Replacement Erlenmeyer Flask Caps**

Corning Polypropylene Erlenmeyer Flask Caps are also available separately. They are sterile, individually packaged and available for the 500 mL and 1L<sup>\*</sup>, 2L and 3L flask sizes.

Cat. No.	Description	Sterile	Qty/Cs
431372*	43 mm Vent Cap, 500 mL and 1L Erlenmeyer Flask*	Yes	50
431339	48 mm Vent Cap, 2L Erlenmeyer Flask	Yes	24
431364	48 mm Flat Cap, 2L Erlenmeyer Flask	Yes	24
431340	70 mm Vent Cap, 3L Erlenmeyer Flask	Yes	24
431363	70 mm Flat Cap, 3L Erlenmeyer Flask	Yes	24

\*The 43 mm cap for the 500 mL and 1L sizes are available Made to Order only with a 5 case minimum.

Worldwide	India	Taiwan	United Kingdom
Support Offices	t 91-124-235 7850	t 886 2-2716-0338	t 0800 376 8660
	f 91-124-401 0207	f 886 2-2716-0339	f 0800 279 1117
ASIA/PACIFIC	Japan		All Other European
Australia	t 81 (o) 3-3586	EUROPE	Countries
t 61 2-9416-0492	1996/1997	France	t 31 (0) 20 659 60 51
f 61 2-9416-0493	f 81 (0) 3-3586	t 0800 916 882	f 31 (0) 20 659 76 73
China	1291/1292	f 0800 918 636	
t 86 21-3222-4666	Korea	Germany	LATIN AMERICA
f 86 21-6288-1575	t 82 2-796-9500	t 0800 101 1153	Brasil
Hong Kong	f 82 2-796-9300	f 0800 101 2427	t (55-11) 3089-7419
t 852-2807-2723	Singapore	The Netherlands	f (55-11) 3167-0700
f 852-2807-2152	t 65 6733-6511	t 31 20 655 79 28	Mexico
. 0,2 200, 21,22	f 65 6861-2913	f 31 20 659 76 73	t (52-81) 8158-8400
		5 551-15	







431363 Flat Cap



431340 Vent Cap

## CORNING

#### **Corning Incorporated**

*Life Sciences* Tower 2, 4th Floor 900 Chelmsford St. Lowell, MA 01851 t 800.492.1110 t 978.442.2200 f 978.442.2476

www.corning.com/lifesciences

f (52-81) 8313-8589

## **Masterflex® I/P® Precision Pump Tubing**

- Ensure optimal Masterflex<sup>®</sup> pump performance
- Custom extruded to fit Masterflex® pumps
- Engineered for long life in peristaltic pumps
- Lot-to-lot consistency provides superior accuracy and repeatability

Masterflex® I/P® pump tubing is manufactured to extremely close tolerances that match our I/P<sup>®</sup> pump heads, ensuring accurate, repeatable flow and long tubing life. Our tubing is factory-tested and optically inspected to provide the best performance from your peristaltic pump.

Our High-Performance precision pump tubing features a thicker wall compared to our Precision pump tubing, making it the best choice for applications involving pressure, suction lift, viscous fluids, or long tubing life. See page 1512 to order.



pump tubing formulation for your application, visit our Web site at www.coleparmer.com/MasterflexTubing

#### I/P® Pump Tubing Specifications

		I/P <sup>®</sup> Precision pump tubing	
Pump tubing cross sections	0	0	Ο
	I/ <b>P</b> ® 26	I/P® 73	I/P <sup>®</sup> 82
Inside diameter (nominal)	0.25" (6.4 mm)	0.37" (9.5 mm)	0.5" (12.7 mm)
Hose barb size (nominal)	1⁄4" (6.4 mm)	¾" (9.5 mm)	½" (12.7 mm)
Flow range (approximate) <sup>†</sup>	0.01 to 4 LPM	0.01 to 8 LPM	0.02 to 13 LPM
with 1 to 650 rpm drive	(0.002 to 1.1 GPM)	(0.002 to 2.1 GPM)	(0.005 to 3.5 GPM)
Maximum pressure <sup>‡</sup> , continuous	25 psi (1.7 bar)	25 psi (1.7 bar)	15 psi (1.0 bar)
Maximum pressure <sup>‡</sup> , intermittent	40 psi (2.7 bar)	40 psi (2.7 bar)	20 psi (1.4 bar)
Maximum vacuum <sup>†</sup>	26" Hg (660 mm Hg)	26" Hg (660 mm Hg)	20" Hg (510 mm Hg)
Suction lift <sup>†</sup>	29 ft H <sub>2</sub> O (8.8 m H <sub>2</sub> O)	29 ft H <sub>2</sub> O (8.8 m H <sub>2</sub> O)	23 ft H <sub>2</sub> O (7.0 m H <sub>2</sub> O)

<sup>†</sup>Determined under the following conditions: 0 psi at inlet, 0.5 psi at outlet; water temperature at 72°F (22°C).

\*Actual performance varies depending on tubing formulation—values shown are for firm tubing. Values for STA-PURE®/CHEM-SURE® pump tubing are 60 psi (4.1 bar) continuous, 100 psi (6.9 bar) intermittent.

Pump Head Compatibility

. 8

#### I/P<sup>®</sup> Precision Pump Tubing a Infe

Ordering Information*	lder de la companya d				
Pump tubing formulation	100 Secondoria	Leon Loon	I/P 26	I/P 73	I/P 82
Silicone (platinum-cured) Masterflex	1	1	<b>R-96410-26</b> /pk 25 ft (7.6 m)/pk	<b>R-96410-73</b> /pk 25 ft (7.6 m)/pk	<b>R-96410-82</b> /pk 25 ft (7.6 m)/pk
Silicone (peroxide-cured) Masterflex	1	1	<b>R-96400-26</b> /pk 25 ft (7.6 m)/pk	<b>R-96400-73</b> /pk 25 ft (7.6 m)/pk	<b>R-96400-82</b> /pk 25 ft (7.6 m)/pk
BioPharm silicone (platinum-cured) Masterflex	1	1	<b>R-96420-26</b> /pk 25 ft (7.6 m)/pk	<b>R-96420-73</b> /pk 25 ft (7.6 m)/pk	<b>R-96420-82</b> /pk 25 ft (7.6 m)/pk
BioPharm Plus silicone (platinum-cured) MASTERHEX	1	1	<b>R-96440-26</b> /pk 25 ft (7.6 m)/pk	<b>R-96440-73</b> /pk 25 ft (7.6 m)/pk	<b>R-96440-82</b> /pk 25 ft (7.6 m)/pk
C-FLEX® (50 A) Masterflex	1	<b>√</b>	<b>R-06424-26</b> /pk 25 ft (7.6 m)/pk	<b>R-06424-73</b> /pk 25 ft (7.6 m)/pk	<b>R-06424-82</b> /pk 25 ft (7.6 m)/pk
PharMed® BPT Masterflex	1	1	<b>R-06508-26</b> /pk 25 ft (7.6 m)/pk	<b>R-06508-73</b> /pk 25 ft (7.6 m)/pk	<b>R-06508-82</b> /pk 25 ft (7.6 m)/pk
PharmaPure® Masterflex		1	<b>R-06435-26</b> /pk 25 ft (7.6 m)/pk	<b>R-06435-73</b> /pk 25 ft (7.6 m)/pk	<b>R-06435-82</b> /pk 25 ft (7.6 m)/pk
STA-PURE®	1	1	<b>R-96211-26</b> /pk 24" (61 cm)/pk	<b>R-96211-73</b> /pk 24" (61 cm)/pk	<b>R-96211-82</b> /pk 24" (61 cm)/pk

\*Discounts: Save 10% on 4–9 pks, 15% on 10–19 pks, and 20% on 20 or more pks; assortable among all types and sizes except for STA-PURE® and CHEM-SURE®.

U.S. Toll-free: 800-323-4340

• Outside the U.S.: 847-549-7600 . www.coleparmer.com Canada 800-363-5900 · India 91-22-6716-2222 · UK 0500-345-300



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#### Flow Rates in LPM (GPM) per Channel

rom.		Precision pump tubing		High-performance precision pump tubing		
rpm	I/P® 26	I/P 73	I/P 82	I/P 70	I/P 88	I/P 89
A Modular digital driv	ves/dispensers					
20 to 650	0.12 to 4.0 (0.03 to 1.0)	0.2 to 8.0 (0.06 to 2.1)	0.4 to 13.0 (0.1 to 3.5)	0.2 to 8.0 (0.06 to 2.1)	0.4 to 17.0 (0.1 to 4.5)	0.5 to 19.0 (0.14 to 5.0)
B Modular digital driv	es/dispensers with wall		(0.1 to 0.3)	(0.00 to 2.1)	(0.1 to 4.3)	(0.14 10 3.0)
20 to 650	0.12 to 4.0 (0.03 to 1.0)	0.2 to 8.0 (0.06 to 2.1)	0.4 to 13.0 (0.1 to 3.5)	0.2 to 8.0 (0.06 to 2.1)	0.4 to 17.0 (0.1 to 4.5)	0.5 to 19.0 (0.14 to 5.0)

#### **Dispensing Precision**

Dianonaing mode		Precision pump tubin	g	High-performance precision pump tubing			
Dispensing mode	I/P 26	I/P 73	I/P 82	I/P 70	I/P 88	I/P 89	
Minimum dose <sup>+</sup>	400 mL	840 mL	1360 mL	840 mL	1360 mL	1750 mL	
Precision	±2.0 mL	±4.2 mL	±6.8 mL	±4.2 mL	±6.8 mL	±8.8 mL	

<sup>†</sup>For up to ±0.5% precision

#### Specifications & Ordering Information for Variable-Speed Drives

Catalog number	Motor size	Motor speed (rpm)	Speed control	Pump heads accepted	IP rating	Dimensions (L x W x H)	Power V VAC (Hz)	AC Amps	Price
A Modular o			Utiliti	uoooptou				Allips	
R-07592-20 R-07592-27	⅓ hp (150 W)	20 to 650	±0.3%	2 <sup>‡</sup>	Controller: IP22 Motor: IP34	Controller: 97%" x 93/16" x 51/16" (25.8 x 23.3 x 12.9 cm) Motor: 141/6" x 59/16" x 6" (35.9 x 14.1 x 15.2 cm)	90 to 130 (60) 190 to 260 (50)	4.4	
		digital drives/d	lispensers	with wall-mou			130 10 200 (30)	2.2	
R-07592-30 R-07592-35	⅓ hp (150 W)	20 to 650	±0.3%	2 <sup>‡</sup>	Controller: IP56 Motor: IP34	Controller: 10¼" x 11" x 4½" (26.0 x 27.9 x 11.4 cm) Motor: 14½" x 5%6" x 6" (35.9 x 14.1 x 15.2 cm)	90 to 130 (60) 190 to 260 (50)	4.4 2.2	
<sup>‡</sup> Accepts two pu	nn heads v	vhen used with	silicone or	C-ELEX tubing		· · · · · · · · · · · · · · · · · · ·			

## **Complete I/P® Variable-Speed Modular Digital Dispensing Pump Systems**

Pump Ho	ead	+ Ti	ubin	g	+	Drive				
<b>I/P Easy-Load® pump head 77601-</b> (page 1508)	-10	<b>Tygon® L</b> tubing OG 10 ft (3 m (page 15	6429-73 )	3	07592	<b>al dispensing drive</b> 2 <b>-20 or -27</b> 650 rpm /e)	Statistics of the second se	77970-20		
Catalog number		Description		Pow	/er	Price	TAX OF ALLS	ERM	1.	
R-77970-20 R-77970-27	I/P digita	al dispensing p		115 VAC, 5 230 VAC, 5						-
	15 male	connector				m) cable vn cable			0	Flow
R-07595-52 DB	15 male tem 2 in	connector		o create				Facetor, 17		Flow I 0.2 to
R-07595-52 DB	15 male tem 2 in ead	connector	Use to Ubin FL I/P 7: 5429-73	o create g	your ow + Modu 07592	vn cable Drive Jlar digital drive 2-30 or -35 650 rpm				0.2 to
R-07595-52 DB Complete Syst Pump Ho I/P® Easy-Load® pump head 77601-	15 male tem 2 in ead	connector cludes: + Ti Tygon® L tubing 00 10 ft (3 m	Use to Ubin FL I/P 7: 5429-73	o create g	• your ow • Modu 07592 20 to 0 (abov	vn cable Drive Jlar digital drive 2-30 or -35 650 rpm		10.00 11.2 - 77		

Tech Information

## MILLIPORE

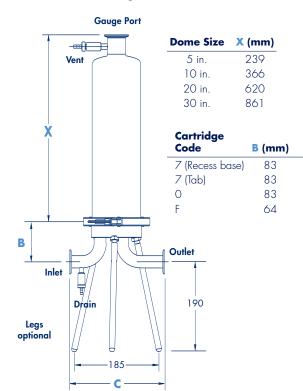


## Series 3000 U.S. Version T-Line Single-Round Housings

ASME® Compliance	ASME compliant housings have been designed in accordance to the requirements of ASME Section VIII Division 1.
CFR Compliance	The sealing materials supplied comply with the Title 21 Code of Federa Regulations, section 177.2600 for rubber compounds or 177.1550 for fluorocarbon resin, 177.1520 for olefin polymers.
USP Class VI Compliance	All seal materials comply with USP <88> Biological Reactivity Tests for Class VI plastics.
Operating Conditions	
Range:	10 bar (145 psig) at 25 °C (77 °F)
	7 bar (100 psig) at 60 °C (140 °F)
	6 bar (87 psig) at 80 °C (176 °F)
	3.2 bar (46 psig) at 145 °C (293 °F)
Materials of Construction (Wette	d Parts)
All metal surfaces in	316L (DIN 1.4404 and DIN 1.4435) stainless steel
contact with the product:	(Code 0 spring is 316 stainless steel)
Plunger valve seal tip:	PTFE (Teflon® polymer)
Diaphragm valve membrane:	EPDM
Gasket and plunger valve seal:	Silicone
Optional gasket materials:	EPDM, PTFE (Teflon polymer encapsulated Viton® fluoroelastomer)
Surface Finish (Stainless Steel Wo	etted Parts)
Electropolished (EP):	Ra ≤ 0.5 µm internal, Ra ≤ 0.8 µm external
Mechanical Polish (MP):	Ra ≤ 0.5 µm internal, Ra ≤ 0.8 µm external
Final Fill:	Electropolished Ra $\leq$ 0.4 $\mu$ m internal, Ra $\leq$ 0.8 $\mu$ m external
ASME:	Electropolished Ra $\leq$ 0.5 µm internal, Ra $\leq$ 0.8 µm external
Connections	
Gauge Port:	1½ in. Sanitary flange
Inlet/Outlet:	1 in. Sanitary flange
Cartridge Code	Code 7, 0 and F
Clamp(s)	
• • •	4 in. Sanitary flange, 3-piece 304 stainless steel clamp
ASME compliant housings:	4 in. Sanitary flange, 2-piece 304 bolted stainless steel clamp

Use our quick and easy on-line selector to configure your housing. www.millipore.com/housings

### T-Line Housing Dimensions

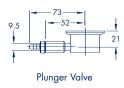


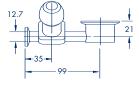
#### Vent and Drain Options





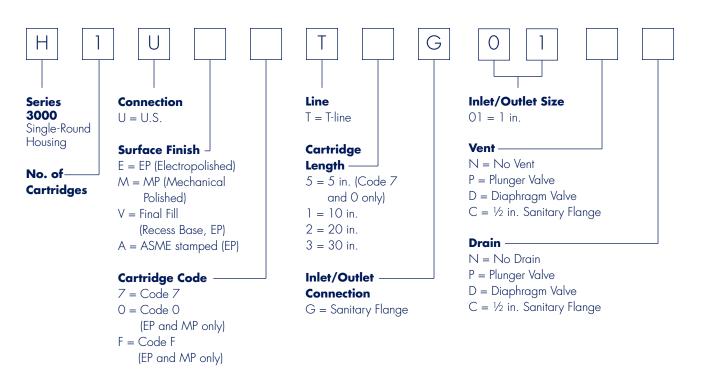
 $^{1\!\!/_2}$  in. Sanitary Flange





Diaphragm Valve

#### **Ordering Information**



**C** (mm)

202

200

202

200

Accessories

Description	Qty/Pk	Catalogue No.
Legs (stand), 304 stainless steel	3	H1S31LEG3
Pressure gauge, Kpa + bar type (0–1,100 Kpa, 0–11 bar)	]	P90005
Pressure gauge, psi + bar type (0–160 psi, 0–11 bar)	1	P90001

## Spare Parts

Description	Qty/Pk	Catalogue No.
Valves		
Plunger valve stem	2	H1PVSTEM2
Sanitary vent/drain valve seal kit with silicone O-rings and virgin Teflon PTFE sealing tips	10	HGPVSOKIT
Sanitary vent/drain valve seal kit with Viton O-rings and virgin Teflon PTFE sealing tips	10	HGPVVOKIT
Sanitary vent/drain valve seal kit with EPDM O-rings and virgin Teflon PTFE sealing tips	10	HGPVEPKIT
Diaphragm for diaphragm valve	2	H1DVDEP02
Diaphragm valve kit (bolts and washers)	1 kit	H1DVBVVKIT

### Gaskets

Silicone dome to base gasket	4 in. Sanitary flange	10	HGTC400SF
EPDM dome to base gasket*	4 in. Sanitary flange	10	HGTC400EP
PTFE (Teflon polymer encapsulated Viton fluoroelastomer)*	4 in. Sanitary flange	10	HGTC400TC
Silicone	3/4 in. Sanitary flange	10	HGTC075SF
	1 in. Sanitary flange	10	HGTC100SF
	1½ in. Sanitary flange	10	YY2004055
EPDM*	3⁄4 in. Sanitary flange	10	HGTC075EF
	1 in. Sanitary flange	10	HGTC100EF
	1½ in. Sanitary flange	10	HGTC150EF
PTFE (Teflon polymer encapsulated Viton fluoroelastomer)*	3⁄4 in. Sanitary flange	10	HGTC075TC
	1 in. Sanitary flange	10	HGTC100T
	1½ in. Sanitary flange	10	HGTC150TC
End Caps			
End cap, 316L stainless steel	¾ in.∕½ in.	2	HPLG00075IN2
	1 in./1½ in.	2	HPLG00150IN2
Clamps			
Sanitary flange	<sup>3</sup> ⁄4 in.	2	HCLMP0075IN2
	1 in./1½ in.	2	HCLMP0150IN2
Sanitary flange, 2-piece bolted 304 stainless steel clamp for ASME compliant housings	4 in.	1	P35015
Sanitary flange, 3-piece 304 stainless steel clamp standard for non-ASME compliant housing	4 in.	1	P34303

\*Silicone is the standard material used with all Series 3000 housings. EPDM and Viton are optional and must be ordered separately.



