NASA/TM—2010-215845/PART1

Portable Diagnostics Technology Assessment for Space Missions

Part 1: General Technology Capabilities for NASA Exploration Missions

Emily S. Nelson and Arnon Chait
Glenn Research Center, Cleveland, Ohio

February 2010

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Executive Summary

The changes in the scope of NASA's mission in the coming decade are profound and demand nimble, yet insightful, responses. On-board clinical and environmental diagnostics must be available for both mid-term lunar and long-term Mars exploration missions in an environment marked by scarce resources. Miniaturization has become an obvious focus. Despite solid achievements in lab-based devices, broad-based, robust tools for application in the field are not yet on the market.

The confluence of rapid, wide-ranging technology evolution and internal planning needs are the impetus behind this work. This report presents an analytical tool for the ongoing evaluation of promising technology platforms based on mission- and application-specific attributes. It is not meant to assess specific devices, but rather to provide objective guidelines for a rational down-select of general categories of technology platforms.

In this study, we have employed our expertise in the microgravity operation of fluidic devices, laboratory diagnostics for space applications, and terrestrial research in biochip development. A rating of the current state of technology development is presented using the present tool. Two mission scenarios are also investigated: a 30-day lunar mission using proven, tested technology in 5 years; and a 2- to 3-year mission to Mars in 10 to 15 years.

For the lunar mission, the key mission requirements are flight readiness and low cost. Our conclusions are as follows:

- Proven **dipstick** technology is the first choice as a diagnostic tool due to its robustness and ready availability. However, we note that no commercially available dipstick performs all of the diagnostic tests required by CHeCS.
- If no dipstick exists for a particular desired measurement, the next technology that is most technically ready is the **microfluidic electrochemical sensor**. Key concerns are resource requirements, multidiagnostic capability and field testing.
- If electrochemical sensors do not meet the requirement, then **antibody-mediated biochips** should be examined. Such technology could provide a definitive measurement due to antibody specificity, *but must be proven in the field before we can recommend them for this application.*

For the Mars mission, the decisive mission requirements are long shelf life, adaptability, relative maturity level, and a confidence level reflecting the surety of obtaining the diagnostic measurement, through both sensor reliability and backup technology availability. Our findings for this mission scenario are as follows:

- **Dipsticks** remain the simplest solution, but are typically rated at a 1-year shelf life. *If this limitation can be overcome*, e.g., through cryogenic storage, or a combination of cryogenic storage and in-flight deposition of the reactant, then dipsticks again rise to the top for their robustness and ready availability.
- If dipsticks cannot make the particular measurement, then **microscopy** techniques have no shelf life issues, are versatile and provide unique information (e.g., cell pathology). Moreover, they are technically mature and can be shared among other mission tasks, e.g., investigation of Martian dust. Issues may remain with biocontainment.

- If microscopy cannot perform the needed diagnostic, then **microfluidic electrochemical sensors** should be investigated next. They could be engineered for multidiagnostic measurements in a resource-efficient manner, but these sensors require some development effort and field testing.
- **Antibody-mediated biochips** could also be multiplexed and represent significant advantages in providing reliable and specific medical data. Developing this technology class for NASA's applications would require more effort, but could provide information that cannot be gleaned from the above technologies. Shelf life issues must be addressed. Specific devices must be thoroughly tested in the field before it can be deemed mature enough for long-term, self-sufficient missions.
- **Microarray-based biochips** may provide genetic information that is considered crucial in long-term missions. The devices and their supporting hardware must be made resource-efficient and shelf life improved. As with the other biochips, field testing is required.

In the next phase of our work, we will apply this methodology to evaluate the technologies against specific medical requirements, as outlined by the ISS Crew Health Care System (CHeCS).

Background

Biochips, miniaturized sensors, and microfluidic devices represent potential solutions for a range of on-board clinical and environmental diagnostics. The devices are typically small, lightweight, and low power (although their supporting hardware may not be similarly resource-efficient). We seek technologies that can be readily adapted to a broad array of diagnostic tests while remaining faithful to mission requirements. In particular, we are interested in finding matching technologies for monitoring the chemical and biochemical composition of the environment, as well as the humans present in that environment including urinalysis, blood analysis and cell/tissue pathology assays.

