



**The importance of clonality in stable cell line development
What is clonality and why is it important?**

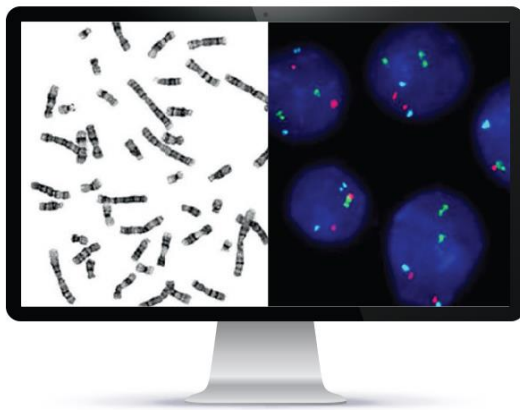
Clonality is a crucial step closely monitored by the regulatory authorities in stable cell line development for biotherapeutic workflows. Their reviews usually lead to two conclusions concerning the importance of clonality:

1. Assurance of the “clonality” of stable cell lines is of major importance in assessing the safety and efficacy of the product.
2. Without adequate proof of “clonality,” additional studies of the cell line and product are often required to ensure their quality and homogeneity. These additional studies and control strategies will also have to be demonstrated for legacy cell lines.

Single-cell cloning is key in a variety of workflows, not just in biotherapeutics and monoclonal antibody production. Companies are increasingly in need of “stable producer” cell lines for gene therapy vector production.

Recent developments such as single-cell sorting and high-throughput imaging allow the acquisition of evidence supporting clonality.

Rederiving a clonal cell line by additional limited dilutions is time-consuming, costly, and most importantly, may affect the production and growth rate of the cell line. This is especially undesired when timelines for the submission are short. Creative Bioarray uses FISH to provide the genetic characterization of producer cell lines, which offers information on transgene integrity and integration sites.



Creative Bioarray's Clonality Analysis Service (FISH) Has The Following Features:

- Detect each integration site
- Analyze 100-200 cells per sample
- Rapid 4 week turnaround time, including additional reporting
- High accuracy and sensitivity
- Competitive pricing

Contact us for details!

Creative Bioarray can be your reliable partner to accelerate your research.

We have the capabilities to provide results that meet your needs!



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