#### Literature for Series 3000 Single-Round Housings

Data Sheet Series 3000 Single-Round Housings

DS4112EN00

#### **Specification Sheets**

Version	Line Style	Literature No.	
U.S. Version	T-line Housings	SP1002ENUS	
	In-line Housings	SP1001ENUS	
	C-line Housings	SP1000ENUS	
European Version	T-line Housings	SP1020EN00	
	In-line Housings	SP1040EN00	
	C-line Housings	SP1030EN00	
Japanese Version	T-line Housings	SP1050EN00	
	In-line Housings	SP1060EN00	
	C-line Housings	SP1070EN00	

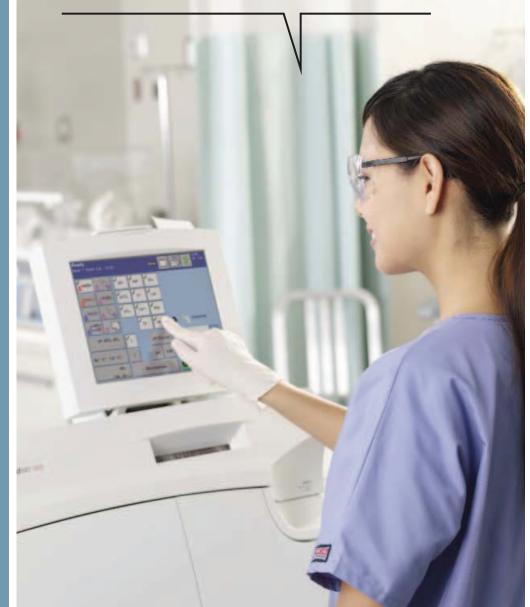
#### To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office: In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)** In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)** Outside of North America contact your local office. To find the office nearest you visit www.millipore.com/offices. Internet: www.millipore.com Technical Service: www.millipore.com/techservice

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# MILLIPORE

How can I extend the capabilities of my RAPIDLab 1200 analyzer?



# Enhanced functionality and performance for better patient care.

Version 3.0 Software for RAPIDLab 1200 Blood Gas Analyzers

Answers for life.

### SIEMENS

### RAPIDLab® 1200 Version 3.0 Software

	Enhancement	Advantage
	Measures neonatal Total Bilirubin	Extends critical decision-making for maternity and clinical staff in the neonatal setting
Enhanced Patient Care	Defines unique custom panels for microsample analysis	Increases the time to re-position the sample in the measurement chamber to 60 seconds Delivers the maximum number of results on very small patient samples Minimizes the risk of sample loss and the need to re-draw the patient
	Expands patient search criteria	Provides quick access to patient data with multiple, simultaneous search options – patient/operator ID, last name, accession number, start/end date, etc.
Fast,	Entry of patient demographic data during sample aspiration and analysis	Allows the operator to multi-task and save time
Accurate	Identification of the most commonly-used panel as the system default panel	Provides a fast, simple process with a single keystroke selection for patients critical panel
Results	Restriction of patient ID data entry to barcode only	Ensures patient ID accuracy and eliminates manual data entry
	Ability to re-install Automatic QC cartridges, if necessary	Resolves an incorrect AQC cartridge installation easily
Ease of Use	Define unique custom panels for microsample analysis	Saves time by offering customized test panels
	Auto-advance barcode entry for fields that accept barcode data	Simplifies barcode entry by minimizing keystrokes
	View, monitor and control remote systems display from RAPIDComm <sup>®</sup> workstation <sup>*</sup>	Simplifies oversight of multiple analyzers Provides the ability to monitor and troubleshoot analyzers remotely
Improved Connectivity	LIS receives sample/calibration data once only	Eliminates data redundancy Sends data automatically
connectivity	Report sO <sub>2</sub> as calculated or measured	Provides flexibility in reporting options
	Synchronize all remote systems to LIS clock	Ensures continuity between the LIS and connected instruments
Simplified	Improved analyzer wash sequences	Increases system uptime; minimizes clots Improves clearance of the waste line and minimizes sample build-up in tubing
Maintenance	Improved waste sensor calibration limits	Assess waste bottle volumes more accurately, resulting in fewer waste calibration errors
	Improved leak test	Facilitates troubleshooting Increases system uptime

\* Available with RAPIDComm Version 3.0 Software.

# Our RAPIDLab 1200 Version 3.0 software increases testing efficiency in the clinical lab and at the point of care.

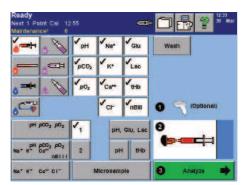




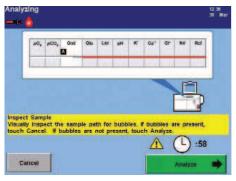
Siemens offers a family of blood gas analyzers and communication tools designed specifically to provide rapid, reliable patient results across the spectrum of critical care settings.

From delivering urgent results near a patient's bedside to supporting the demands of high-volume clinical laboratories, Siemens offers analyzers designed to help improve clinical outcomes and increase overall operational and financial efficiencies. Plus, our RAPIDComm Data Management software pulls it all together by providing access to critical blood gas results from a central workstation.

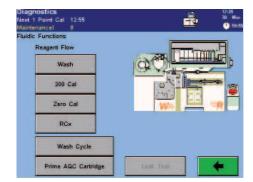
For more information, contact your Siemens Healthcare Diagnostics Representative today.



Comprehensive test menu includes optional neonatal Total Bilirubin on RAPIDLab 1245 and 1265 Blood Gas Analyzers.



Unique microsample analysis – obtain results on very small sample sizes.



Fluidic function tests facilitate troubleshooting for improved system uptime.

Siemens Healthcare Diagnostics, the leading clinical diagnostics company, is committed to providing clinicians with the vital information they need for the accurate diagnosis, treatment and monitoring of patients. Our comprehensive portfolio of performance-driven systems, unmatched menu offering and IT solutions, in conjunction with highly responsive service, is designed to streamline workflow, enhance operational efficiency and support improved patient care.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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#### www.siemens.com/diagnostics

# MILLIPORE



# **Viresolve**® NFR Filters

### Fast, reliable retrovirus removal

- ≥6 log removal of retroviruses
- >98% recovery of protein
- Robust processing
- ▶ Fast alcohol-free integrity testing
- Multiple formats available for easy scaling
- Each lot is 100% integrity tested

#### Membrane Type

Retropore void-free membrane

#### **Filter Formats**

- OptiScale<sup>®</sup>-25 disposable devices
- Opticap<sup>®</sup>, Opticap XL and XLT disposable capsule filters
- Cartridge filters

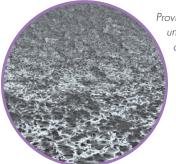
Viresolve NFR filters quickly and efficiently remove retroviruses from recombinant protein solutions or human plasma sources. Viresolve NFR filters are ideal for polishing monoclonal antibodies, and provide an easy-to-implement technology that eliminates retrovirus contaminants in essential media and protein feed streams. When placed downstream of a bioreactor, Viresolve NFR filters help you minimize product and process risk caused by viruses common to mammalian cell expression systems.

### Fast, Reliable Clearance

Cast from polyethersulfone, Retropore® membrane exhibits a patented void-free pore structure characterized by superior clearance and high flow rates. Denser internally than on its surface, the asymmetrical matrix of the membrane effectively traps large viruses and efficiently passes smaller proteins. By providing fast and highly reliable clearance, Viresolve NFR filters improve product safety and protect downstream processes.

#### **High Yields and Product Quality**

Unlike inactivation methods, filters are inert and do not degrade proteins. High protein passage and low protein binding provide >98% protein product yields, while low extractables ensure product quality. Retropore membrane technology passes proteins up to 700 kDa and consistently clears retroviruses at >6 LRV (Log Reduction Value).



Providing fast flow and unmatched retrovirus clearance, the Retropore membrane used in Viresolve NFR filters features a void-free structure in an asymmetrical matrix.

#### Improving Viral Safety Assurance

Viresolve NFR code 7 cartridges contain SMART Technology, an RFID (radio frequency identification) tag

SMART technology

embedded in the spear. Key filter data, including a filter specific diffusion value, are stored on the tag and can be read with our AccuSMART<sup>™</sup> RFID reader. You can use the reader to scan each cartridge in your multi-round housing and calculate a more accurate integrity testing specification for each housing. A print out is generated for accurate record keeping. Unlike manual methods, SMART Technology replaces the need to visually read, transcribe and manipulate this information preventing transcription and calculation mistakes.

#### Predictable Scale-up and Scale-down

Viresolve NFR filters with Retropore membrane are available in three formats and multiple configurations that vary by filtration area and the type of inlet/outlet connection. Choose the best format for your process requirements.

#### **Regulatory Compliance**

All Viresolve NFR filters are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to ISO® 9001. Viresolve NFR capsules and cartridge filters are integrity tested during manufacturing and are supported by a Validation Guide for compliance with regulatory requirements.

For traceability and easy identification, each filter is shipped with a Certificate of Quality in a sealed bag clearly labeled with the product name and identifying characteristics. Code 7 cartridges come with SMART Technology. This SMART filter has an embedded RFID tag preloaded with Catalogue Number, Lot Number, Serial Number and cartridge specific diffusion value.

Millipore has submitted a Biological Master File to the FDA and will submit it to other worldwide regulatory agencies needed to support customer applications. Please contact Millipore to obtain a Letter of Authorization to reference in your application.

#### Sizing

Sizing requires bench scale trials with small volumes of representative fluid samples, OptiScale-25 (25 mm) devices, the Low Hold Up Volume V<sub>max</sub>™ Test Kit, and comparable operating parameters to production. Flow decay is measured to assess the capacity of the filter. The volume per surface area of the trial then translates to the area needed to process a specific batch size. For a wide range of different solutions, minimal plugging is observed and sizing is based primarily on flow. The results of a typical sizing study are shown in Table 1.

#### Water Wettable Fast Integrity Testing

A convenient air-water diffusion based integrity test has been developed which relates to  $\phi 6$  retention. Passing this test provides assurance of consistent and reliable virus retention. Retropore membrane is water wettable and does not require the use of solvents such as alcohol for integrity testing.

#### **Virus Retention**

Pleated filters and OptiScale-25 disposable devices have been extensively tested using the 78 nm diameter ¢6. This bacteriophage is readily grown to monodispersed, uniform size, high titer challenges. A consistent >6.5 LRV has been observed over the range of feedstock and processing conditions shown in Table 2.

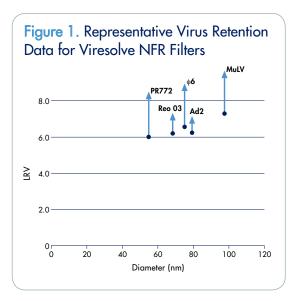
#### Table 1. Typical Process Sizing Study

Parameter	Performance
Full batch size	150 L
Process time	2 hrs
Pressure	30 psid
Feed	2.5 mg/mL
Prefiltration	None
Flow decay	<5%
Test filter	47 mm disk
Batch filter size	4-inch capsule
ф6 LRV	>6.9 LRV
MAb quality	Unchanged
MAb yield	>98%

Summary of an evaluation performed at a biotech manufacturer to determine sizing and retention for a monoclonal antibody product processed on Viresolve NFR.

# Table 2. Feedwater and ProcessingConditions for >6.5 LRV Virus RetentionUsing Viresolve NFR Filters

Condition	Range
рН	4.5-8.5
Ionic Strength	25-250 mM
Process time	up to 4 hrs
Pressure	0.3–4.1 bar (5–60 psi)
Protein concentration	0–25 g/L



## From process development to full-scale production,

#### OptiScale-25 Small Volume Disposable Devices



**OptiScale-25** Filters

OptiScale-25 disposable devices are used in small volume applications where feedstock requirements are minimal. Providing filtration area of  $3.5 \text{ cm}^2$ , these small devices are useful as an evaluation tool for impurity studies, protein passage studies, membrane area determination, and virus validation. A female Luer-Lok®/male luer slip connection ensures fast and secure setup. OptiScale-25 devices are sold as Evaluation Kits, each kit including 9 capsules: 3 devices each of 3 different membrane lots. These



kits are ideal for use in validation and sizing studies with Millipore's Low Hold Up Volume V<sub>max</sub> Test Kit.

Evaluation Kit

#### **Opticap XL and XLT Disposable Capsule Filters**



Opticap XL Filters

#### Convenient and Easy to Use

Capsule filters eliminate the time and expense associated with assembling, cleaning, and validating stainless steel housings. Adjustable, easy-to-turn, upstream vents and drain valves with O-ring seals

and hose barb connections allow for easy process control. Other ease-of-use



#### The Right Connections

Self-contained and disposable, Opticap XL and XLT capsule filters are supplied with a choice of inlet and outlet connections to optimize your filtration process, including sanitary flanges which provide a high flow rate and hose barb.

#### **Proven Integrity**

Each capsule is integrity tested during the manufacturing process to ensure reliable performance in your process.



Opticap XLT Filters

#### **Robust Construction**

Opticap XL and XLT's capsule design allows unparalleled thermal and hydraulic stress resistance in a disposable filter, resulting in reliability, high confidence in the sterilization process, and improved cleanliness.

#### **Opticap XL Capsule Filters**

Opticap XL disposable capsule filters offer a unique design which minimizes hold-up volume and reduces production losses. Available in the XL10 capsule size.

#### **Opticap XLT Capsule Filters**

Opticap XLT disposable capsule filters offer a T-line design that accommodates series or parallel filtration and a specially-designed stand enables quick and easy



integration into your process. Available in Opticap XLT10, XLT20 and XLT30 capsule sizes.

XLT Capsule Stand

## Millipore has the right format for you!

#### **Opticap Disposable Capsule Filters**



**Opticap** Filters

The capsule's unique construction and pleated membrane minimize hold-up volume and reduce production loss. Opticap housings feature a patented design that withstands high thermal and hydraulic stress, assuring sterilization compatibility and the cleanest process possible.

#### **Cartridge Filters**



Cartridge Filters

Viresolve NFR 10-, 20- and 30inch cartridge filters are ideally suited for processes that require maximum pressure differentials. Each cartridge is integrity tested during the manufacturing process. A range of filtration areas is available to suit medium and large volume requirements.



### **SMART Filters**

#### Additional Viral Safety Assurance Built In

Viresolve NFR code 7 cartridges contain SMART Technology, an RFID (radio frequency identification) tag embedded in the spear. These tags are fully isolated from the flow path and do not affect filter performance. Each tag is capable of reliably storing several hundred alphanumeric characters. Key filter data including; catalogue number, lot number, serial number and cartridge specific diffusion value are stored on the tag and can be read with our AccuSMART RFID reader. The reader software will read each cartridge in your multi-round housing and then calculate the integrity testing specification for this housing. A print out can be generated for accurate record keeping. Unlike manual methods, SMART Technology replaces the need to visually read, transcribe and manipulate this information preventing transcription and calculation mistakes.

Save time and prevent errors make SMART decisions today.



SMART

#### A Mobius technology.

Mobius solutions feature a range of disposable technologies and services to optimize biopharmaceutical processes. 2 mobius"

flexible bioprocessing solutions

### Specifications

	OptiScale-25	10-inch Cartridge	20-inch Cartridge	30-inch Cartridge
Materials of Construction				
Filter membrane:	Polyethersulfone	Polyethersulfone		
O-ring:	Silicone	Silicone		
Cage, core, end caps, non-				
woven supports, film edge:		Polypropylene		
Cap and base:	Acrylic	N/A		
RFID tag:	_		PS), overmolded in polypropy	lene spear
Standard Connections	Female Luer-Lok, male luer slip fittings	Code 7 (2–226) O-ring	g, bayonet with spear	
Maximum Operating Line Pressure (at 25 °C)	4.1 bar (60 psi)	5.5 bar (80 psi)		
Maximum Differential				
Pressure (at 25 °C)				
Forward:	4.1 bar (60 psi)	5.5 bar (80 psi)		
Reverse:	0.7 bar (10 psi)	3.4 bar (50 psi)		
Wetting/Flushing	Water wet filter for 10 min c	at 2 bar (30 psi) or for 5	min at 3.4 bar (50 psi) to a v	olume of 75 L/m².
Autoclaving	Not autoclavable. Sold gamma irradiated	After wetting, may be a using liquid cycle, slow	utoclaved for 3 cycles of up to exhaust.	o 60 min at 125 °C,
Non-volatile Residue (NVR) <sup>1</sup>	_		a 10 min 1.5 Lpm/ft² flush, af controlled room temperature:	ter 24 hrs in ASTM® Type 1
		≤ 35 mg	≤ 70 mg	≤105 mg
Bacteriophage Retention <sup>1</sup>	Lot release testing on sample	es exhibited ≥6 LRV for ¢ć	o (78 nm) at a challenge of 10	0 <sup>7</sup> pfu∕cm².
Bacterial Endotoxin <sup>1</sup>	Aqueous extraction contains	< 0.5 EU/mL as determined	ined by the Limulus Amebocyte	e Lysate (LAL) test.
Non-fiber Releasing <sup>1</sup>	Component materials meet o	criteria for a "non fiber rel	easing" filter as defined in 21	CFR 210.3 (b)(6).
Oxidizable Substances <sup>1</sup>	_	Meet the requirements of	of the USP Oxidizable Substar	nces Test after a water flush of:
		4,000 mL	8,000 mL	12,000 mL
Component Materials Toxicity <sup>1</sup>	Component materials were t toxic per the USP <88> Rea		a of USP <88> Reactivity Tes	t Class VI Plastics, and are nor
Integrity Test Specification <sup>1</sup>	_	Air/water diffusion rate	s at 23 °C, 3.4 bar (50 psi):	
		≤ 16 cc/min	≤ 32 cc/min	≤48 cc/min
Thermal and Hydraulic Stress <sup>1</sup>	_		·	xhibited integrity after a forwar psid (3.4 bar).
Good Manufacturing Practices	These products are manufac FDA Good Manufacturing P	tured in a Millipore facilit		
SMART Data	—	Embedded on the RFID	tag: Catalogue No., Lot No., ge Specific Diffusion Value.	SMAR

<sup>1</sup>A Certificate of Quality validating these specification is included with every shipment.