A key problem for technology evaluators has been the rapid pace of research and development in the field, primarily in academic and proprietary labs. NASA and its contractors have also developed or have been involved with many such devices. However, it is challenging to compare and contrast the features of such devices, their relative merit with respect to mission needs, and their relative maturity levels based solely on lab-scale results and technical descriptions.

Moreover, there is a wide gap between the spectrum of potential solutions in the R&D stage and the few marketed applications today. The presence of such a wide range of specifically targeted devices poses a range of problems. It is not straightforward to extrapolate data among devices. Different targets may be used for similar diagnostic information, such as: prothrombin time versus activated partial prothrombin time; BNP, N-terminal pro-A-type natriuretic peptide, NT-proBNP; intact βHCG versus nicked βHCG, and other forms of pregnancy hormones; and cardiac biomarkers cTnT versus cTnI. The resulting measurement can differ in sensitivity and specificity. Even for the same target, results among different methods or devices are generally not comparable. Other issues arise in the interpretation of results due to the type of sample (e.g., capillary vs. venous blood), calibration, reference procedures, and the wide variation in the device interface to external world. The wisest course for NASA missions is to settle on using specific devices and methods and develop a comprehensive knowledge base in storing, using, and interpreting the results in the context of spaceflight.

Of course, for any assay, the fundamental measure of utility is the extent to which it informs medical diagnosis and recommendations. However, concerns such as optimization of system mass, volume, power requirements for the devices and their consumables, crew time and safety, and waste generation also become critical in a resource-limited environment. Where possible, we choose least upmass and storage volume. For example, Roche's line of Chemstrips dipsticks can be used with a reader for automated readings of its colorimatric data, but they can also be visually examined without resorting to a separate reader. For NASA's purposes, the latter is preferred to reduce resource requirements.

Also, we must predict any issues with fluids handling or other design problems in hardware, operation and maintenance in a reduced g environment. We also need protocols and hardware for sample collection,

preprocessing and delivery to the device. Fortunately, there is a rich history of such space system analysis at NASA, as well as documented flight experience.

Moreover, the rigorous demands of spaceflight subject the devices to an application far outside of the manufacturers' development targets. Shelf life, radiation and dust exposure.

This study assumes that NASA will always have a narrow range of targeted applications and an even narrower budget opportunity. Thus NASA cannot be an innovator, but must rely primarily on well-tested, available or nearly available technology platforms for its needs. NASA's unique set of mission requirements also translates into a different set of selection criteria than those commonly used to evaluate such technologies for terrestrial applications. NASA must reach a decision point relatively soon for mid-term exploration initiatives, while recognizing the nature of this moving scientific field. The analysis tool described here is meant to provide technology analysts and decision-makers with a guide to efficient allocation of scarce NASA resources for specific missions.

Purpose

The objectives of this study are to:

- Provide an impartial technology assessment of the state-of-the-art and its suitability for specific exploration missions, independent of the specific state of development of any specific device.
- Develop an analytical tool to evaluate broad categories of technology platforms against mission requirements, with specific emphasis on biochips.
- Provide a first cut assessment of seven identified key technology platform categories.
- Provide recommendations for early selection of technology platforms for lunar and Mars missions.
- Develop a template for future analyses of new or existing technology platforms.
- Initiate dialog for next steps, including matching NASA and outside available specific devices using these recommendations.
- Identify gaps, opportunities, and areas for efficient resource allocation.

Technology Assessment

The methodology used to derive the technology assessment tool is based on an objective benefit/risk assessment, centered on scoring and weighting mission- and performance-related attributes for each technology platform (columns in Table 1). We defined a few distinct general categories of technology platforms. Attention is focused on biochip-based technology for medical and environmental diagnostics, including biochips based on microarrays, electrochemistry, antibody binding, and separations. Other commonly used medical tests employ ready-to-use lateral flow immunoassays (dipsticks) and various types of microscopy. We also included a category, "Exotic", as a catchall for those platforms that may provide effective solutions but are as yet immature as medical diagnostics for space. Examples of this category include mass spectrometry and laser light scattering.

