

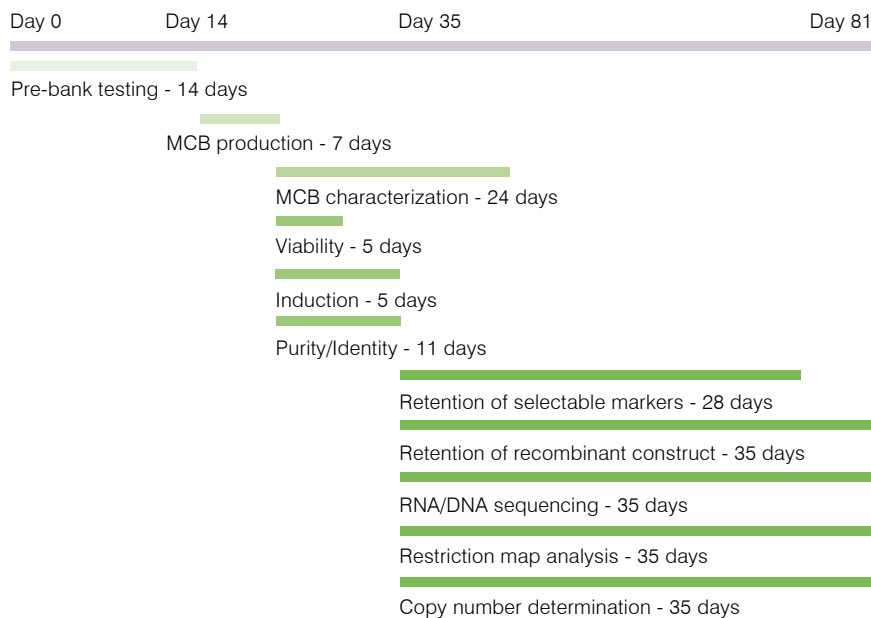


Microbial Cell Bank Characterization

A well-characterized cell bank provides a consistent source of contaminant-free production cells throughout the life of your product. Potential sources of cell bank contamination include the origin of the cell line, raw materials to which it has been initially exposed, and contaminants inadvertently introduced during the preparation of the bank.

The Biopharmaceutical Services (BPS) group at Charles River works closely with clients to develop cost-effective and validated testing programs for use in the characterization of a microbial cell bank. Our experience with over 1,000 cell banks is one of the most extensive in the industry.

Characterization of a Typical *E.coli* Cell Line



In general, pre-bank testing takes 14 days and includes testing for bacteriophages. The duration of master cell bank (MCB) production depends on growth characteristics, media formulations, and batch record preparation.

Service Areas

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

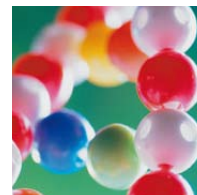
Cell bank Experience

- Mammalian
- Microbial
- Insect
- Yeast
- Avian
- Stem Cell



We offer characterization programs designed to include testing panels that detect the presence of contaminants and verify cell line identity for the MCBs, working cell banks (WCBs), and end-of-production cells (EOPC), which are cells at the limit of *in vitro* age as designated by the International Conference on Harmonisation (ICH).

A list of potential assays associated with the characterization of microbial cell banks is outlined below. Characterization of the cell line includes phenotypic and genotypic analyses.



Assays for Testing MCBs, WCBs, and EOPC	
Purity/identity	Determines the presence of contaminating organisms and identity of the parental organism
Bacterial viruses (bacteriophage)	Determines the presence of bacterial virus by induction with Mitomycin C or exposure to UV irradiation
Viability	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 transcript of a gene to verify consistency over multiple generations
Retention of selectable markers	Evaluates plasmid stability using selectable and non-selectable media
Retention of recombinant construct	Verifies the stability of the recombinant construct over multiple generations
Copy number determination	Indicates the number of copies of a construct in the cellular genome
Restriction map analysis	Determines the presence of any major alterations in the recombinant DNA over multiple generations