#### SMART technology

### Sizing Guidelines

Device	Effective Filtration Area	Typical Processing Volume	Length	Typical Hold-up Volume*
OptiScale-25 Capsule	3.5 cm <sup>2</sup> (0.54 in. <sup>2</sup> )	0.165 L	2.2 cm (0.87 in.)	1 mL
4-inch Opticap Capsule	0.093 m <sup>2</sup> (1.0 ft <sup>2</sup> )	120–240 L	17.2 cm (6.75 in.)	35 mL
10-inch Opticap Capsule	0.43 m <sup>2</sup> (4.6 ft <sup>2</sup> )	600–1,200 L	34.8 cm (13.7 in.)	175 mL
10-inch Cartridge Filter	0.43 m <sup>2</sup> (4.6 ft <sup>2</sup> )	600–1,200 L	30.5 cm (12 in.)	175 mL
20-inch Cartridge Filter	0.854 m <sup>2</sup> (9.2 ft <sup>2</sup> )	1,200–2,400 L	60.5 cm (22 in.)	325 mL
30-inch Cartridge Filter	1.281 m² (13.8 ft²)	1,800–3,600 L	86.6 cm (31.5 in.)	490 mL

\*On filtrate side, after 1 minute of 20 psi upstream air pressurization.

### Specifications

	4-inch Opticap	10-inch Opticap	Opticap XL 10	Opticap XLT 10	Opticap XLT 20	Opticap XLT 30
Materials of Construction						
Filter membrane:	Polyethersulfone					
Cage, core, end caps,						
non-woven supports,						
film edge, capsule						
housing: Vent O-rings:	Polypropylene Silicone					
Standard Connections	1 <sup>1</sup> /2 in. Sanitary flan	0.0				
Vent/Drain	$\frac{1}{4}$ in. Hose barb wi	•	eal			
Maximum Operating	5.5 bar (80 psi)		eui			
Line Pressure (at 25 °C)	5.5 bdi (80 psi)					
Maximum Differential						
Pressure (at 25 °C)						
Forward:	5.5 bar (80 psi)					
Reverse:	3.4 bar (50 psi)					
Wetting/Flushing	Water wet filter for 10 min at 2 bar (30 psi) or for 5 min at 3.4 bar (50 psi) to a volume of $75 \text{ L/m}^2$ .					
Autoclaving	After wetting, may be autoclaved for 3 cycles of up to 60 min at 125 °C, using liquid cycle, slow exhaust.					
Non-volatile Residue (NVR) <sup>1</sup>	Extractables level aft room temperature:	era 10 min 1.5 L	pm/ft² flush, after 24	hrs in ASTM® Type	1 reagent-grade wat	er at controlled
	≤7 mg	≤ 35 mg	≤ 35 mg	≤ 35 mg	≤ 70 mg	≤ 105 mg
Bacteriophage Retention <sup>1</sup>	Lot release testing or	samples exhibited	d ≥6 LRV for <b>φ</b> 6 (78	nm) at a challenge c	of 10 <sup>7</sup> pfu/cm².	
Bacterial Endotoxin <sup>1</sup>	Aqueous extraction of	contains <0.5 EU/	mL as determined by	r the Limulus Amebo	cyte Lysate (LAL) test.	
Non-fiber Releasing <sup>1</sup>	Component material	s meet criteria for	a "non fiber releasing	g" filter as defined ir	n 21 CFR 210.3 (b)(6	»).
Oxidizable Substances <sup>1</sup>	Meet the requiremen	ts of the USP Oxic	lizable Substances Te	est after a water flusl	n of:	
	800 mL	4,000 mL	4,000 mL	4,000 mL	8,000 mL	12,000 mL
Component Materials Toxicity <sup>1</sup>					Test Class VI Plastics. % sodium chloride ex	traction.
Integrity Test Specification <sup>1</sup>	Air/water diffusion r					
<b>3</b> / 1		≤ 16 cc/min	≤ 16 cc/min	≤ 16 cc/min	≤ 32 cc/mi	≤ 48 cc/min
Thermal and Hydraulic Stress <sup>1</sup>	Lot release testing or and a reverse stress			d integrity after a fo	orward stress to 80 ps	id (5.5 bar)
Good Manufacturing Practices	These products are r	nanufactured in a	Millipore facility which	ch adheres to FDA C	Good Manufacturing F	Practices.

<sup>1</sup>A Certificate of Quality validating these specifications is included with every shipment.

### Sizing Guidelines

Device	Effective Filtration Area	Typical Processing Volume	Length	Typical Hold-up Volume*
Opticap XL 10 Capsule	0.43 m² (4.6 ft²)	600-1,200 L	34 cm (13 in.)	175 mL
Opticap XLT 10 Capsule	0.43 m <sup>2</sup> (4.6 ft <sup>2</sup> )	600–1,200 L	38 cm (15 in.)	175 mL
Opticap XLT 20 Capsule	0.854 m² (9.2 ft²)	1,200–2,400 L	62 cm (25 in.)	325 mL
Opticap XLT 30 Capsule	1.281 m² (13.8 ft²)	1,800–3,600 L	87 cm (34 in.)	490 mL

\*On filtrate side, after 1 minute of 20 psi upstream air pressurization.

### Ordering Information

Device	Connections	Qty/Pk	Catalogue No.
OptiScale-25 Capsule Evaluation Kit	Female Luer-Lok, male luer slip	3 × 3 (9)	SZRV A25 NB9
Low Hold Up Volume V <sub>max</sub> Test Kit	For use with OptiScale-25 devices	1	VIRUSVMAX
4-inch Opticap Capsule	1 1⁄2 in. Sanitary flange inlet and outlet	3	KZRV 04T C3
10-inch Opticap Capsule	1 1⁄2 in. Sanitary flange inlet and outlet	1	KZRV 01T C1
Opticap XL 10 Capsule	1 1⁄2 in. Sanitary flange inlet and outlet	]	KZRV A1OT T1
Opticap XLT 10 Capsule	1 1⁄2 in. Sanitary flange inlet and outlet	1	KZRV A1TT T1
Opticap XLT 20 Capsule	1 1⁄2 in. Sanitary flange inlet and outlet	1	KZRV A2TT T1
Opticap XLT 30 Capsule	1 1⁄2 in. Sanitary flange inlet and outlet	1	KZRV A3TT T1
10-inch Cartridge Filter	Code 7 (2-226) O-ring bayonet with spear	]	CZRV 71T P1
20-inch Cartridge Filter	Code 7 (2-226) O-ring bayonet with spear	1	CZRV 72T P1
30-inch Cartridge Filter	Code 7 (2-226) O-ring bayonet with spear	1	CZRV 73T P1
Standard Opticap XLT Capsule Stand		1	XLTS TAN D1

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# MILLIPORE

Good Day

I am pleased to submit the following quotation for a Gruenberg Cabinet Oven. Please carefully review the technical details of this proposal. We have done our best to match the appropriate oven technology to the requirements of your process, as we understand them. However, we would be happy to revise the proposal if there is a need to change the approach.

#### OVEN PROPOSAL AND SPECIFICATION GRUENBERG MODEL CG65V240SS DEPYROGENATION OVEN

The unit proposed is an NFPA 86 Class "B" oven that is not designed or equipped for use with solvents or combustible material of any kind.

#### **1.0 PROCESS AND OVEN OVERVIEW**

Gruenberg shall design and build a cabinet oven to be used for glassware drying and depyrogenation.

AIR CIRCULATION	HEAT RATING	HEAT TYPE
Vertical Up	27 kW	Electric
OPERATING TEMPERATURE	MAXIMUM TEMPERATURE	VOLTAGE
250°C	343°C	208V/3Ø/60Hz (83 FLA)

#### 2.0 EQUIPMENT DESCRIPTIONS AND MATERIALS

NOMINAL OVEN DIMENSIONS*	WIDTH	DEPTH	HEIGHT
Interior	30"	30"	42"
Exterior	36 ½" Cabinet	48.38"	84" cabinet
Material of Construction	Material	Thickness	Finish
Interior:			
Floor	304L Stainless Steel	16 ga.	2-В
Walls	304L Stainless Steel	18 and 20 ga	2-В
Ceiling	304L Stainless Steel	18 and 20 ga.	2-В
Hardware	304 Stainless Steel	As required	As required
Exterior	304 Stainless Steel	18 and 20 ga.	#4 polish
Insulation	Fiberex	3"	

\* Subject to minor modifications if dictated by further engineering design study.

#### **3.0 EQUIPMENT DESCRIPTIONS**

#### 3.1 CHAMBER CONSTRUCTION

The oven shall be constructed from a welded heavy-duty steel frame that supports the interior stainless steel chamber and the exterior sheet metal. All interconnecting struts are non-continuous from inner to outer walls, thus keeping the exterior as cool as possible. Insulation will surround the work chamber on all sides including the floor.

#### 3.2 CONTINUOUSLY WELDED, SEALED LINER: 304L STAINLESS STEEL

All materials within the oven's interior are 304L stainless steel. A continuously welded liner separates the oven environment from the insulation and helps prevent contamination of the product. The design is such that the effect is one continuously welded sealed vessel from the point in make up air intake to the point of worked exhaust.

#### 3.3 DOOR

A single door of double wall construction, hung on the left by heavy-duty industrial hinges, shall be provided. Both door and oven are reinforced at all attachment points in order to maintain true door operation. The door closes against the oven cabinet over a stn. stl. wire mesh gasket and is held closed by dual cam-action latch.

#### 3.4 AIR HEATING SYSTEM (ELECTRIC)

Electric heat is supplied by seamless-tubular incolloy type heaters that produce a high energy, efficient output. The heaters are suspended in the plenum, adjacent to, but separate from the process chamber, so that work in progress and operators are protected. Terminal ends are inserted through the walls of the oven and use sufficient dead zones so that heat is not generated beyond the plenum. All heaters are wired with double nut connections.

#### 3.5 PROCESS AIR CIRCULATION

To insure uniform heat distribution throughout the oven chamber and optimize efficiency, a high volume vertical up airflow system is installed in the unit. A circulation fan, located in a plenum chamber on the top of the oven, directs air to a circulation duct down the back of the oven. The air enters the work space near the bottom of the work chamber and flows vertically up through the product, and is directed back to the fan for reheating and recirculation.

The circulation fan is located entirely within the insulated walls of the oven. It is connected to an extended shaft directly to a suitable ball bearing electric motor, which is mounted to the exterior of the oven cabinet.

#### 3.6 SHELVING

Four (4), wire rack, 304 stainless steel shelves are provided standard with the unit. Seven shelf slides will be installed on 6" centers.

#### 3.7 AIR FILTER

An aluminum mesh filter shall be installed on the air inlet. The filter will be contained in a separate housing designed for easy replacement.

#### 3.8 INTERNAL LIGHT (OPTIONAL)

A light shall be installed in the internal chamber with a separate switch on the control panel.

#### 3.9 POWERED EXHAUST

A 140 CFM powered exhauster is installed to remove water vapor created during the drying process. A butterfly exhaust damper shall be included on the exhaust tube to allow the customer to optimize the exhaust rate to dry the glassware and minimize heat loss out of the chamber.

#### **4.0 CONTROLS AND INSTRUMENTATION**

4.1 CONTROL PANEL NEMA 1

All operating controls for the oven are housed in a single NEMA 1 UL approved panel, thermally insulated from the hot work chamber, mounted on the top of the oven. Circuit wiring is complete, including a step-down transformer to provide the control circuits with 110-volt power. Wiring in the panel terminates in a suitable block for connection to the customer's power supply.

#### 4.2 TEMPERATURE CONTROLLER

A Yokogawa UP350 programmable controller shall be supplied as the temperature control device. The UP 350 is a precision controller, featuring two program profiles and universal input/output. For easy operation, it is provided with a large display for process variables, two program operation keys, and a program reset key. It also has a retransmission output and loop power supply for a sensor as standard.

#### 4.3 HIGH LIMIT THERMOSTAT

A separate, independent Yokogawa UT150L-RN/AL high limit thermostat shall be provided to deenergize the heating system should the process temperature reach the customer's preset limit. The high limit control must be manually reset to reactivate heating.

#### 4.4 AUDIBLE / VISUAL ALARM

A pilot light shall be installed on the control panel that will indicate a high/low limit temperature condition. Also, at the same time an audible buzzer will sound. The light and buzzer will remain on until manually shut off.

#### 4.5 AIRFLOW SWITCH

A pressure differential switch shall be installed and located in the air stream of the circulation system. Upon failure of the circulation system, the airflow switch will de-energize the heater circuit.

#### 4.6 SEPARATE MAIN POWER RELAY

This relay is in addition to the normal relays serving the heater circuits. It is wired into the control circuit so that the high limit thermostat activates it. Should the main relays become mechanically frozen, as a result of extended use, this "back up" relay is deactivated and the heat system will be de-energized.

#### 4.7 DOOR SWITCH

A door switch is installed on the oven to de-energize the heating and circulation systems when the oven door is opened. This is to prevent hot air from being expelled from the oven should the door be opened during the heating cycle.

#### 4.8 TEMPERATURE RECORDER (OPTIONAL)

A Honeywell DR4300GP single pen recorder, with a 10" diameter circular chart and 24-hour chart speed is provided. The unit includes a thermocouple type J temperature sensor.

#### 4.9 PROCESS TIMER

The oven shall be supplied with a microprocessor-based, solid-state timer that features a 4½ digit display with ½" tall digits. Programming is entered through a sealed, membrane keypad. Operational mode enunciators also appear on the display. The timer provides 5 user-selectable timing ranges up to 200 hours. Unless otherwise specified, the timer will be factory set for the 199-hour range. Timing accuracy is  $\pm 0.001\%$ . U.L. and C.S.A. recognized.

#### 4.10 SCR / SSR

The power controls are installed to proportion power to the heaters only as necessary to maintain setpoint temperature. This minimizes swings in setpoint temperature, provides good temperature uniformity within the chamber, and conserves energy.

#### 5.0 INSTALLATION AND START UP (OPTIONAL)

Installation is not a part of the base Proposal cost. Gruenberg personnel are available to supervise the installation and/or start up of this equipment. The charge for these services is \$1075.00 per man per day plus meals, lodging, and travel expenses.

#### 6.0 ENERGY EFFICIENCY

Connected Services: Maximum usage under all systems full-load operation shall be supplied with confirmation drawings.

#### 7.0 ENGINEERING AND DRAWINGS

General Assembly confirmation drawings, when specified, shall be made available within 3 weeks of order placement.

#### 7.1 MANUALS

Gruenberg shall supply one- (1) operation and maintenance manual, complete with lubrication specifications, routine maintenance, complete parts list, wiring, mechanical drawings, electrical schematics, ladder logic, and sequence of operations. Additional manuals are available for \$150.00 each.

#### **8.0 EQUIPMENT GUARANTEE**

Gruenberg guarantees that the oven will perform the conditions described in this proposal for a minimum of one year. Standard Gruenberg warranty shall apply in the case of any necessary repairs: 90 days parts and labor, 12 months on parts.

#### 9.0 SCHEDULE

#### IMPORTANT INFORMATION REGARDING YOUR DELIVERY DATE:

1) 10 to 12 weeks after receipt of customer signed approval drawings.

- 2) Approval drawings will be available for customer review approximately 3 weeks after receipt of order.
  - a) approval drawings need to be signed and returned to TPS within one week after receipt.
  - b) any delay beyond one week may cause the delivery date to be adjusted.

#### 3) The quoted delivery date, as stated above:

- a) is based on the best estimate at time of quotation.
- b) can vary depending on the current backlog at the time of order placement.
- c) is subject to credit approval
- d) is subject to mutually agreed to Terms & Conditions
- e) is valid for 60 days from date of quote

10.0 QUOTATI	ON
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Item	Qty.	Description	Cost
11.1	1	Gruenberg Model CG65V240SS Cabinet Oven as described in this proposal.	\$
		Optional	
3.6	1	Additional stainless steel wire rack shelf	\$
3.8	1	Internal Light with light switch	\$
4.8	1	Temperature Recorder, Honeywell DR4300	\$
5.0	1	Gruenberg Installation	Inquire

\*The prices quoted are valid for a period of 30 days from the date of this proposal.

#### **11.0 OTHER TERMS AND CONDITIONS**

#### 11.1 SHIPMENT

Shipments are F.O.B. New Columbia, PA, and unless the customer specifies otherwise, a common carrier shall be used, and the freight charges shall be pre-paid and added to the invoice. Gruenberg shall select our preferred shipper for the product being shipped. A customer supplied freight carrier can be used if the shipment is to be "collect." Should the customer request the shipping costs be "collect," the carrier needs to be specified.

#### **11.2 PAYMENT TERMS**

The costing of the equipment and scope of work outlined in this proposal is based on the following payment schedule.

25% with order placement, to be invoiced after receipt of purchase order 75% net 30 days

Either tax exemption certificates are to be supplied with all sales within PA, NJ, CA, NY, and MN, or tax exemption is to be stated on the purchase order along with the exemption number.

SIGNED: Greg Mitcheltree	TITLE	DATE			
Greç Mitcheltree	Applications Engineer				
Thermal Product Solutions -a unit of SPX, 2821 Old Route 15, New Columbia, PA 17856 PHONE: 570-538-7220 FAX 570-538-7390					

**Confidentiality Notice:** The information contained in this Proposal is confidential, may be privileged and is intended by Lunaire Limited, an SPX Corporation, for the individual or entity named in the proposal. If you the reader of this proposal are not the intended recipient, you are expressly prohibited from copying, disseminating, distributing, or in any other way using any of this information contained in this proposal.