We then defined mission and performance attributes, and segregated them into general categories (rows in Table 1). For clarity, we specified performance targets in column 2 for each attribute, e.g., the desired target for the power requirement is "low". The third column labeled "Importance" is assigned a value from 1 to 5, based on mission parameters. We used literature and web surveys, along with our understanding of microgravity fluid physics, to assign values from 1 to 5 in the balance of the table for each combination of attribute and platform. Explanations of each technology platform, category, attribute, and scoring guidelines are presented in Appendix A. Color saturation based on the assigned value gives a quick visual display of the leading candidates and potential pitfalls. The procedure resulted in an overall score for each platform that reflects both the maturity of a given platform and its mission suitability.

Undoubtedly, individual devices will score differently from the values assigned here, which leads to blurring of the boundaries between technologies. However, we expect that the data will lead to groupings

of technologies within bands, say those between 4.7 and 5.0. Rather than wading through all possible devices for each diagnostic test, it would be efficacious to examine the highest-ranking technologies first.

We also note that some technologies may provide absolutely unique information, such as cell morphology through microscopy, while some diagnostic tests can be obtained in a variety of ways (e.g., measurement of cell count through flow cytometry or visual imaging).

Attributes of a technology are classified into five categories. "Medical usefulness" consists of attributes such as diagnostic value and diagnostic capability. "Astronaut impact" represents traits that specifically affect the test operator, i.e., the astronaut. This includes operator time and training, portability, and invasiveness. The latter becomes important in light of the observations of poorer wound healing in space. Thus, a score of 1 in that attribute denotes a grossly invasive procedure such as excision of tissue. On the other hand, 5 indicates a test method that is completely external to the astronaut, such as dipstick testing of urinalysis or infrared determination of glucose concentration in the blood.

TABLE 1.—DIAGNOSTIC ASSESSMENT FOR A LUNAR MISSION WITHIN ABOUT 5 YEARS

Portable Diagnostics Technical Assessment for Space Missions

30-day Lunar Mission within 5 years

Desired attributes	Target	Impor=tance	Dipsticks	Microscopy	Biochips: Microarray-based	Biochips: Electro-chemical	Biochips: Antibody-mediated	Biochips: Separation-based	"Exotic"	Other
Medical usefulness		3								
diagnostic value	high	5	3	3	3	3	3	3	2	1
multi-diagnostic capability	high	3	4	2	3	2	3	5	3	1
accuracy	high	3	5	2	2	4	4	3	3	1
repeatability	high	3	5	2	4	4	3	2	3	1
validation depth	high	4	5	2	3	3	3	2	1	1
complex media	high	2	2	5	2	2	2	2	1	1
flexibility/adaptability to new uses	high	2	1	5	1	1	1	4	4	1
unique information	high	5	2	5	3	3	3	3	1	1
			3.4	3.2	2.8	2.9	2.9	3.0	2.1	1.0
Astronaut impact		2								
operator time	low	4	4	1	2	3	3	2	1	1
operator training	low	2	5	1	2	3	3	2	1	1
invasiveness	low	5	3	2	3	3	3	3	3	1
portability	high	3	5	1	3	3	4	2	1	1
ease of interpretation	high	2	5	2	2	2	4	2	1	1
			4.1	1.4	2.5	2.9	3.3	2.3	1.6	1.0
Flight constraints		5								
mass	low	5	5	1	3	3	3	3	1	1
volume	low	5	1	1	4	4	4	3	1	1
consumables	low	3	4	3	4	4	4	4	3	1
power	low	5	5	3	2	2	2	2	1	1
containment	high	3	2	2	3	3	3	3	3	1
shelf life	high	4	4	5	2	3	2	3	3	1
creation of biohazardous waste	low	4	3	5	3	3	3	3	3	1
maintenance	low	2	5	2	2	3	3	2	2	1
			3.6	2.7	2.9	3.1	3.0	2.9	2.0	1.0
Technical characteristics		3								
sensor complexity	low	5	5	2	3	3	3	3	1	1
sample preparation	low	3	4	1	1	4	3	2	1	1
fluid handling problems in device	low	3	5	2	2	2	2	2	1	1
need for supporting equipment	low	1	5	3	3	4	3	2	1	1
supporting system complexity	low	2	5	2	2	3	3	2	1	1
probable success on earth	high	5	5	5	4	5	5	3	4	1
probable success in microgravity	high	5	4	4	3	4	4	3	1	1
			4.7	3.0	2.8	3.7	3.5	2.6	1.6	1.0
Development issues		5								
maturity level wrt on-orbit today	high	3	5	3	2	2	2	1	1	1
time to TRL7	low	4	5	3	2	4	3	2	2	1
cost to TRL7	low	3	5	3	2	4	3	2	1	1
robustness	high	5	5	2	1	3	3	2	2	1
ease of field testing	high	2	5	3	2	4	4	2	1	1
			5.0	2.7	1.7	3.4	2.9	1.8	1.5	1.0
		SCORE	4.2	2.7	2.5	3.2	3.1	2.5	1.8	1.0

