



BIOLOGICS TESTING SOLUTIONS

Microbial Cell Bank Characterization

Assay Offerings

- Identity testing
- Purity testing
- Viability testing
- Genetic stability testing
 - Copy number determination
 - DNA and RNA sequencing
 - Restriction endonuclease analysis
 - Retention of selectable markers
 - Retention of recombinant construct

A well-characterized cell bank provides a consistent source of contaminant-free production cells throughout a product’s life. Our team works closely with clients to develop cost-effective, validated testing programs for use in the characterization of a microbial cell bank. Our experience with manufacturing and testing over 1,500 cell banks is one of the most extensive in the industry.

Manufacturing and Characterization of a Typical Microbial Cell Bank

Week	4	8	12	16
Pre-bank testing				
	Cell Bank production and release - including bacteriophage, viability, purity, and identification testing			
			Retention of selectable markers	
			Retention of recombinant construct	
			Sequencing	
			Restriction endonuclease analysis	
			Copy number determination	

Cell Bank Release and Characterization Testing

Our cell bank characterization programs include testing of master cell banks, working cell banks, and end-of-production cells/cells at limit. Charles River concentrates on developing client-focused project designs tailored to the product, its stage of development, and the required regulations. A list of assays associated with the characterization of microbial cell banks is outlined on the next page. While many of the key aspects of testing are similar across the industry, our customized programs aim to ensure an appropriate testing plan is developed for our clients’ specific cell lines.

EVERY STEP OF THE WAY



Cell Banking Experience

- Yeast
- *E. coli*
- *Streptococcus* species
- *Pseudomonas* species

Release and Characterization Testing Available

Purity and Identification	Determines the presence of contaminating organisms and identity of the parental organism
Bacteriophage Testing	Determines the presence of bacterial virus by induction with mitomycin C or exposure to UV radiation
Viability Testing	Determines the number of viable organisms
DNA Sequence Analysis	Establishes the nucleotide sequence of a gene to verify the consistency of the sequence over multiple generations
RNA Sequence Analysis	Establishes the nucleotide sequence of a gene's transcript to verify consistency over multiple generations
Copy Number Determination	Indicates the number of copies of a construct in the cellular genome
Restriction Endonuclease Analysis	Determines the presence of any major alterations in the recombinant DNA over multiple generations
Retention of Selectable Marker	Evaluates plasmid stability using selectable and non-selectable media
Retention of Recombinant Construct	Verifies the stability of the recombinant construct over multiple generations