#### TERMS AND CONDITIONS OF SALE

1. ACCEPTANCE, GOVERNING PROVISIONS AND CANCELLATION. No orders for equipment, machinery, parts, or other products (collectively "Products") or Services shall be binding upon TPS ("Seller") d/b/a Blue M Electric, Gruenberg, Lunaire or Tenney until accepted in writing by an authorized official of Seller at its home office in New Columbia, Pennsylvania or at its plant handling and processing such orders, and in all events any sale by Seller to Buyer is expressly conditioned upon Buyer's acceptance of the terms and conditions set forth herein. They supersede and reject any conflicting terms and conditions of Buyer, any statement therein to the contrary notwithstanding. Exceptions to or modifications of any of Seller's terms and conditions, at any time, must be contained in a written or typed (not printed) statement from Buyer. Seller shall not be deemed to have waived any of its terms and conditions or to have assented to any exception to or modification of such terms and conditions unless such waiver or assent is in writing and signed by Seller's authorized officer. No order accepted by Seller may be canceled or altered by the Purchaser except upon terms and conditions acceptable to Seller.

No representation of any kind is made by Seller except as set forth herein. The Agreement formed upon these terms conclusively supersedes all prior writings and negotiations with respect to the Products or Services to be furnished hereunder and Seller shall furnish only the quantities and Products or Services specifically listed on the face hereof or the pages attached hereto; Seller assumes no responsibility for furnishing other equipment or material shown in any plans or specifications for a project to which the Products or Services ordered herein pertain. Seller's published or quoted prices, terms and conditions are subject to change without notice. All quotations are subject to correction for clerical errors.

2. **PRICES.** Unless otherwise noted in the quotation, published or quoted prices are net F.O.B. Seller's factory (location of factory determined by Products ordered). Unless otherwise noted in the quotation, service time of factory-trained service personnel is not included and may be charged extra.

3. **DELIVERY AND DELAY.** Delivery of Products to a carrier at Seller's plant or other loading point shall constitute delivery to Purchaser and any further cost and responsibility thereafter, for claims, delivery, loss or damage, including placement and storage at installation site, shall be borne by Purchaser. Seller reserves the right to make delivery in installments, and all such installments to be separately invoiced and paid for when due per invoice, without regard to subsequent deliveries. Delay in delivery of any installment shall not relieve Purchaser of its obligations to accept remaining deliveries. Claims for shortages or other errors in delivery must be made in writing to Seller within ten (10) days after receipt of shipment and failure to give such notice shall constitute unqualified acceptance and a waiver of all such claims by Purchaser. On all shipments F.O.B. Seller's plant, delivery of Product to initial carrier will constitute delivery to Purchaser and all Products will be shipped at Purchaser's risk. For all Products exported by Seller from the U.S. legal title to the goods shall pass at the Seller's shipping point, with all risk of loss and damage to Products and liability for shipment transferring F.O.B. Seller's shipping point. A claim for loss or damage in transit must be entered with the carrier and prosecuted by the Purchaser.

All supervision and labor for Services provided by Seller shall be on the basis of eight (8) hours per day, Monday through Friday, inclusive. If it is mutually agreed that other working periods are required, Purchaser shall pay the additional charges, allowances and any other costs resulting therefrom.

Dates for the furnishing of Services or delivery, shipment and installation of Products are estimated dates only, and are figured from the date of receipt of complete technical data and approved drawings as such may be necessary. In estimating such dates, no allowance has been made, nor shall Seller be liable directly or indirectly for any of the following delays whether they affect Seller or any of its suppliers or subcontractors: delays of carriers or delays from labor difficulties, shortages, strikes or stoppages of any sort, fires, accidents, failure or delay in obtaining materials or manufacturing facilities, acts of government affecting Seller directly or indirectly, bad weather, any causes beyond Seller's reasonable control, or any causes designated Acts of God or force majeure by any court of law. In the event such delays arise, Seller shall be granted a reasonable time to resume performance and the estimated

delivery date shall be extended accordingly. Seller shall not be liable for any damages or penalties whatsoever, whether direct, indirect, special or consequential, resulting from its failure to perform or delay in performing, whether or not such failure or delay is attributable to the causes specified in this section 3. If shipping or progress of the work is delayed or interrupted by the Purchaser, directly or indirectly, the Purchaser shall pay Seller for all additional charges resulting therefrom.

4. **SUBSTITUTES, CHANGES AND IMPROVEMENTS.** Seller may, at its option, furnish suitable substitutes for materials unobtainable because of priorities or regulations established by government authority or unavailability of materials from suppliers. Details of design and construction as stated in the quotation may be only approximate and are therefore subject to revision by Seller. If any changes in the layout or arrangement for Product are desired or required by conditions of which Seller was unaware or which were unforeseen at the time the quotation was submitted, the price is subject to revision.

5. **STORAGE.** If the Products are not shipped within five (5) days after notification has been made to the Purchaser that they are ready for shipping, for any reason beyond Seller's reasonable control, including without limitation the Purchaser's failure to give shipping instructions, Seller may store the Products at the Purchaser's risk and expense in a warehouse or upon Seller's premises, and the Purchaser shall pay all handling, transportation and storage costs at the prevailing commercial rates upon submission of invoices for such charges.

6. **INSURANCE.** Prior to full payment of the purchase price, Purchaser shall keep insured, Products shipped to Purchaser by Seller under policies naming Seller as coinsured party with such provisions, for such amounts and with such insurers as shall be satisfactory to Seller and, upon Seller's request, Purchaser shall furnish evidence of such insurance satisfactory to Seller.

7. **INSTALLATION.** When specified in Seller's quotation, the Services of a competent service technician to supervise the starting and/or installation or erection of the equipment and to instruct the Purchaser's representative in its operation are included. These Services will be supplied for the specified number of days. If such Services are required for a period in excess of that time, the Purchaser will pay for such additional Services at the specified rate per day plus additional living expenses and travel expenses as may be incurred by reason of the extension of the period of service. Supervision of installation shall run concurrently with dryout time, start up time and instruction of the Purchaser's personnel.

When installation, assembly or erection is specified in the quotation, Purchaser shall deliver all of Seller's material to erection site, obtain all necessary licenses and permits and pay all inspection fees. Also Purchaser shall provide, at its expense, the following: erection site; all building modifications, pits, covers, grates, stairs, ladders, rails, foundations, floor reinforcements and bolts, footings, shims, grouting; cleared floor space maintained free of water, debris and obstructions on ground and overhead; safe and convenient storage area adjacent to the installation site for Seller's equipment and material; crane with operator, and all electric current, compressed air, fuel, clean water, drains, sewers, ventilation, hoods, stacks, terminal circuit breakers, cut-off valves, etc. as required for erection or installation, and operation at the site of erection. Purchaser shall also supply oil for quench tanks and hydraulic systems, salt for salt baths and quench tanks, fuses for all electrical components, and replaceable filters and gas, where required. The current, and kind of electricity, and the pressure and quality of fuel, air, water, etc. shall be maintained within the specifications set forth in the quotation. If work is required in freezing or severe weather, Purchaser will furnish heat and covering as required by Seller for suitable installation progress. Seller may delay such installation or erection until work conditions at installation site have been prepared so as to permit work to proceed without interruption due to elements or other causes.

Surplus materials supplied by Seller remain Seller's property and will be disposed of by it.

Seller will not be responsible for work done or material furnished by the Purchaser for Seller's benefit without written orders signed by authorized representatives of both parties at agreed-upon total rates. Back charges will not be recognized without Seller's prior written acceptance of such charges and approval of amounts.

8. **PAYMENT.** Payment dependent on dollar value of the contract shall be due, subject to credit approval, as follows:

- A. Standard Units
- B. Custom Units

- = Net 30 days after shipment, with approved credit.
- = 25% advance payment due with order
- 25% upon delivery of approval drawings
- 25% with completion of material fabrication
- 15% at the time of shipment
- 10% due net 30 days following shipment.

All orders for Products or Services to be shipped to any destination outside the U.S., shall be paid either in cash in advance or by a clean, irrevocable letter of credit confirmed to Seller by a U.S. bank acceptable to Seller. All banking charges shall be paid by Purchaser.

A service charge of 1.5% per month (18% per annum) or the maximum permitted by law, whichever is less, shall be added to past due balances. If at any time the financial condition of the Purchaser does not justify the terms of payment specified, Seller may demand full or partial payment and other assurances in advance before proceeding with the work, or at its option without prejudice to other remedies, Seller may defer delivery or cancel this contract. If delivery is deferred, the Products may be stored as provided in Paragraph 5 above and Seller may submit a new estimate and cost for completion based upon prevailing conditions.

9. **TEST AND USE OF EQUIPMENT.** If the quotation sets forth performance specifications of any kind, testing to prove compliance shall be based on specifications approved by Seller that indicate the procedure to be followed, the responsibility of each party, and the place at which the test will be performed. If tests are performed in the Purchaser's plant, Purchaser shall assume all responsibility for fire or explosion or damage of any kind in the starting, testing, and subsequent operation of the equipment. When such tests have been successfully completed, Seller shall have no further liability or obligation under the contract except under Paragraph 13 (Warranty) and Paragraph 16 (Patents) hereof. Any use or operation of the equipment by the Purchaser shall constitute acceptance thereof and payment in full shall be required.

10. **TAXES AND OTHER CHARGES.** Any manufacturer's tax, retailer's occupational tax, use tax, excise tax, duty, custom inspection or testing fee, or any other tax, fee or charge of any nature whatsoever imposed by any governmental authority, on or measured by the transaction between Seller and the Purchaser shall be paid by the Purchaser in addition to the prices quoted or invoiced. In the event Seller is required to pay any such tax, fee or charge, the Purchaser shall reimburse Seller therefor or, in lieu of such payment, the Purchaser shall provide Seller at the time the order is submitted with an exemption certificate or other document acceptable to the authority imposing same.

11. **OSHA, SAFETY DEVICES, F.M., F.I.A., ETC.** Products are not required to conform to any standards, except OSHA, unless the same are set forth in the quotation. Where conformance is part of the installation, Seller will furnish any required equipment or appurtenances, beyond those specifically indicated in the quotation only when mutually agreed upon in a written agreement signed by Seller.

12. **RETURN OF MATERIAL.** Equipment must not be returned without obtaining return material authorization and shipping instructions from Seller. Any material returned shall be subject to restocking and reconditioning charges and must be returned with all shipping charges prepaid by Purchaser.

LIMITED WARRANTY. Seller warrants that equipment and parts manufactured by it and supplied hereunder to be free from 13. defects in materials and workmanship for a period of ninety (90) days after shipment (or installation, if by Seller), unless an extended warranty for specific equipment and parts is expressly stated in Seller's quotation or in an authorized warranty policy document issued to Purchaser by Seller for specific equipment or parts. Seller warrants, for a period of ninety (90) days from the date of service performance, that any Service performed for the Purchaser hereunder to be free from defects in workmanship. If within such period any such equipment, parts or Services shall be proved to Seller's satisfaction to be defective, such equipment or parts shall be repaired or replaced at Seller's option, and defective Services shall be corrected. All removal and installation of equipment or parts shall be at Purchaser's expense. Seller's obligation regarding equipment or parts hereunder shall be limited to such repair and replacement, F.O.B. its factory, and shall be conditioned upon Seller receiving written notice of any alleged defect within ten (10) days after its discovery and at Seller's option, return of such equipment or parts prepaid to its factory, and shall not be enforceable until Purchaser has paid Seller in full for all Products and Services. Seller may in its sole discretion elect to perform warranty work at the site of the equipment or parts, and if so elected, Purchaser shall provide reasonable access and facilities for Seller to perform such warranty work. This warranty shall not apply to equipment or parts not manufactured by Seller or to equipment or parts or Services which were repaired or altered by a party other than Seller which were subject to negligence, accident, damage or circumstances beyond Seller's control, or improper operation, maintenance or storage, or to other than normal use or service or to consumable parts whose normal span of life might be shorter than the overall warranty period. With respect to equipment and parts not manufactured by Seller, the warranty obligations of Seller shall in all respects conform and be limited to the warranty extended to Seller by the supplier.

Seller's obligation and liability with respect to such warranty shall be limited to the amount received by Seller from the Purchaser on account of such specific equipment, parts, or Services.

Purchaser agrees that if equipment and parts sold hereunder are resold by Purchaser, Purchaser will include in the contract for resale provisions, which limit recoveries against Seller in accordance with this contract. In case of Purchaser's failure to include in any such contract for resale the terms providing for such limitations, Purchaser shall indemnify and hold Seller harmless against any liability, loss, cost, damage, or expense (including reasonable attorney's fees) arising out of or resulting from such failure. No employee or agent of Seller is authorized to make any warranty other than that which is specifically set forth herein. The provisions in any specification, brochure or chart issued by Seller attached hereto are descriptive only and are not warranties.

Seller shall in no event be liable for any direct, indirect, special or consequential damages whatsoever, whether grounded in tort (including negligence), strict liability or contract, and under no circumstances will its liability exceed the contract price for the Products or Services upon which liability is claimed. Any action for breach of contract or tort must be commenced within one year after the cause of action has accrued.

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING ALL WARRANTIES OF FITNESS OR OF MERCHANTABILITY OR OTHERWISE, EXPRESS OR IMPLIED IN FACT OR BY LAW, and state Seller's entire and exclusive liability and Purchaser's exclusive remedy for any claims in connection with the sale or furnishing of Services equipment, parts or Products, their design, suitability for use, installation or operations.

14 **LIMITATION OF LIABILITY**. Except as specifically provided in Article 16 below, Seller shall in no event be liable for any direct, indirect, special or consequential damages whatsoever, whether grounded in tort (including negligence), strict liability or contract, and under no circumstances will Seller's liability exceed the contract price for Products and Services upon which liability is claimed. Any action by Purchaser against Seller must be commenced within one year after the cause of action has accrued.

15. **GAS HAZARD.** Certain equipment quoted herein may be of a special gaseous atmosphere type. Also, certain materials may generate explosive gas while being processed in the equipment. It is generally known that gas may be a hazard to health and/or explosive under certain conditions. Seller shall not be responsible for personnel hazard and/or explosion damage when gas is used or present.

#### 16. **PATENTS, COPYRIGHTS AND MASK WORKS.**

A. If Purchaser receives a claim that any product or part thereof manufactured by Seller infringes a U. S. Patent, Copyright or Mask Work, Purchaser shall promptly notify Seller in writing and give Seller information, assistance and exclusive authority to evaluate, defend, and settle such claim. Seller shall then at its own expense and option (1) settle such claim; (2) procure for Purchaser the right to use such Product; (3) replace or modify it to avoid infringement; (4) remove it and refund the purchase price, less accrued depreciation; or (5) defend against such claim. Provided such timely notice, information, assistance and authority has been given by Purchaser to Seller, should any court of competent jurisdiction hold such product to constitute infringement, Seller shall pay any costs and damages finally awarded on account of such infringement and, if the use of such Product is enjoined, Seller, the patent indemnity, if any, given by the manufacturer thereof shall apply in place of the foregoing indemnity.

B. The foregoing indemnity shall not apply to any claim that arises out of Seller's compliance with the specification or design of Purchaser and it shall not apply to any claim of infringement resulting from the use of Product in combination with other equipment and materials not furnished by Seller. Purchaser shall hold Seller harmless and indemnified against all claims described in this paragraph B. The sale of Products hereunder does not carry with it any license to use such Products in combination with other Products not purchased from Seller and which combination is the subject of any patent owned or controlled by Seller.

C. The rights and obligations of the parties with respect to Patents, Copyrights and Mask Works are solely and exclusively as stated herein.

17. **DRAWINGS, ETC.** All specifications, drawings, design, data, information, ideas, methods, patterns and/or inventions, made, conceived, developed, or acquired by Seller incident to procuring and/or carrying out its contract will vest in and inure to Seller's sole benefit. Purchaser agrees to hold in confidence and not to give, Ioan, disclose, exhibit or sell to any other party or interest, outside of its own company, any drawing, photograph, specification or other technical information furnished by Seller or any reproduction thereof. Such charges as may be made for patterns, etc., cover use only. All such equipment shall remain the property of and in Seller's possession.

Drawings are not subject to Purchaser's prior approval. Purchaser agrees to hold in confidence and not to give, loan, disclose, exhibit or sell to any other party or interest, outside of its own company, any drawing, photograph, or specification furnished by Seller or reproduction thereof. Such charges as may be made by Seller for patterns, etc., cover use only. All such equipment shall remain the property of and in Seller's possession.

Tracings and reproducible drawings are not provided by Seller, unless expressly stated in the quotation.

Seller may take photographs of its installed equipment for record purpose but agrees not to use them for sales or advertising without the written consent of the Purchaser.

18. **APPLICABLE LAW.** The rights and duties of the parties to any contract resulting herefrom shall be governed by the laws of the State of Pennsylvania, without reference to principles of conflicts of law and excluding any application of the United Nations Convention on Contracts for the International Sale of Products.

19. ASSIGNMENT. Purchaser's rights and obligations hereunder may not be assigned without Seller's prior written consent.

20. **NON-WAIVER.** Seller's failure at any time to require strict performance by Purchaser of any of the provisions herein shall not waive or diminish its right thereafter to demand strict compliance therewith or with any other provision. Waiver of any default shall not waive any other default.

# Gruenberg



Gruenberg S-Series Class 100 Pharmaceutical Sterilizer Our new sterilizer is cGMP compliant, Flush Front, and offers more standard features



### Gruenberg Pharmaceutical Sterilizers and Depyrogenation Ovens

Gruenberg designs and manufactures a complete line of standard and custom pharmaceutical sterilizers and depyrogenation ovens. Pharmaceutical sterilizer configurations include laboratory, cabinet, truck-in, pass-through, and continuous arrangements. pharmaceutical sterilizers and depyrogenation ovens are designed to reach maximum temperatures up to 536 F (280 C). All sterilizers are custom designed for your specific temperature and cycle time requirements.

The control systems can be self-sufficient relay logic or PLC, or they can be integrated with your process PLC.

#### More standard features than competing products!

	Gruenberg S-Series	Competing Models
21 CFR Ready Controls	Standard	Option
Pressure Locks	Standard	Option
Web-Based Service Connectivity	Standard	Option
Factory Acceptance Test	Standard	Option

TTPS

Mailing Address: P.O. Box 150 White Deer, PA | 17887-0150 USA Phone: (800) 586-2473 | (570) 538-7200 | Fax: (570) 538-7380 Physical Address: 2821 Old Route 15 | New Columbia, PA 17856-9396 tpsinfo@tps.spx.com Specifications and Product Information are subject to change without notice.