"Flight constraints" are primarily dependent on the use of precious resources, such as mass and power, and on details associated with extended spaceflight, such as shelf life and maintenance. "Technical characteristics" assesses the level of simplicity of the diagnostic tool and its supporting hardware, and fluid handling issues. Finally, "Development issues" incorporates maturity level today, time and cost to TRL 7, and ease of field testing.

For assessing a longer duration Mars mission, for which more planning time and resources are available, the scores for each technology remain the same, but the importance changes for attributes and attribute categories. We assumed that flight constraints are just as important as for the lunar mission, but the urgency for immediate availability is not as pronounced. We also assumed that astronaut invasiveness and medical value should increase for a longer term mission.

Recommendations

30-day Lunar Mission in 5 Years

Due to the relatively short time frame and a tight budget, the key requirements for the lunar mission are flight readiness and low cost. For each required diagnostic test, the top-rated platform(s) should be investigated first. If no reasonable solution is available in that category of platforms, then the next-rated platform(s) should be explored, and so on. The results of this assessment show that:

- **Dipstick-based technology platforms** are simple, robust, available, and have high TRL. No technical issues are foreseen at this time, with the possible exception of biocontainment, but no off-the-shelf dipstick can perform all of the diagnostics required by the current requirements for the Crew Health Care System. Some level of development of dipsticks and/or the following platforms are necessary to meet CHeCS requirements.
- **Electrochemical biochips** are relatively simple and robust, are at relatively high TRL, and are easier to develop than other biochips. A key concern is the resource requirements of the sensor and its supporting hardware. Multidiagnostic capability is highly desirable. We believe that field testing is a crucial component for any such device.
- **Antibody-mediated biochips** are highly versatile, reasonably well-studied, and possess an inherent richness of possibilities that make it a plausible addition. However, *we cannot recommend any device in this category unless it successfully passes extensive field testing.*

2- to 3-year Mars Mission in 10 to 15 Years

The Mars mission is of much longer duration and must be entirely self-sufficient. Most dipsticks and antibodies have a rated shelf life on the order of 1 year, which is a reasonable time frame in an earth environment. In the context of a multiple-year mission to Mars, however, the shelf life of these devices could be a show-stopper. Longevity testing is needed, including perhaps some novel approach to extending shelf life, such as cryostorage and *in situ* deposition of biological substrates. Other key issues for this type of mission include adaptability, since the desired diagnostics may evolve along with the mission. If the platform should fail, redundancy, or the ability to make the required measurement with another available device, should be factored into the measurement strategy. The device should also be at a relatively mature TRL level in order to meet the demands of the mission. With that said, we recommend the following:

- **Dipsticks** remain a top choice due to their simplicity and robustness, *if the shelf life issue can be overcome.* At this time, no commercially available dipstick can perform all of the diagnostics required by CHECS.
- **Microscopy** is versatile, provides unique information, has no shelf life issues and is mature. It is limited in the types of information it can generate, but it can perform blood counts, hematocrit (and

hemoglobin can be derived from that). It can also provide unique information on diagnostics such as cell pathology. Finally, it can be a shared resource with other mission tasks.

- **Electrochemical biochips** (see above).
- **Antibody-mediated biochips** (see above).
- **Microarray-based biochips** may provide genetic information that is considered crucial in long-term missions. The devices and their supporting hardware must be made resource-efficient and shelf life improved. As with the other biochips, field testing is required.

How to Use These Recommendations

The above recommendations were reached using the risk/benefit analysis protocol described above. We selected the attribute list, their relative importance, and other criteria based on our expertise in spacebound hardware operation and biochip development. Other analysts are invited to modify the assessment to their understanding and compare to our conclusions.

This study is a technology platform assessment relative to mission-specific issues. It is not meant to rank or evaluate any specific technology or device. It provides a first cut at an analytical tool for ranking the suitability of a technology platform before any specific device/application decision is being contemplated. While the performance for specific devices may cause some blurring of the boundaries among the general technologies, we suggest that this analysis be used as a starting point for efficient resource allocation in internal planning.

Using similar methodology, a follow-up study that focuses specifically on CHeCS requirements is in process.

Appendix A. Glossary

Diagnostic Technologies

Dipsticks	Lateral flow immunoassay
Microscopy	Light, fluorescence, confocal or other microscopy. Also flow cytometry.
Microarray-based biochip	genetics, PCR
Electrochemical chip	Detection of ionic species, chemical compounds
Antibody-mediated biochip	Detection based on antibody recognition in a microfluidic device
Separation-based biochip	Electrophoresis, HPLC, TLC,etc, in a microfluidic device
"Exotic"	Mass spectrometry, laser light scattering, other high-tech technology that is immature as medical diagnostics for space

Attributes

Attribute	Target	Description	1	2	3	4	5
Medical usefulness							
diagnostic value	high	Do results yield a definitive, specific medical diagnosis? Desired to be high (i.e., target is high)	poor (low diagnostic value)	fair	good	very good	best (high diagnostic value)
multi-diagnostic capability	high	Can this device measure multiple targets? More functionality in detecting many items is preferable.	poor (device has no multi-diagnostic capability)	fair	good	very good	best (high multi-diagnostic capability)
accuracy	high	Is the result verifiable to within an acceptable margin of error? Low margin of error, high accuracy is preferred.	poor (low accuracy)	fair	good	very good	best (high accuracy)
repeatability	high	Are repeated measurements of the same quantity equivalent?	poor (poor repeatability)	fair	good	very good	best (high repeatability)
validation depth	high	Is there a significant validation/knowledge database supporting diagnostic interpretation? Larger bodies of knowledge are preferred.	poor (small database)	fair	good	very good	best (large database)
complex media	high	Can this device handle many types of complex media (e.g., blood, urine, saliva, tissues, gray water, potable water, ...) More is preferred.	poor (one type of medium only)	fair	good	very good	best (any type of complex media)
flexibility/adaptability to new uses	high	Can the device be adapted on-orbit to detect other targets? If so, its flexibility as a dynamic assessment tool under unusual or unexpected conditions is improved.	poor (device is built for a single type of test only)	fair	good	very good	best (device can be adapted on-orbit to measure new targets)
unique information	high	Of the technologies listed in this workbook, can the information obtained by this device be obtained through any other diagnostic technique? If not, its value in obtaining unique information is high.	poor (can be obtained through other devices listed here)	fair	good	very good	best (can not be obtained through other devices listed here)
Astronaut impact							
operator time	low	Amount of time required on-orbit for sample preparation, processing and analysis. Less time is preferable.	poor (requires much astronaut time)	fair	good	very good	best (requires little or no astronaut time)
operator training	low	Amount of time required to achieve proficiency in sample acquisition, preparation, processing and analysis. Simpler systems will, in general, require less training.	poor (requires much training)	fair	good	very good	best (requires little or no training)
invasiveness	low	Extent to which astronaut's body must be invaded to yield a clinically significant sample. Low invasiveness is highly preferable due to lower rate of wound healing in space.	completely external	microneedles	pinprick	venipuncture	excision of tissue
portability	high	Extent to which astronaut can conveniently carry the device on extra-vehicular or extra-habitat missions for on-the-spot diagnostics. High portability is desired.	poor (is not portable)	fair	good	very good	best (sensor and supporting hardware are handheld or better)
ease of reading results	high	Results that are unambiguous, instantaneous, and easily read without supporting equipment are preferred.	poor (not so easy to read)	fair	good	very good	best (easy to read results)
Flight constraints							
mass	low	Mass of sensor and its infrastructure. Lower is preferred.	poor (high mass)	fair	good	very good	best (low mass)
volume	low	Volume of sensor and its infrastructure. Lower is preferred.	poor (high volume)	fair	good	very good	best (low volume)
consumables	low	Reagents, storage containers, needles, mixing containers, device disposables, cleaning supplies. Lower is preferred	poor (lots of consumables)	fair	good	very good	best (few or no consumables)