#### Pharmaceutical Sterilizer Features

- Heavy-duty, fully-welded, structural steel frame
- Exteriors constructed of 16 and 18 304L stainless steel with a #4 polish to withstand frequent wash downs
- Side walls and loading tracks are removable for easy clean-up and maintenance.
- HEPA filters installed on the air intake, exhaust, and recirculation air flow to ensure a class 100 environment
- S Interior chamber seams are 100% continuously heliarc welded to eliminate risk of process contamination
- Scustom trucks, trays, and transfer carts are available

#### Class 100 Sterilizer Guaranteed Class 100 Conditions

To maintain class 100 quality throughout the process chamber, HEPA filters are installed in the air intake, exhaust and recirculation wall.

The HEPA filters are a minimum 99.97% efficient at 0.3 microns.

The intake HEPA filter prevents contaminates from entering the sterilizer during operation.

The exhaust HEPA filter ensures that contamination will not be drawn into the sterilizer as the cycle ends.

Side wall filters provide distinct advantages.

Filtration takes place just before the air enters the sterilization chamber so that class 100 conditions are ensured. Plus, they afford easy access to filters for validation and maintenance.

#### Gruenberg S-Series Sterilizer Standard Features

Designed and manufactured to comply with all pertinent cGMP requirements. Interior is manufactured with a fully welded 304L-2B stainless steel liner. All interior corners are rounded with a <sup>3</sup>/<sub>4</sub>" radius to provide ease of wipe downs.

Standard Sterilizers are rated for 536 F (260 C) depyrogenation

ISO14644-1, ISO Class 5 (209e Full Class 100) sterilizing conditions throughout the process cycle (1.5 C / Minute ramp rate, with option of rapid capacity filters up to 10 C/minute ramp rate.) HEPA filters are installed in the air intake, exhaust and recirculation wall. The intake HEPA filter prevents contaminates from entering the sterilizer during operation and is protected with an upstream prefilter. The exhaust HEPA filter ensures contamination will not be drawn into the sterilizer at the cycles end. Side wall filters provide filtration immediately prior to the process air



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entering the sterilization chamber.

A Bio-seal flange is provided to seal the sterilizer into the facility wall at the "clean" side of the system and ensures a positive barrier preventing particulate from entering the room from the maintenance area.

Pass Through with interlocked Pressure Sensitive doors. The doors are provided with a pneumatic latching and locking system. The door will latch automatically and will remain locked to provide proper pass-through operation.

- UL Listed Control Panel.
- Lockable Disconnect Switch on Control Panel Door. Lockout Tagout capable.
- Both Control Systems are 21 CFR Part 11 Ready.

#### Pharmaceutical Sterilizer Optional Equipment

- Accelerated Sterilizer Cycle Time (10 C / minute)
- The standard HEPA filters will be replaced by advanced filters that can operate under greater differential thermal expansion. In addition to the upgrade in filtration, the system will require additional heat input to maintain the accelerated heat up rate.
- 316L Stainless Steel Interior
- Cooling Coil in Intake Stream
- Pressure Differential Control System
- GAMP 4 Documentation
- IQ/OQ Protocols (unexecuted or executed) Full validation documentation in accordance with the GAMP regulations.
- Isolator compatible
- Stainless steel trucks and trays in standard and custom sizes.

#### Custom Sterilizer Configurations Available

All sterilizers are designed for your specific temperature and cycle time requirements.



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#### Sterilizer Automated Process Controls



Gruenberg offers the standard control system with the S-Series line and the SCADA control system as an option.

#### STANDARD CONTROL SYSTEM

As a standard feature, Gruenberg provides a 21 CFR 11 ready control system equipped with PLC and OIT (Operator Interface Terminal) technology. The Allen Bradley Compact Logix PLC with on board Ethernet communications to connect to the Allen Bradley Panelview Plus 700 touch screen OIT. The Panelview Plus offers a TFT color screen, on board Ethernet connectivity, network security and audit trail capabilities (using A/B Factory Talk) for 21 CFR applications, data logging, alarm logging and the ability to store up to 10 recipe profiles.

A multitude of screens offer the customer user friendly interfaces for security, maintenance screens including autotune, recipe generation and storage.

#### SCADA CONTROL SYSTEM

The SCADA (Supervisory Control and Data Acquisition) control system comes equipped with PLC and HMI (Human Machine Interface) technology. The Allen Bradley Compact Logix PLC with on board Ethernet communications to connect to a desktop or panel mounted touchscreen PC.

The PC is loaded with Windows and Wonderware's Intouch 8.0 - HMI for standard or custom designs to meet the customers control system requirements.

The HMI comes complete with field installed and validated 21 CFR Part 11 ready control and data acquisition system.

Gruenberg Pharmaceutical Sterilizers and Depyrogenation Ovens

Physical Specifications of Pharmaceutical Sterlizers and Depyrogenation Ovens



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Model	Interior Dimensions W" x D" x H"	Exterior Dimensions W" x D" x H"	Heating Input (Std. Ramp Rate)	Chamber Capacity (cubic feet)
SC55H8.3PTSS	20 x 30 x 24 (50.8 x 76.2 x 61)	45.75 x 50.44 x 85.38 (116.2 x 128.1 x 216.9)	9 kW	8.3 (21.1)
SC55H13.2PTSS	24 x 34 x 28 (61 x 86.4 x 71.1)	49.75 x 54.44 x 93.38 (126.4 x 138.3 x 237.2)	18 kW	13.2 (33.5)
ST55H31.4PTSS	32 x 34 x 50 (81.3 x 86.4 x 127)	70.75 x 54.44 x 97.38 (179.7 x 138.3 x 247.3)	24 kW	31.4 (79.8)
ST55H59.9PTSS	37 x 56 x 50 (94 x 142.2 x 127)	75.75 x 76.44 x 103.38 (192.4 x 194.2 x 262.6)	45 kW	59.9 (152.1)
ST55H95.8PTSS	48 x 69 x 50 (121.9 x 175.3 x 127)	86.75 x 89.44 x 103.38 (220.3 x 227.2 x 262.6)	54 kW	95.8 (243.3)

Gruenberg has available a variety of additional pharmaceutical sterilizers and depyrogenation ovens to meet your specific requirements. Note: exterior dimensions are overall cabinet dimensions.

#### Performance Specifications of Pharmaceutical Sterlizers and Depyrogenation Ovens

	Maximum Heating Rate	Maximum Cooling Rate (to 40°C)	Maximum Temperature	Estimated Cycle Time
Accelerated Ramp	10°C / Min.	4°C / Min. Air	260°C	2.3 Hours
	10°C / Min.	8°C / Min. Water	260°C	1.9 Hours
Standard Ramp	1.5°C / Min.	1.5°C / Min.	260°C	6.0 Hours



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Standard Models	Max. Temp.	Interior Width (in.)	Interior Depth (in.)	Interior Height (in.)	Exterior Width (in.)	Exterior Depth (in.)	Exterior Height (in.)	KW	Cubic Feet of Interior Chamber Capacity
L55H8.3	280C	20 (50.8)	30 (76.2)	24 (61)	48.75 (123.8)	38.5 (97.8)	54.5 (138.4)	7.5	8.3
L55H13.7	280C	24 (61)	38 (96.5)	26 (66)	52.75 (134)	46.5 (118.1)	56.5 (143.5)	15	13.7
C55H15.17	280C	24 (61)	26 (66)	42 (106.7)	52.75 (134)	34.5 (87.6)	72.5 (184.2)	18	15.17
C55H17.69	280C	28 (71.1)	26 (66)	42 (106.7)	55.75 (141.6)	34.5 (87.6)	72.5 (184.2)	18	17.69
T55H20.2	280C	26 (66)	28 (71.1)	48 (121.9)	54.5 (138.4)	36.5 (92.7)	78.5 (199.4)	18	20.2
T55H25.4	280C	29 (73.7)	42 (106.7)	36 (91.4)	57.5 (146.1)	50.5 (128.3)	66.5 (168.9)	18	25.4
C55H30.2	280C	27 (68.6)	42 (106.7)	46 (116.8)	55.75 (141.6)	50.5 (128.3)	76.5 (194.3)	24	30.2
T55H32	280C	32 (81.3)	48 (121.9)	36 (91.4)	60.75 (154.3)	56.5 (143.5)	66.5 (168.9)	24	32
T55H43.9	280C	43 (109.2)	34 (86.4)	52 (132.1)	71.75 (182.2)	42.5 (108)	82.5 (209.6)	30	43.9
T55H45.5	280C	36 (91.4)	42 (106.7)	52 (132.1)	64.75 (164.5)	50.5 (128.3)	82.5 (209.6)	30	45.5
T55H52.52	280C	30.5 (77.5)	42.5 (108)	70 (177.8)	59.25 (150.5)	51 (129.5)	100.5 (255.3)	30	52.52
T55H63.7	280C	44 (111.8)	41 (104.1)	57 (144.8)	72.75 (184.8)	49.5 (125.7)	87.5 (222.3)	36	63.7
T55H76.3	280C	47 (119.4)	61 (154.9)	46 (116.8)	75.75	70.5 (179.1)	76.5 (194.3)	45	76.3

#### Non S-Series Gruenberg Sterilizers and Depyrogenation Ovens Specifications



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						(192.4)				
·	T55H79.4	280C	44 (111.8)	52 (132.1)	60 (152.4)	72.75 (184.8)	60.5 (153.7)	90.5 (229.9)	45	79.4
	T55H89.3	280C	45 (114.3)	52 (132.1)	66 (167.6)	73.75 (187.3)	60.5 (153.7)	96.5 (245.1)	45	89.3
	T55H93.3	280C	40 (101.6)	72 (182.9)	56 (142.2)	68.75 (174.6)	80.5 (204.5)	86.5 (219.7)	45	93.3



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Standard Models	Max. Temp.	Interior Width (in.)	Interior Depth (in.)	Interior Height (in.)	Exterior Width (in.)	Exterior Depth (in.)	Exterior Height (in.)	KW	Cubic Feet of Interior Chamber Capacity
T55H109	280C	43 (109.2)	80 (203.2)	55 (139.7)	77.75 (197.5)	88.5 (224.8)	85.5 (217.2)	45	109
T55H110	280C	70 (177.8)	44 (111.8)	70 (177.8)	104.75 (266.1)	52.5 (133.4)	100.5 (255.3)	54	110
T55H134.1	280C	48 (121.9)	67 (170.2)	72 (182.9)	82.75 (210.2)	75.5 (191.8)	102.5 (260.4)	54	134.1
T55H138.3	280C	49 (124.5)	80 (203.2)	61 (154.9)	83.75 (212.7)	88.5 (224.8)	91.5 (232.4)	60	138.3
T55H209.5	280C	48 (121.9)	130 (330.2)	58 (147.3)	81 (205.7)	150 (381)	112 (284.5)	72	209.5
T55H216	280C	48 (121.9)	108 (274.3)	72 (182.9)	82.75 (210.2)	166.5 (422.9)	102.5 (260.4)	75	216
T55H245.4	280C	57 (144.8)	120 (304.8)	62 (157.5)	91.75 (233)	128.5 (326.4)	92.5 (235)	90	245.4
T55H277.3	280C	72 (182.9)	96 (243.8)	78 (198.1)	106.75 (271.1)	104.5 (265.4)	108.5 (275.6)	108	277.3
T55H335.9	280C	62 (157.5)	120 (304.8)	78 (198.1)	96.75 (245.7)	128.5 (326.4)	108.5 (275.6)	108	335.9
T55H364.5	280C	92 (233.7)	125 (317.5)	60 (152.4)	126.75 (321.9)	133.5 (339.1)	90.5 (229.9)	126	364.5
T55H582.6	280C	56 (142.2)	214 (543.6)	84 (213.4)	90.75 (230.5)	222.5 (565.2)	114.5 (290.8)	144	582.6

\* Note: The exterior dimensions listed above represent the cabinet dimensions of each unit. Typically, add 24" to the cabinet width for the control cabinet, 14-36" to the cabinet height for the top mounted equipment, and 10-12" to the cabinet depth for door and door hardware.



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## Xcellerex presents the world's first 2000 Liter GMP Single-Use Bioreactor



#### Make your next bioreactor choice with confidence

ADR single-usebioreactors delver performance features that surpass any bioreactor-sciolers or dependie. But XDR systems also come with something no other bioreactor maker can match: The Justices area. With yers of experience running GNP biomanufacturing operations, Xeellers, designed the XDR system to delver complete process control from the moment yee start-up year system. And with "Xeellers," in-house process optimization and biomanufacturing teams running



every day, you can be sure you'liget the help you need to getyour process right the first time and to keep it running.

So whether you've already committed to single-use systems or are considering a switch from traditional stainless steel, Xeellere, invites you to decover how the robust performance and control of an XDR bioreactor can be yours

in 12 weeks or less.

# Xcellerex

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For a free application brief on JDR perfusion performance,

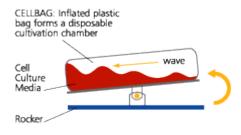
## **How it works - WAVE Bioreactor Concept**

Proven for animal, virus, insect, and plant cell culture in suspension, or on carriers.

### The WAVE Bioreactor consists of two components:

1. **Disposable Cellbag:** Cells and media are contained inside a single-use bag. These radiation sterilized Cellbags include filters, tubes and all necessary fittings. They are delivered ready for use. Cellbags are available in several sizes for 0.1 to 500 liters of culture volume.

2. **Rocker:** The rocker unit has optimized devices designed to inflate and rock the Cellbag for oxygen transfer and mixing. These rugged machines are designed to give years of reliable service. Options include CO2 control, DO monitoring, temperature control, weight control, pH control, and data acquisition. Units can be used in an incubator or standalone.



The WAVE Bioreactor is the ideal device for cell culture. Culture medium and cells only contact a presterile, disposable chamber called a Cellbag that is placed on a special rocking platform. The rocking motion of this platform induces waves in the culture fluid. These waves provide mixing and oxygen transfer, resulting in a perfect environment for cell growth that can easily support over  $10 \times 10^6$  cells/ml. The bioreactor requires no cleaning or sterilization, providing the ultimate ease in operation and protection against cross-contamination.

### Scalable to 500 Liters

The WAVE Bioreactor is available in sizes up to 500 liter culture volume:

- <u>SYSTEM2/10</u> for **100ml to 5 liters**
- SYSTEM20/50 for 1 to 25 liters
- <u>SYSTEM200</u> for **10 to 100 liters**
- <u>SYSTEM500/1000</u> for **50 to 500 liters**

### **Disposable Bioreactor Chamber**

Culture only contacts a presterile plastic disposable cultivation chamber. No cross-contamination, cleaning, sterilization or other validation headaches.

### **Completely Closed System**

Ideal for virus or vaccine production, high containment applications, and cGMP operations. No biosafety cabinet is needed, even for additions and sampling.

### Versatile

Multiple instrument configurations specifically designed for suspension, microcarrier, batch, fed-batch or perfusion culture. Use inside an incubator or benchtop models with integral temperature control.

### **Suitable for cGMP Operations**

Used in the cGMP production of human therapeutics. Closed system is easy to validate. All Cellbag contact materials conform to USP Class VI and ISO 10993.

### **Perfusion Culture Option**

Patented internal perfusion filters enable perfusion of media for high-density cell culture. No pumparound or external cell separator needed.

### Easy to Operate

No complex piping or sterilization sequences. Simply place a new presterile Cellbag on the rocker; fill with media, and add your cells.

#### Data File 18-1125-19 AD

# nProtein A Sepharose 4 Fast Flow

nProtein A Sepharose<sup>™</sup> 4 Fast Flow is native protein A coupled to Sepharose 4 Fast Flow. It has nearly twice the total IgG binding capacity of Protein A Sepharose CL-4B, and is the ideal adsorbent for recovery and purification of monoclonal antibodies from cell culture at both laboratory and process scale.

nProtein A Sepharose 4 Fast Flow (Fig 1) has been developed and tested in cooperation with leading manufacturers of purified monoclonal antibody products, and is used in routine commercial production.

nProtein A Sepharose 4 Fast Flow features:

- Low leakage of protein A
- Used in large-scale FDA approved processes
- Manufactured without using animal-derived components

#### **Medium characteristics**

Native protein A has a molecular weight of 42 000 daltons and a structure consisting of several regions (Fig 2). Five of these (E, D, A, B, and C) show strong specific affinity for the Fc part of IgG, leaving the antigen combining sites within the regions free. One molecule of immobilized protein A binds at least two molecules of IgG.

#### Staphylococcal Protein A

|--|

**Fig 2.** Schematic drawing of regions encoded by the gene for Staphylococcal protein A. S is the signal sequence. E, D, A, B, and C are the homologous repetitive immunoglobulin binding regions. Xr and Xc are C-terminal located, non-immunoglobulin binding regions thought to be responsible for the binding of Protein A to the bacterial cell.



Fig 1. nProtein A Sepharose 4 Fast Flow is available in a range of pack sizes.

GE Healthcare's native protein A is produced by fermenting a selected strain of *Staphylococcus aureus*. The purified protein is coupled to Sepharose 4 Fast Flow by the cyanogen bromide technique, giving a highly stable medium with minimal non-specific adsorption. nProtein A Sepharose 4 Fast Flow is manufactured without using animal-derived components.

The swollen medium has a protein A content of approximately 6 mg/ml drained medium. The total binding capacity for human IgG is approximately 35 mg/ml drained medium. Sepharose 4 Fast Flow is a highly cross-linked, 4% agarose derivative with impressive kinetics, leading to excellent chromatographic qualities in the immobilized affinity adsorbent. Its rigidity also makes it well-suited for process scale applications. nProtein A Sepharose 4 Fast Flow is particularly suitable for recovery and purification of monoclonal antibodies from cell culture supernatants. The rigidity and high degree of substitution of the Sepharose 4 Fast Flow matrix enables the rapid processing of large volumes of dilute cell culture fluid.





#### Stability

nProtein A Sepharose 4 Fast Flow has high chemical and mechanical stability. It withstands high concentrations of hydrogen bond disrupting agents such as urea, guanidine hydrochloride, and sodium thiocyanate. It has high thermal stability, but is not autoclavable. The characteristics of the product are summarized in Table 1. When packing the medium at a 5-cm bed height, the recommended packing flow velocity is at least 700 cm/h, and at a 15-cm bed height at least 300 cm/h. The working flow velocity should not exceed 80% of the packing flow velocity. As a guide, pressure/flow velocity curves for the Sepharose 4 Fast Flow base matrix packed in XK 50/30 Fast Flow and BP 113 columns are shown in Figure 3.