power	low	Lower power consumption is preferred.	poor (high power required)	fair	good	very good	best (low or no power requirement)
containment	high	3 levels of containment at all times is desirable; also weighted by volume of analyte required for testing, with lower volume requirements being better.	poor (poor containment)	fair	good	very good	best (highly contained)
shelf life	high	Shelf life of reagents and devices in an extraterrestrial environment, with consideration of biological, material and mechanical wear. This feature will determine mission appropriateness.	6 months	1 year	3 years	5 years	indefinitely
creation of biohazardous waste	low	Waste includes leftover bodily fluids, waste fluids, device disposables, supporting disposables (needles, etc.). Minimal waste creation is preferred.	poor (lots of waste is generated)	fair	good	very good	best (little or no waste is generated)
maintenance	low	Need for cleaning, calibrating, storing, monitoring, etc. Low maintenance is preferred.	poor (lots of maintenance is required)	fair	good	very good	best (little or no maintenance is required)
Technical characteristics							
sensor complexity	low	geometric, chemical, mechanical or other complexity	poor (very complex sensor)	fair	good	very good	best (very simple sensor)
sample preparation	low	sample acquisition, mixing, separating, lysing, and introduction to device	poor (much sample prep is required)	fair	good	very good	best (little or no sample prep required)
fluid handling problems in device	low	potential for issues with clogging, clearing, cleaning, ...	poor (likely to develop problems)	fair	good	very good	best (unlikely to develop problems)
need for supporting equipment	low	requirements for a reader, power, electronics, etc.	poor (requires lots of supporting equipment)	fair	good	very good	best (needs no supporting equipment)
supporting system complexity	low	geometric, chemical, mechanical or other complexity of entire system	poor (very complex supporting system)	fair	good	very good	best (simple supporting system)
probable success on earth	high	a measure of the degree of difficulty in producing reliable results	poor (low likelihood of success)	fair	good	very good	best (likely to be successful)
probable success in microgravity	high	likelihood of issues associated with fluids in space, e.g., bubble management, multiphase flow, wetting problems, containment	poor (low likelihood of success)	fair	good	very good	best (likely to be successful)
Development issues							
maturity level wrt on-orbit today	high	readiness for flight	poor (substantial development needed before flight)	fair	good	very good	best (flight-qualified and tested)
time to TRL7	low	cost to become routine for medical diagnostics	poor (substantial development time is needed)	fair	good	very good	best (technology is at or beyond TRL7)
cost to TRL7	low	time to become routine for medical diagnostics	poor (significant development cost is needed)	fair	good	very good	best (technology is at or beyond TRL7)
robustness	high	unlikely to break or malfunction during routine use	poor (not robust)	fair	good	very good	best (robust)
ease of field testing	high	ease of in situ diagnostics	poor (difficult to test in field)	fair	good	very good	best (easy to test in field)

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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The changes in the scope of NASA's mission in the coming decade are profound and demand nimble, yet insightful, responses. On-board clinical and environmental diagnostics must be available for both mid-term lunar and long-term Mars exploration missions in an environment marked by scarce resources. Miniaturization has become an obvious focus. Despite solid achievements in lab-based devices, broad-based, robust tools for application in the field are not yet on the market. The confluence of rapid, wide-ranging technology evolution and internal planning needs are the impetus behind this work. This report presents an analytical tool for the ongoing evaluation of promising technology platforms based on mission- and application-specific attributes. It is not meant to assess specific devices, but rather to provide objective guidelines for a rational down-select of general categories of technology platforms. In this study, we have employed our expertise in the microgravity operation of fluidic devices, laboratory diagnostics for space applications, and terrestrial research in biochip development. A rating of the current state of technology development is presented using the present tool. Two mission scenarios are also investigated: a 30-day lunar mission using proven, tested technology in 5 years; and a 2- to 3-year mission to Mars in 10 to 15 years.

15. SUBJECT TERMS
Aerospace medicine; Diagnosis; Technology assessment; Blood; Chemical analysis; Urinalysis

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