Ligand	native Staphylococcal protein A		
Ligand density	approx. 6 mg native protein A/ml drained medium		
Ligand coupling method	cyanogen bromide activation		
Dynamic binding capacity <sup>1</sup>	min 20 mg human IgG/ml drained medium		
Matrix	highly cross-linked 4% agarose		
Average particle size	90 μm (45–165 mm)		
Chemical stability	no significant change in chromatographic performance after 1 week storage using 8 M urea, 6 M guanidine-HCl, 2% benzyl alcohol or 20% ethanol		
pH stability <sup>2</sup>			
Long term	3–9		
Short term	2–10		
Recommended flow rate	50–300 cm/h		
Max operating back pressure	0.1 MPa (1 bar, 14 psi)		
Sanitization	wash the packed column with 2% hibitane/ 20% ethanol or 70% ethanol		
Storage	20% ethanol at $+4^{\circ}C$ to $+8^{\circ}C$		

<sup>1</sup> The binding capacity was determined at a linear flow rate of 100 cm/h, column:

 $7.5 \times 50$  mm, sample volume: 250 ml, sample concentration: 1 mg human IgG/ml. Please note that there might be considerable deviations in binding capacity for different immunoglobulins derived form the same species even if they are of the same subclass.

<sup>2</sup> Complete data on the stability of protein A as a function of pH are not available The ranges given are estimates based on our knowledge and experience. Please note the following:

pH stability, long term refers to the pH interval where the medium is stable over a long period of time without adverse effects on its subsequent chromatographic performance.

*pH stability, short term* refers to the pH interval for regeneration, cleaning-inplace, and sanitization procedures.

pH below 3 is sometimes required to elute strongly bound Ig's. However, protein ligands may hydrolyze at very low pH.

#### **Process-scale use**

#### Columns

Columns recommended for nProtein A Sepharose 4 Fast Flow are shown in Table 2.

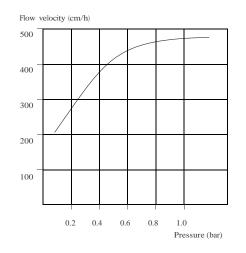
 Table 2. Recommended GE Healthcare columns for nProtein A Sepharose 4

 Fast Flow

Column	Bed height	Medium volume
XK Column 50/30 Fast Flow <sup>1</sup>	5–15 cm	100–300 ml
BPG <sup>TM</sup> 100/500		Up to 2.4 l

<sup>1</sup> These are columns fitted with a special Fast Flow adaptor to increase throughput.





(b)



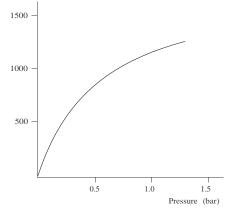


Fig 3. Pressure/flow velocity curve for Sepharose 4 Fast Flow in XK 50/30, bed height 15 cm (a) and BP 113, bed height 5 cm (b); mobile phase  $H_20$ .

#### Dynamic capacity

The dynamic capacity of chromatographic adsorbents is a function of the flow velocity used for loading samples, and increases with decreasing flow velocity. Furthermore, individual antibodies differ in their affinity to protein A. To obtain an optimal purification scheme with respect to capacity and time, it is necessary to first determine the capacity for the specific antibody to be purified over a range of different flow velocities (see the example in Fig 4). Once this is known it is then possible to control the flow velocity during the loading phase to achieve maximum binding of the antibody in minimum time. In practice, this means initially loading the sample at a high flow velocity (e.g., 300 cm/h) and reducing the flow velocity successively with increasing sample load.

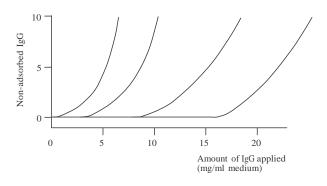


Fig 4. One example of how the capacity for human IgG depends on the flow velocity with nProtein A Sepharose 4 Fast Flow. The non-adsorbed IgG (%) was measured as a function of the amount applied to the column at 4 different flow velocities, 300, 200, 100, and 30 cm/h. Concentration of the applied sample: 0.33 mg IgG/ml. Column:  $0.5 \times 5$  cm (i.d.  $\times$  h). Buffer system: 0.1 M Na<sub>2</sub>HPO<sub>4</sub>, pH 7.0.

#### **Operation**

nProtein A Sepharose 4 Fast Flow is supplied in suspension in 20% ethanol.

- 1. After packing, wash the medium bed with at least three column volumes of starting buffer to remove preservative.
- 2. Note the following points when loading the sample:
  - The sample pH should be the same as the starting buffer pH.
  - The sample should be filtered through a 0.22–0.45  $\mu$ m filter (This prolongs the working life of the medium).
- 3. After loading the sample, wash the medium with starting buffer until the baseline is stable.
- 4. When eluting the sample, reverse the direction of flow.

#### **Process Hygiene**

Good process hygiene ensures the safety and integrity of the final product by removing or controlling any unwanted substances that might be present or generated in the raw material, or derived from the purification system itself. In practice, process hygiene of most affinity media usually means reduction of product contamination by sanitization, followed by a cleaning step.

#### Sanitization

Sanitization is the reduction of microbial populations on the medium. Two suggested alternative protocols are:

- i) Equilibrate with a buffer consisting of 2% hibitane digluconate and 20% ethanol.
- ii) Allow to stand for 6 hours.
- iii) Wash with sterile buffer.
  - or
- i) Equilibrate with 70% ethanol.
- ii) Allow to stand for 12 hours.
- iii) Wash with sterile buffer.

#### Cleaning

The general recommendation for cleaning nProtein A Sepharose 4 Fast Flow is to use a mixture of 50 mM NaOH and 1 M NaCl. As an alternative cleaning protocol, 6 M guanidine hydrochloride can be used. Phosphoric acid (100 mM) has also been used for cleaning. To remove hydrophobically-bound substances, a solution of non-ionic detergent or ethanol is recommended.

#### Regeneration

After each separation cycle, regenerate the medium bed by washing with approximately three column volumes of 0.1 M citrate buffer, pH 3 until the baseline is stable.

#### Storage

For longer periods of storage, keep nProtein A Sepharose 4 Fast Flow in a suitable bacteriostat (e.g., 20% ethanol), at 4°C to 8°C. The medium must not be frozen.

#### Applications

The most important application area for nProtein A Sepharose 4 Fast Flow is the purification of monoclonal antibodies from cell culture. High IgG capacity and high flow velocities make the medium ideal for both laboratory- and process-scale separations.

There is a natural diversity between the different subclasses of IgG and even within subclasses. Therefore the binding and elution system must be optimized for every monoclonal antibody to be purified.

#### **Ordering information**

Product	Pack size	Code No.
nProtein A Sepharose 4 Fast Flow	5 ml	17-5280-01
nProtein A Sepharose 4 Fast Flow	25 ml	17-5280-04
nProtein A Sepharose 4 Fast Flow	200 ml	17-5280-02
nProtein A Sepharose 4 Fast Flow	1 liter	17-5280-03
nProtein A Sepharose 4 Fast Flow	5 liter	17-5280-05

#### **Related products**

Product	Pack size	Code No.
HiTrap <sup>™</sup> Protein A HP	$2 \times 1 \text{ ml}$	17-0402-03
HiTrap Protein A HP	$5 \times 1 \text{ ml}$	17-0402-01
HiTrap Protein A HP	$1 \times 5 ml$	17-0403-01
HiTrap Protein A HP	$5 \times 5 \text{ ml}$	17-0403-03

#### Literature

Product	Code No.
Antibody Purification Handbook	18-1037-46
Affinity Chromatography Handbook	18-1022-29
Affinity Columns and Media, Selection Guide	18-1121-86
Convenient Protein Purification, HiTrap Column Selection Guide	18-1129-81

www.gelifesciences.com/protein-purification

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GE Healthcare Bio-Sciences KK Sanken Bldg. 3-25-1, Hyakunincho Shinjuku-ku, Tokyo 169-0073, Japan

# Chromaflow columns

Chromaflow<sup>™</sup> columns are a family of convenient to use, process-scale columns. A patented nozzle in the top and bottom of the column allows packing, unpacking, and cleaning when fully assembled, that is with the lid in place. Chromaflow columns simplify chromatographic procedures and offer:

- convenience
- saving of labor
- reproducibility
- contained packing
- scalability

### **General column description**

Chromaflow low-pressure columns (Fig 1) are available in a choice of dimensions and materials. The complete range offers inner diameters (i.d.) from 300 to 2000 mm (Table 1), with column tubes manufactured from cast acrylic (Fig 1). All dimensions are available with variable bed heights, providing a wide variety of bed volumes. All columns are pressure rated for operation at 3 bar.

Chromaflow columns incorporate a patented, pack-in-place nozzle (Fig 2) through which process liquids enter and exit. Manual or automated versions of the nozzles are available. The automated nozzle is controlled from the packing station or the nozzle control unit. The nozzle has three positions to facilitate the different aspects of column operation: packing, operation, unpacking and cleaning. In addition to this packin-place functionality, the nozzle also contains the process liquid flow path to provide a consolidated solution to the process stream handling.

Bed supports are available in 316L stainless steel or polyethylene. The multilayer, woven stainless steel bed supports have very high chemical resistance and longevity for use in applications where salt concentrations are low and pH is above 5. Polyethylene bed supports are recommended for applications with low pH and high salt concentrations. All other wetted parts in columns with polyethylene bed supports are manufactured from plastic or noncorrodible materials for use in low pH /high salt applications.





Fig 1. A Chromaflow column, 2000 mm i.d.



Fig 2. The Chromaflow nozzle that enables packing in place in af uly assembled column (GE Healthcare patent).



The construction materials include 316L stainless steel, acrylic, polypropylene, polyethylene, PEEK 450 G, EPDM rubber and FEP encapsulated silicone. These materials have high chemical resistance to the liquids typically used in process chromatography (Table 2). Furthermore, all polymeric materials are approved according to USP class VI tests for toxicity.

As an option, a dedicated packing station is available for Chromaflow columns. The packing station speeds up the packing procedure by eliminating the more time-consuming, manual maneuvers (Fig 3).

Comprehensive documentation is delivered with each column and includes a User manual, a Maintenance manual, assembly drawings, a full spare part list, materials certificates etc.

A Validation Support File containing information on column component composition, materials of construction and toxicity studies is also available.



**Fig 3.** Packing Chromaflow columns with the dedicated packing station is convenient and simple.

### **Convenient and labor saving**

Once the column is assembled and the lid in place, no lifting gear is required for packing, operation, unpacking or cleaning-in-place (CIP). This means that a single operator can perform all column operations, thereby reducing labor costs and increasing convenience in large-scale operations.

### Reproducibility

Packing with the lid in place allows the packing parameters to be easily set and fixed. Manual operation is minimized and standard operating procedures can be followed, helping to give reproducible column packing and results.

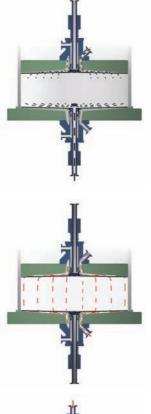
### **Contained packing**

Improved safety is another advantage of the Chromaflow column concept . Because all the column operations are performed in a "closed system" environment , there is less risk of the operator coming into contact with hazardous chemicals and of the target product being exposed to contamination. In this way, overall safety and hygienic operation are improved.

### **Principle of operation**

The column has a three-position nozzle located in the center of the top and bottom bed support. These three positions enable packing, unpacking, operation and cleaning to be performed without any adjustments to the assembled column, that is the lid remains in place.

Flow profiles from the two nozzles are identical. Packing direction will depend on the characteristics of the media and packing method used. The three positions are illustrated in Figure 4.



#### Packing position

The bottom nozzle is extended part of the way (mid position) into the column. The top nozzle is fully retracted. Slurry enters the column via the bottom nozzle and excess liquid exits via the top mobile phase outlet. After packing, the slurry lines are isolated from the mobile phase and can be cleaned independently from the rest of the column.

#### **Running position**

The bottom and top nozzles are retracted. Mobile phase enters the column directly into an annulus, immediately behind the bed support

The annulus is cut through at an angle to ensure that linear flow is kept constant during distribution of the mobile phase across the bed.

#### **Unpacking position**

In this position, both bottom and top nozzles are fully extended into the column thereby exposing a third passage through which medium leaves the column.

Cleaning solution can be pumped through the nozzles and sprayed into the column. In this way the column is easily and effectively cleaned without exposing the interior or the medium to the environment , and without dismantling the column.

Fig 4. The three positions of the Chromaflow nozzle showing packing from the top.

### Scalability

Chromaflow columns are available in a wide range of dimensions, all designed and constructed around the same design principle. Standard range columns come in dimensions from 400 to 1000 mm, for more information about columns and dimensions, see Ordering information. Scaling up a chromatographic process from small to larger diameters is easily performed with maintained reproducibility, safety and convenience.

### **Column dimensions**

A selection of Chromaflow columns in the range 400 to 2000 mm i.d. are presented in Table 1. The adapter stroke length is a standard 200 mm. Variable bed heights are available in the ranges 100–300 mm, 200–400 mm and 300–500 mm.

### **Chromaflow 400 SFP columns**

Chromaflow 400 SFP (small flow path) columns are specially designed for low-flow applications. The dimensions in the mobile phase have been optimized to reduce dead volumes to a minimum and the area behind the nozzle tip has also been reduced.

## Column materials and their chemical resistance

Table 2 lists the major components of Chromaflow columns in contact with process fluids (wetted parts) and Table 3 lists the chemical resistance of materials using data compiled from several published sources. It is important to note that columns with stainless steel bed supports and other stainless steel wetted components must be appropriately maintained when exposed to NaCl. Since salt can be corrosive to stainless steel over time, it is recommended that residual salt is removed by rinsing columns with at least five column volumes (CV) of clean water.

Table 1. Weights, volumes and dimensions for variable bed height Chromaflow columns

Description	Max operating pressure (bar)	Volume (l)	Column overall height (mm)	Weight, dry (kg)	Footprint (mm×mm)
Chromaflow column 400/100-300*	3	12.6-37.8	1568	230	$700 \times 700$
Chromaflow column 600/100-300	3	28.3-84.9	1568	375	800  imes 800
Chromaflow column 800/100-300	3	50.3-150.9	1572	610	$1000\times 1000$
Chromaflow column 1000/100-300	3	78.5-235.5	1573	930	$1200 \times 1200$
Chromaflow column 1200/100-300	3	113.1-339.3			
Chromaflow column 1400/100-300	3	153.9–461.7			
Chromaflow column 1600/100-300	3	201.1-603.3			
Chromaflow column 1800/100-300	3	254.5-763.5			
Chromaflow column 2000/100-300	3	314.2–942.6			

\* The first figure in the column name indicates the inner diameter and the second figure indicates stoke length.

#### Table 2. Major components and their composition

Component	Material	In contact with process stream
Column tube	Acrylic or stainless steel 316L	Yes
Column lids	Stainless steel 316L	No
Distributor	Polypropylene	Yes
Bed support	Stainless steel 316L or polyethylene	Yes
Chromaflow nozzle	Polypropylene, stainless steel 316L, PEEK 450 G	Yes
Seals	EPDM or FEP encapsulated silicone	Yes
Stand	Stainless steel 316L	No

EPDM = ethylene propylene diene, FEP = fluoroethenepropene, PEEK = polyetherether ketone

Table 3. Chemical resistance of materials	used in Chromaflow columns	(60 days)
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Chemical	Acrylic	SS 316L	EPDM	FEP	PEEK 450 G	PE	PP
Acetic acid 1.7 M	+	+	+	+	+	+	+
EtOH 20% <sup>1</sup>	+	+	+	+	+	+	+
EtOH 40%	_	+	+	+	+	(+)	+
Ethylene glycol 50%	+	+	+	+	+	+	+
Formaldehyde 1.7 M	+	+	+	+	+	+	+
Formic acid 10%	(+)	+	+	+	+	+	+
Glycerol 100%	+	+	+	+	+	+	+
Hydrochloric acid 0.1 M	+	_	+	+	+	+	+
Isopropyl alcohol 30%	_	+	+	+	+	(+)	+
Nitric acid 0.1 M	+	+	+	+	+	(+)	+
Phosphoric acid 25%	+	(+)	+	+	+	+	+
Sodium chloride 0.5 M	+	$+^{2}$	+	+	+	+	+
Sodium hydroxide 2 M <sup>3</sup>	+	+	+	+	+	+	+
Trifluoroacetic acid 0.1%	(+)	+	+	+	+	+	+
Triton <sup>™</sup> X-100 100%	+	+	+	+	+	+	+
Urea 8 M	+	+	+	+	+	+	+

+ Resistant (+) Limited resistance - Not recommended

<sup>1</sup> Do not expose acrylic to concentrations of ethanol greater than 20%. Do not exceed the following parameters during storage: 5 yr,  $23^{\circ}$ C, 0.5 bar g. <sup>2</sup> NaCl can cause corrosion on stainless steel at pH <5. Do not use NaCl in storage solutions. Rinse with at least 5 CV of clean water after use with

<sup>3</sup> NaCl. Maximum exposure 4 h.

 $SS = stainless \quad steel, \quad EPDM = ethylene \quad propylene \quad diene, \quad FEP = fluoroethene propene, \quad PEEK = polyethere there \quad ketone, \quad PE = polyethylene, \quad PP = polypropylene.$ 

### Sanitizing Chromaflow columns

The design of Chromaflow columns facilitates cleaning-inplace. Below is a recommended cleaning protocol suitable for most applications.

- 1. Circulate 1.5 CV of 20% acetic acid at a low flow velocity (60 cm/h) for 15 min, upward flow. Then reverse the flow for 15 min.
- 2. Repeat this procedure with 1.0 M NaOH.
- 3. Following step 2, slowly circulate 1.0 M NaOH in the column for 60 min.
- 4. Re-equilibrate the column with a storing or starting buffer.

### **Chromaflow Packing stations**

Chromaflow Packing stations make column priming and packing a simple operation, reducing the operator's time to a minimum. The packing stations consist of a control panel with pumps and valves fitted underneath (Fig 5). Valves and diaphragm pumps are actuated pneumatically from the control panel. As they are brought into operation indicators on the control panel display the relevant flow paths. For operation, packing stations only require a supply of compressed air. To select an appropriate packing station for jour column and media, refer to Tables 4 and 5.



Fig 5. Chromaflow Packing station Pack 100.

Table 4. Specifications of Chromaflow packing stations

Desmgnatmon*	Pump	Pump flow capacity (I/mmn)	Req. amr supply (m <sup>3</sup> /mmn)	InIet pmpmng/ outlet i.d. (mm)	TC connections (mm)	Wemght, dry (kg)	$Smze  W \times H \times D (mm)$
Pack 50	Tapflo <sup>™</sup> T53	10–50	0.5	22.1/22.1	50.5	115	810 × 1175 × 715
Pack 100	Tapflo T103	30-100	1.0	34.8/22.1	50.5	130	$810\times1175\times715$

\* Packing stations, Pack 200 and Pack 400 with pump flow capacities of 60 to 200 l/min and 100 to 400 l/min are available as custom orders.

Table 5. Approximate packing flow rates for different media at two different bed heights

Column																
diameter (mm)		40	00			6	00			80	00			10	00	
Bed height (mm)	15	50	30	00	15	50	30	0	15	50	30	0	15	50	30	)0
Flow	cm/h	I/mmn														
Sepharose <sup>™</sup>																
Fast Flow media	500	11	250	5.5	500	24	250	12	500	42	250	21	500	66	250	33
Sepharose																
Big Beads media	1600	34	1200	25	1600	75	1200	57	1600	134	1200	101	1600	209	1200	157

### What else do I need?

### The column

Column

The columns are supplied ready for use and are equipped with adjustable feet. Castors can be ordered separately for columns up to 1000 mm in diameter.

### Isolating the column after packing

We recommend using sanitary stainless steel valves (of the appropriate inner diameter) on the mobile phase to prevent contamination of the packed bed. For storage purposes, blind flanges with a clamp and gasket can be used to seal off the column.

## Connecting the column to your system and packing station

Clamps and gaskets of suitable size are required to connect the sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing is also available.

### Assembly or disassembly of the column

An adequate sized wrench is needed for assembly or disassemblj of the column. A hoist is needed to remove the adapter or top lid from the column.

### Spare parts to keep on site

It is recommended that nozzle seals, column seals, and column bed support kits are kept as spare parts.

### Useful accessories

**Safety valve:** Precalibrated valve which releases pressure if the calibrated value is exceeded. Recommended to install on the mobile phase inlet if no other pressure sensor is included in the chromatography system. The T-junction, clamps and gaskets must be ordered separately.

**Pressure sensor:** The sensor is installed inline, preferablj on the mobile phase inlet. Clamps and gaskets have to be ordered separatelj.

### **Ordering information**

### Columns

Chromaflow coIumns with acrylic tubes	Bed support 10 mm SS sinter	Bed support 20 mm SS sinter	Bed support 20 mm PE sinter
I.d. 400 mm Man. nozzle			
Stroke length 100-300	18-1150-40	18-1159-40	18-1161-40
Stroke length 200-400	18-1157-42	18-1159-42	18-1161-42
Stroke length 300-500	18-1157-44	18-1159-44	18-1161-44
I.d. 400 mm Auto. nozzle			
Stroke length 100-300	18-1157-41	18-1159-41	18-1161-41
Stroke length 200-400	18-1157-43	18-1159-43	18-1161-43
Stroke length 300-500	18-1157-45	18-1159-45	18-1161-45
I.d. 400 mm SFP* Man. nozzle			
Stroke length 100-300	18-1170-53	18-1176-12	11-0011-85
Stroke length 200-400	11-0011-80	11-0011-83	11-0011-86
Stroke length 300-500	11-0011-82	11-0011-84	11-0011-87
I.d. 400 mm SFP Auto. nozzle			
Stroke length 100-300	11-0011-89	11-0011-91	11-0011-94
Stroke length 200-400	11-0011-88	11-0011-92	11-0011-95
Stroke length 300-500	11-0011-90	11-0011-93	11-0011-96
I.d. 600 mm Man. nozzle			
Stroke length 100-300	18-1150-60	18-1159-60	18-1161-60
Stroke length 200-400	18-1157-62	18-1159-62	18-1161-62
Stroke length 300-500	18-1157-64	18-1159-64	18-1161-64
I.d. 600 mm Auto. nozzle			
Stroke length 100-300	18-1157-61	18-1159-61	18-1161-61
Stroke length 200-400	18-1157-63	18-1159-63	18-1161-63
Stroke length 300-500	18-1157-65	18-1159-65	18-1161-65
I.d. 800 mm Man. nozzle			
Stroke length 100-300	18-1150-80	18-1159-80	18-1161-80
Stroke length 200-400	18-1157-82	18-1159-82	18-1161-82
Stroke length 300-500	18-1157-84	18-1159-84	18-1161-84
I.d. 800 mm Auto. nozzle			
Stroke length 100-300	18-1157-81	18-1159-81	18-1161-81
Stroke length 200-400	18-1157-83	18-1159-83	18-1161-83
Stroke length 300-500	18-1157-85	18-1159-85	18-1161-85
I.d. 1000 mm Man. nozzle			
Stroke length 100-300	18-1150-10	18-1160-10	18-1162-10
Stroke length 200-400	18-1158-12	18-1160-12	18-1162-12
Stroke length 300-500	18-1158-14	18-1160-14	18-1162-14
I.d. 1000 mm Auto. nozzle			
Stroke length 100-300	18-1158-11	18-1160-11	18-1162-11
Stroke length 200-400	18-1158-13	18-1160-13	18-1162-13
Stroke length 300-500	18-1158-15	18-1160-15	18-1162-15

For column specifications other than listed in the table, please contact your local GE Healthcare representative.

 $\ast$  SFP = Small Flow Path on mobile phase, only available on 400 mm i.d. columns.

### Packing stations

	Min	Max (I/mmn)	Code No.
	(I/mmn)	(I/mmn)	Coue No.
Pack 50	10	50	18-1163-74
Pack 100	30	100	18-1162-08
Pack 200	60	200	Custom order
Pack 400	100	400	Custom order

### Accessories

Desmgnatmon	Code No.
Valves	
4 port 2 way, i.d. 10 mm, 25 mm TC	18-1012-56
4 port 4 way, i.d. 10 mm, 25 mm TC	18-1012-57
3 port 2 way, i.d. 15 mm, 25 mm TC	44-5499-90
4 port 4 way, i.d. 20 mm, 51 mm TC	44-2302-01
3 port 2 way, i.d. 22 mm, 51 mm TC	44-1583-01
3 port 2 way, i.d. 35 mm, 51 mm TC	44-5494-65
Valve sealing washer	18-1128-69
Fits 10 mm 2- and 4-way valves	
PVC tubing with sanitary fitting 25 mm TC	
i.d. 10 mm, 900 mm	18-1012-62
i.d. 10 mm, 1400 mm	18-1012-63
i.d. 10 mm, 1700 mm	18-1012-64
i.d. 10 mm, 2000 mm	18-1012-87
i.d. 14 mm, 750 mm	18-1027-28
i	.d. 14 mm,
1800 mm	18-1027-29
PVC tubing with sanitary fitting 51 mm TC	
i.d. 22 mm, 900 mm	44-1616-09
i.d. 22 mm, 1400 mm	44-1616-08
i.d. 22 mm, 2000 mm	44-1616-07
È	d. 22 mm,
4000 mm	44-1616-06
Clamp gasket	
25 mm i.d., 10 mm	18-1035-79
25 mm i.d., 12 mm	18-0200-00
51 mm i.d., 22 mm	44-7133-01
51 mm i.d., 38 mm	44-0515-01
Clamp 25 mm	18-1001-31
Clamp 51 mm	44-7134-01
Blind flange 25 mm incl. gasket	18-1001-25
Blind flange 51 mm incl. gasket	44-7135-01
Safety valve, 3 bar, 51 mm TC	18-5738-01
Safety valve, 5 bar, 51 mm TC	44-5498-97
T-junction i.d., 10 mm, 2×25 mm TC, 1×51 mm TC	18-1003-63
Castors, assembly kit 400-600	18-1171-51
Castors, assembly kit 800-1000	18-1171-52
The kit contains a complete set of wheels, fasteners and adapters for a column.	
Pressure sensor i.d. 10 mm, 25 mm TC	44-0507-02
Pressure sensor i.d. 22 mm, 51 mm TC44-0507-03	

Desmgnatmon	Code No.
Media stirrers	
Media stirrer, 80 cm	18-1149-80
Media stirrer, 150 cm	18-1149-81
Connectors	
i.d. 10, 25 mm TC-3/4"-20 UNF threaded	18-1012-68
i.d. 10, 25 mm TC-i.d. 14, 51 mm TC	18-1027-25
i.d. 14, 51 mm TC-i.d. 22, 51 mm TC	18-1027-26
Chromaflow Nozzle control unit	18-1164-61
Chromaflow Nozzle pipings	
Chromaflow Nozzle piping 400 1/2"	18-1172-01
Chromaflow Nozzle piping 400 3/4"	18-1172-00
Chromaflow Nozzle piping 400 1"	18-1171-99
Chromaflow Nozzle piping 600 1/2"	18-1172-06
Chromaflow Nozzle piping 600 3/4"	18-1172-05
Chromaflow Nozzle piping 600 1"	18-1172-04
Chromaflow Nozzle piping 800 1/2"	18-1171-94
Chromaflow Nozzle piping 800 3/4"	18-1171-93
Chromaflow Nozzle piping 800 1"	18-1171-92
Chromaflow Nozzle piping 1000 1/2"	18-1172-09
Chromaflow Nozzle piping 1000 3/4"	18-1172-08
Chromaflow Nozzle piping 1000 1"	18-1172-07

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#### **Fisher Scientific\*** Isotemp\* Plus Lab Freezers

Microprocessor temperature control



13-986-147

Click in the table below to view accessories.

 Items
 Details
 Images

 Description

 Temperature range, -30° to -12°C (-22° to +10.4°F), with average ±3°C stability
 Capacities from 23.1 to 46.6 cu. ft. (654 to 1320L)
 Interior adjustment control, user-selectable in °C or °F with 0.1°C resolution
 Exterior-mounted digital display
 Automatic defrost and condensate removal
 Construction
 Stainless steel exterior and interior
 CFC-free R404A refrigerant
 Foamed-in polyurethane insulation
 White epoxy-coated steel-wire shelves, adjustable in 1/2 in. increments
 Cherement insulation with the motion
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- Fluorescent lighting with door-activated light switch
- Hinged lockable doors
- Keyed ON/OFF power switch
- Four adjustable leveling legs (casters provided)

#### Alarms

- Panel-mounted, factory installed
- Digital display with minimum/maximum setpoints, audible alarm, and 24V, 0.5A SPST N.O. relay contacts
- Freestanding (13-986-160), Standard Remote (13-968-32A) and Deluxe Remote (13-986-100) alarm systems available separately

#### Seven-day Selectable Temperature Recorder

- Panel-mounted, factory installed
- 6 in. dia. (15.2cm) chart
- User-selectable temperature ranges
- Single-point calibration; individually calibrated against equipment with calibration certified traceable to NIST\*
- Supplied with 60 charts and 7-day scale

#### Specifications & Ordering Information:

International models are available; contact your Fisher Scientific Customer Service Representative for details.

Certifications: CUL listed Warranty: 13 months parts and labor Service agreement available.

#### Items Details Images

#### Description

- Temperature range, -30° to -12°C (-22° to +10.4°F), with average ±3°C stability
- Capacities from 23.1 to 46.6 cu. ft. (654 to 1320L)
- Interior adjustment control, user-selectable in °C or °F with 0.1°C resolution
- Exterior-mounted digital display
- Automatic defrost and condensate removal

Construction

- Stainless steel exterior and interior
- CFC-free R404A refrigerant
- Foamed-in polyurethane insulation
- White epoxy-coated steel-wire shelves, adjustable in 1/2 in. increments
- Fluorescent lighting with door-activated light switch
- Hinged lockable doors
- Keyed ON/OFF power switch
- Four adjustable leveling legs (casters provided)

Alarms

- Panel-mounted, factory installed
- Digital display with minimum/maximum setpoints, audible alarm, and 24V, 0.5A SPST N.O. relay contacts
- Freestanding (13-986-160), Standard Remote (13-968-32A) and Deluxe Remote (13-986-100) alarm systems available separately

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Specifications & Ordering Information:

International models are available; contact your Fisher Scientific Customer Service Representative for details.

#### Certifications: CUL listed Warranty: 13 months parts and labor Service agreement available.

	46.6 cu. ft. (1320L), 2 hinged solid doors												
Basic	26 x 48 x 59 in. (66 x 122 x 150cm)	8	34 x 52 x84.5 in. (86 x 132 x 215cm)	527 lb. (239kg)	208/230V 60Hz	L14-20P	12/15	<u>13-986-147</u>		Each for \$11,478.25			
With Recorder/Alarm	26 x 48 x 59 in. (66 x 122 x 150cm)	8	34 x 52 x 84.5 in. (86 x 132 x 215cm)	532 lb. (242kg)	208/230V 60Hz	L14-20P	12/15	<u>13-986-147RA</u>		Each for \$12,385.63			

### SIEMENS

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### RAPIDLab® 1200 Systems - Features & Benefits

Specifically designed to meet the challenges of the busy clinical lab or various hospital settings, the RAPIDLab 1200 Systems address all your critical care testing needs:

- · Extensive test menu includes CO-oximetry and neonatal total bilirubin
- · Ready Sensor® electrode technology for industry-proven reliability
- · Cost-effective, cartridge-based system
- · Simplified, safer operation with biosafe sampling
- · Automatic quality control and documentation
- · Seamless integration with your LIS/HIS
- · Dedicated technical support and on-site service

### Enhanced critical care testing in the NICU

While RAPIDLab 1200 Systems' array of features make it stand out from other blood gas analyzers, it's the exceptional testing performance, accuracy and consistency of RAPIDLab Systems that make it your ideal NICU monitoring solution:

- · Ultra-fast sample processing enables immediate physician intervention
- · Unparalleled clinical parameter excellence reduces the need to repeat tests
- Microsample capability enables testing of very small sample volumes without compromising accuracy
- Full test menu from a single sample

Because when it comes to the smallest and most vulnerable of patients, fast results, delivered instantly, can make all the difference in the world.

### Get the complete picture in just one minute

- RAPIDLab 1200 System parameter listing: Blood Gas (pH, pCO<sub>2</sub>, pO<sub>2</sub>)
   Electrolytes (Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>)
   Metabolites (Glucose, Lactate, Neonatal Total Bilirubin)
   CO-oximetry (tHb, HHb, O<sub>2</sub>Hb, sO<sub>2</sub>, COHb, MetHb)
- · Testing panels can be customized to meet specific needs
- · Capable of running the full test menu on short-sample patient draws (microsamples)
- > RAPIDLab 1200 Systems parameter listing





### SIEMENS

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RAPIDLab® 1200 Systems - Technical Specifications

| March 25, 2010

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### **RAPIDLab® 1200 Systems - Technical Specifications**

### **Technical Specifications**

Sample Volume				
Platform	Syringe(1ml) Min. Vol.	Mode	Capillary Min. Vol.	Mode
RAPIDLab 1240 System	90 ul	Full menu	90 ul	Full menu
	-	-	35 ul	pH
RAPIDLab 1245 System	140 ul	Full menu	140 ul	Full menu
	100 ul	pH	35 ul	pH
RAPIDLab 1260 System	150 ul	Full menu	125 ul	Full menu
	100 ul	pH	95 ul	pH
RAPIDLab 1265 System	175 ul	Full menu	175 ul	Full menu
	95 ul	pH	95 ul	pH

Analysis	
Time to Results:	60 seconds

QC/AQC	
Analysis Time:	130 seconds (automatic QC or ampule)

Reagent Cartridge	
Use Life:	30-32 days

Wash Cartridge	
Use Life:	Sample dependent

Calibration	
1 point Calibration	Every 30 minutes
Full Cal Calibration	Every 8 hours

Environmental	
Temperature:	15°C-32°C
Humidity:	5%-85% non-condensing

System Dimensions	
Width:	58.4 cm (23.0 in.)
Height:	57.2 cm (22.5 in.)
Depth:	55.9 cm (22 in.)
Weight:	29.5 kg (65 lb)

Power Requirement	
Rating:	150VA
Voltage:	100-240V
Frequency:	50/60Hz

### External Interfaces

USB Printer Port, RS232 Port, Bar Code Scanner Port, RJ10/100 Base T Ethernet Port

### Approvals

EN 60601-1-2:2001, Group 1, Class B, CB Test Certificate, UL Certificate, CSA Certified

### Thermo Scientific\* CryoMed Controlled-Rate Freezers

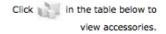


Cabinet Material

Precise freezing from -180° to +50°C for maximum accuracy of cell freezing

With six standard preset and 10 user-defined (20 steps each) freezing profiles that can be modified for custom protocols.

Includes: 6 ft. (1.8m) flexible stainless-steel transfer hose, 0.5 in. 35° flare, thermal paper, 25- to 9-pin serial interface cable/adapter, and 10 ft. (3m) RS-232 cable



escription	
asy Programming and Monitoring	
<ul> <li>Chamber temperature monitored by fixe</li> <li>Sample temperature monitored by Type</li> <li>Pre-Cool step automatically begins temp</li> <li>Audible indicators alert operator when h</li> </ul>	T thermocouple with flexible cable (included) perature ramp when chamber and sample temperatures are equilibrated within 1°C hold time has elapsed ts less than 10 seconds; audible/visual alarm for outages lasting longer than 10 seconds
N <sub>2</sub> Freezing System Components	
<ul> <li>Intuitive control panel and integrated th</li> <li>Dual solenoid valves increase LN<sub>2</sub> inject</li> </ul>	nermal printer tion volume for precise temperature control and accelerated freezing for optimum cell
viability <ul> <li>Specially designed air handling system</li> <li>Overtemperature protection on heating</li> </ul>	and liquid nitrogen ring work in tandem for precise temperature control and uniformity element
onstruction	
<ul> <li>Type 304 stainless-steel construction</li> <li>Exterior powder-coat finish</li> <li>Foamed in-place polyurethane insulation</li> <li>Bulb-style gaskets ensure tight door sea</li> <li>Front- and top-access models are designed</li> </ul>	al; PTFE heat-breaks prevent door from freezing closed
compliance: UL listed to U.S. and Canadian requirer	ments; CE marked
Front- and top-access models are desig	ned for human IVF and easy "seeding"

Stainless steel with power-coat paint finish

Capacity	Interior D x W x H	Exterior L x W x H†	Net Weight	Electrical Reqts.	Plug Type	Cat. No.	Quantity	Price
	Front Access Models							
0.6 cu. ft. (17L)	13 x 7 x 12 in. (33 x 17.8 x 30.5cm)	20.4 x 31.7 x 20.4 in. (51.8 x 80.5 x 51.8cm)	140 lb. (63.5kg)	120V 60Hz 12A	NEMA 5-15P	TF7450		Each for \$23,990.91
1.2 cu. ft. (34L)	13 x 13 x 12 in. (33 x 33 x 30.5cm)	20.4 x 37.7 x 21.2 in. (51.8 x 95.8 x 53.8cm)	160 lb. (72.6kg)	120V 60Hz 12A	NEMA 5-15P	<u>TF7452</u>		Each for \$24,345.45
1.7 cu. ft. (48.1L)	13 x 19 x 12 in. (33 x 48.3 x 30.5cm)	20.4 x 43.7 x 21.2 in. (51.8 x 111 x 53.8cm)	180 lb. (81.6kg)	120V 60Hz 12A	NEMA 5-15P	TF7454		Each for \$24,581.82
		Front and	Top Acces	s IVF Unit	s			
0.6 cu. ft. (17L)	13 x 7 x 12 in. (33 x 17.8 x 30.5cm)	20.4 x 31.7 x 21.2 in. (78.7 x 80.5 x 57.2cm)	140 lb. (63.5kg)	120V 60Hz 12A	NEMA 5-15P	TF7456		Each for \$24,109.09
1.2 cu. ft. (34L)	13 x 13 x 12 in. (33 x 33 x 30.5cm)	20.4 x 37.7 x 21.2 in. (51.8 x 95.8 x 53.8cm)	160 lb. (72.6kg)	120V 60Hz 12A	NEMA 5-15P	TF7458		Each for \$22,300.00

### SCIENTIFIC About Us My Account



autoclaving.

- Spin up to 14x50ml conical tubes in a single run.
- Achieve superspeed performance with RCFs over 24000xg on the benchtop.
- Safely perform high RCF, single-step separations using sterile, disposable conical tubes.

#### Enhanced user and sample safety

- The SMARTspin® imbalance detection system allows for eye balancing of samples with automatic termination of a run if excessive imbalance occurs.
- Automatic rotor recognition ensures precise rotor performance while preventing the use of incorrect accessories or parameters.



Sorvall Legend T Plus and RT Series Benchtop Centrifuges: The next generation Legend in sample preparation.

#### Modular, ergonomic design

- The Sorvall Legend T Plus and RT Plus Benchtop Centrifuge Series' low deck height – just 12" high -- allows for easy loading and unloading of samples.
- The unique soft-touch lid effortlessly clicks into place for worry-free centrifugation.

#### User-friendly operation

- The EASYset™ soft-touch keypad allows for one-touch control of speed, programming and pre-cooling functions.
- A bright, easy-to-read LED display allows easy monitoring from across the lab.

#### Exceptional reliability

The brushless induction drive system of the Sorvall Legend T Plus and RT Plus Centrifuges guarantee years of dependable performance with minimal maintenance along with whisper-quiet operation and powerful acceleration and braking.

#### Contact a Thermo Scientific Sales Representative

The Sorvall Legend T/RT Plus Series Benchtop Centrifuge combines outstanding speed and powerful separation in a quiet, compact design. For more information about this high-quality benchtop centrifuge, **contact a Thermo Scientific sales rep**.

Browse our other centrifuge options.

Download our centrifugation application notes and articles.

Angle Kotor .	6x94 ml
	48x2 ml
	8x50c
Control System :	Digital Set-Point,
	Microprocessor;
	self-diagnostics
Timer :	1 min - 99 h + hold
Braking :	9 rates
Acceleration :	9 rates
Programs :	4, direct keystroke
	access + pre-cooling
	program
Temperature range :	Legend RT+:
	-9 °C to 40°C
Max Power (120V) :	Legend T+: 900 W
	Legend RT+: 1220 W
Max Power (230V) :	Legend T+: 1250 W
	Legend RT+: 1900 W
Dimensions	Legend T+:
(H x W x D)	14.3 x 21.7 x 26.2
inch (mm) :	(362 x 551 x 666)
	Legend RT+:
	14.3 x 28.7 x 26.2
	(362 x 733 x 666)
Weight Ib (kg) :	Legend T+: 196 (89)
	Legend RT+: 288 (131)

### Sorvall Legend T/RT Plus Series Benchtop Centrifuge

Product#	Price	Description	Power Requirement	
75004367	-	SORVALL Legend T Plus Benchtop Centrifuge	120V (60 Hz)	SELECT
75004363	-	SORVALL Legend T Plus Benchtop Centrifuge	230 V (50/60 Hz)	SELECT
75004377	-	SORVALL Legend RT Plus Benchtop Centrifuge	120V (60 Hz)	SELECT
75004373	-	SORVALL Legend RT Plus Benchtop Centrifuge	230 V (50/60 Hz)	SELECT

Details All Product Numbers

Related Products					
Product#	Product Name	Image			
75003334	6 x 94 ml Fixed-Angle Rotor		Select		
75006435	Bioshield Windshielded Swinging Bucket Rotor		Select		
75006444	HIGHplate Windshielded Microplate Rotor		Select		
75003057	Highconic Rotor		Select		
75003332	Microliter Rotor (3SR Plus Only)		Select		
75006445	TTH-750 High-Capacity Swing-Out Rotor		Select		



Automated viability solutions

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Vi-CELL

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BECKMAN COULTER.

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VI-CELL<sup>TM</sup> SERIES CELL VIABILITY ANALYZERS

Part of the Cell Lab family

viability %

cell counting & sizing

total cell concentration

21 CFR Part II

validation

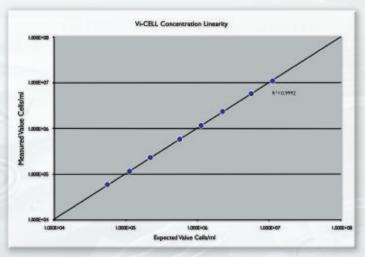
# VI-CELL SERIES

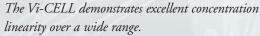
### Cell Viability Analyzers

The Beckman Coulter Vi-CELL automates the widely accepted trypan blue dye exclusion method for cell viability that has historically been performed manually with a light microscope and hemacytometer. In minutes, the Vi-CELL system measures 15 to 30 times the volume of the hemacytometer method with a more comprehensive number of parameters enhancing statistical reliability of the results.

The Vi-CELL Series features the following key benefits:

- Automated viability analysis using the trypan blue standard.
- Rapid, reliable and objective results over manual hemacytometer methods.
- Cell Imaging provides critical information not available using conventional methods.
- Enhanced Image resolution provides cellular detail 10x better than other image viability analyzers.





### Theory and Function

### TRYPAN BLUE DYE EXCLUSION METHOD

The Vi-CELL utilizes the widely accepted trypan blue dye exclusion method to determine cellular viability. When cells die their membranes become permeable, thus allowing for the uptake of the trypan blue dye. As a result, the dead or non-viable cells become darker than the viable cells. It is this contrast that is measured to determine viability.

### INSTRUMENT OPERATION

The Vi-CELL, while simple to use, represents the very latest in cutting edge image analysis technology and fluidics management. At the heart of the Vi-CELL is our customized liquid handling system. This system, which allows sample aspiration, reagent handling, and subsequent instrument cleaning, is fully automated. Once the cellular suspension has been aspirated and mixed with the trypan blue, it is pumped to the flow cell for imaging. The Vi-CELL will analyze up to 100 images for a determination of cellular viability. This whole process and the subsequent cleaning cycle takes approximately 2.5 minutes.

### IMAGING TECHNOLOGY

In the Vi-CELL system a proprietary algorithm is utilized to determine which cells have absorbed the trypan blue dye and which have not.

The first step is to digitize the collected video image and transform this from a continuous smooth image into an array of distinct elements or pixels. The Vi-CELL provides enhanced magnification and an effective pixel area size resulting in superior image resolution. Each element is assigned a "gray level" or brightness value from 0 (black) to 255 (white).

Thresholds within the software then determine which cells have absorbed trypan blue dye and which have not. Those cells that have lower gray values appear "dark" and are determined to be non-viable. Those with high "gray levels" are determined to be viable. Sample Analysis has never been so simple, it's as easy as ...



STEP : Load your sample.

og in sample

Position 2

Cell type

Date

Antibody Monoclonal # 285

Dilution factor

V OK

Sample ID Reactor 1

CHO

1.0

.

4/24/2002 ÷ Time 12:42:14 PM ÷ Comment

Save images Print results

Next sample X Cancel

\* •

+

STEP.	2:	
	Log-in your	sample.

-	-
STE	P.S:

View your results.

Stored Run Resu	lts			
Sample ID	15mlBIIC			
Cell type	СНО			
	Image 4	Total		
Cell count	34	4032		
Viable cells	32	3768		
Viability	94.1 %	93.5 %		
Total cells / ml	2.71 ×10 <sup>6</sup>	3.23 x 10 <sup>6</sup>		
Viable cells / ml	2.55 × 10 <sup>6</sup>	3.02 ×10 °		

## Software with power, flexibility, and simplicity

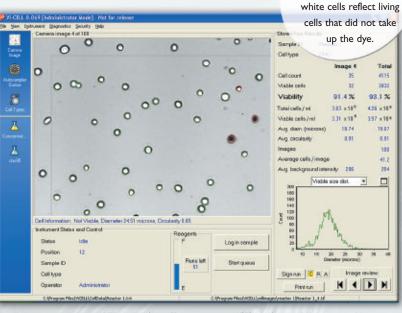
### Power and Flexibility for R&D, QC and Manufacturing Applications - at Your Fingertips

The Vi-CELL software interface has been designed to be simple to use, yet offers numerous innovative features for those users demanding the maximum flexibility.

For many users the main screen may be the only one they need. Everything the user requires to log in samples and view results is right there. All of the available graphs, including Viability %, Viable size distribution, and Total cells/mL are easily selectable via the drop-down menu.

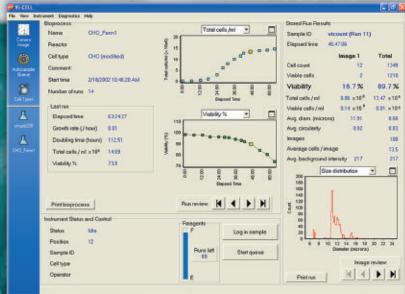
The bioprocess tracking, auto-sampler queue and control monitoring features are easily accessed via the novel navigation bar on the left side of the screen.

Real-time cellular imaging provides additional information not available using standard aperture cell counting methods. This image enhances the results, combining cellular detail with viability, size and concentration.



### Real-time cellular imaging enhances results

## Optimize your bioreactor data Monitor your culture over time 🕮



### BIOPROCESS-TRACKING

The trypan blue dye uptake by the dark

cells here indicate they

are dead, whereas the

The Vi-CELL bioprocess-tracking feature allows convenient, automated tracking of your cell culture parameters, essential for optimum bioreactor productivity. Data points of total cell counts and viability percent are electronically recorded and stored, eliminating potential errors in manual recording. Thus, the bioprocesstracking feature offers the complete solution for your bioreactor's cellular growth cycle.



### 21 CFR PART II

The Electronic Records and Electronic Signatures Rule (21 CFR Part 11) was established by the FDA to define the requirements for submitting documentation in electronic form and the criteria for approved electronic signatures. Since analytical instrument systems such as the Vi-CELL generate

electronic records, these systems must facilitate compliance with the Electronic Records Rule. By selecting the 21 CFR Part 11 option in the software, it automatically allows the user to configure the system for compliance.

The Vi-CELL features the following key system components to facilitate 21 CFR 11 compliance:

- Audit trail
- Electronic signature capability
- Secure user sign-on
- User level permissions
- Administrative configuration tools

Jser name	Tom Breen
Password	
Confirm password	-
C Advanced Use	er.
Administrator	
	:\Program Files\ViCELL\CelData\TB
Data directory	:\Program Files\ViCELL\CelData\TB :\Program Files\ViCELL\CelImages\TE
Data directory	

### V-CHECK PROGRAM

BICKPHA

Beckman Coulter Inc. complies with current Good Manufacturing Practices (cGMP's). This gives Beckman Coulter a unique understanding of the strict requirements that users in regulated industries are subjected to. As a result, Beckman Coulter has established a comprehensive program to address all aspects of the instrument validation.

The V-Check program is a comprehensive package that addresses all appropriate aspects of a product's life cycle,

from instrument development to ongoing performance verification (SQ, DQ, IQ, OQ, PQ). The V-Check program contains all the necessary documentation for instrument validation. This documentation is required to show auditors and investigators proof of proper instrument validation. It consists of a number of functional inter-linked components, which have been

> designed to give the user assurance that the product is fit for the purpose that it has been designed for and will perform on a consistent basis for these tasks. Where other instrument manufacturers leave off, Beckman Coulter and the V-Check program assists with ongoing quality checks of the instrument (PQ). This demonstrates that it is important to consider products from a manufacturer that not only understands your needs, but is also willing to develop a Partnership for quality.

## Vi-CELL Series Solutions for low and high-throughput environments

### THE VI-CELL S (Single Position)

Allows individual sample runs for most all cell types in the size range of 5 to 70 micron diameter.

### THE VI-CELL AS (Auto-Sampler)

Offers identical capabilities with the added feature of a 12-position sample carrousel for increased sample throughput and enhanced automation.

### THE VI-CELL XR (Extended Range)

Offers additional benefits over the S and AS Models:

- Extended size range to 2 microns, allowing additional analyses of yeast, and smaller cells.
- Increased sample throughput with greater efficiency.
- Reduced sample volume results in less reagent use.
- Auto focus capability increases instrument ease of use.
- Variable aspiration and mixing cycles optimize results.
- Enhanced image magnification (6.75×), provides unparalleled cellular detail.
- Circularity measurement helps isolate debris from cells.

The 12-position 'continuous' auto-sampler for high-throughput environments eliminates the need to remove the carrousel.

### INTEGRATED, VALIDATED REAGENT SOLUTIONS

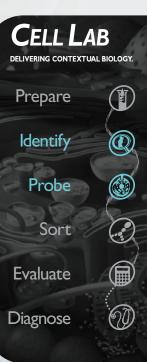
- Color coded packs
- Quick & easy installation
- Validated reproducibility



### Vi-CELL XR Vi-CELL AS Vi-CELL S

**Benefits** 

	VI-CELL AR	VI-CELL AS	VI-CELL 3	Benefits				
Part Number	383556	6605769	383080					
Auto Sampler	Yes	Yes	No	Eliminates need to remove carrousel				
Size Range (µm)	2-70	5-70		Improved measuring range for small cells and yeast				
Sample Volume (mL)	0.5		I	Reduced reagent consumption, nearly double the sample runs				
Analysis Time (min.)	2.5	3	.5	Time savings, increased throughput				
Imaging Technology Camera Focus Image Collection Camera	Auto Firewire 1394x1040 CCD	Maı Image Fran 640x48	ne Grabber	Resolution increased 2x, providing for better analysis of small cells and yeast. Higher resolution improves identification of clustered cells for optimum analysis				
Image Zoom	Yes	N	lo	Helps identify and optimize cell types and cell clustering				
Aspiration and Trypan Blue Mixing	Variable	Fixed		Helps optimize cell types, such as fragile cell lines. Added mixing helps separate sticky cells before analysis, improving results.				
Out of Range Concentration Flag	Yes	No		Automatically keeps operator informed				
Filled Dispense Tray Flag	Yes	No		Automatically keeps operator informed				
Bioprocess 3D, Rotateable Plotting	Yes	Ν	lo	Visually see trend changes				
Export Multi-run Files to MS Excel	Yes	Ν	lo	Facilitates Data Handling				
Upgraded Audit Trail	Yes	No		Assists in system validation requirements				
Non-viable Cell Declustering User-defineable Declustering Options	Yes	No		Helps in optimizing cell types, such as "sticky cell lines" and helps number cells in clusters				
Added Preferences for Secured Users	Yes	None		None		None		Assists in system validation requirements
Enhanced Circularity Measurement	Yes	Ν	lo	Helps in isolating debris from sample				



7



### Technical Specifications

Instrument Function: Concentration Range
Operating System
Instrument TypeVideo imaging through a quartz flow cell
Power RequirementsPower 50 watts (65 Watts Max.) Voltages 100V, 120V, 220V or 240V 50/60 Hz
<b>Temperature</b>
<b>Weight</b>
<b>Unit Dimensions (H×W×D)</b>

### Ordering Information

Part Number		Auto Sample	Size Range (µM)	Sample Volume (mL)	CYCLE TIME (MIN)	VIABILITY RANGE	Imaging Technology	
383556	Vi-CELL XR	Yes	2-70	0.5	<2.5	0-100	Auto-focus routine Firewire Camera 1394 × 1040 CCD array	
6605769	Vi-CELL AS	Yes	5-70	1.0	<3.5	0-100	See VI-CELL S	
383080	Vi-CELL S	No	5-70	1.0	<3.5	0-100	Manual focus routine Image frame grabber 640 × 480 CCD array	
383722	Vi-CELL XR Quad Pack							
383198	Vi-CELL AS, S Quad Pack							
175478	Vi-CELL Concentration Control							
175474	Vi-CELL Focus	Control						

The Vi-CELL Series – and all our Cell Lab offerings – are an important part of a broad continuum of Beckman Coulter products, including automated liquid handling, capillary electrophoresis, centrifugation, ultracentrifugation, DNA sequencing, electrochemistry, flow cytometry, fragment analysis, HPLC, integrated core systems, microarrays, particle characterization, scintillation counting, and spectrophotometry.

For information on our comprehensive line of systems, please contact your local Beckman Coulter representative or visit our web site at www.beckmancoulter.com/cell.lab

\* Against the Coulter Counter® reference method



Developing innovative solutions in Systems Biology.

Innovate Automate SIMPLIFY

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