

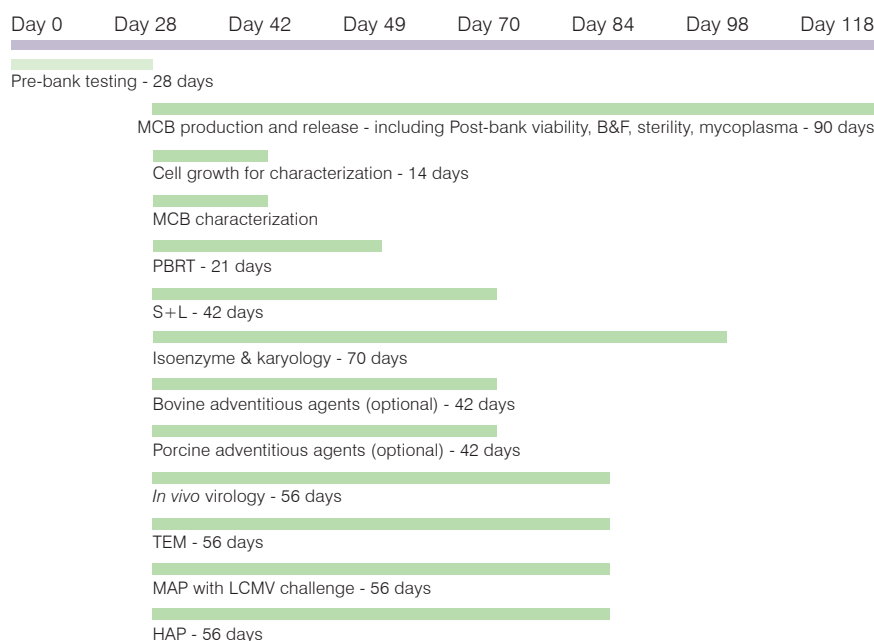


# Mammalian and Other Eukaryotic Cell Bank Characterization

The characterization and testing of cell banks is a critical component of the control of biopharmaceutical or biological products. The objective of this testing is to confirm the identity, purity, and genetic stability of the cell line. The potential risk of introducing adventitious agents such as bacteria, mycoplasma, fungi, or viruses to the biopharmaceutical must be eliminated or minimized. Therefore, cell banks are thoroughly tested to ensure the starting material for your product is free from contamination.

The Biopharmaceutical Services (BPS) group at Charles River works closely with clients to develop cost-effective, scientifically sound, validated testing programs for the characterization of cell banks used to produce biopharmaceutical products. BPS offers characterization programs that include testing panels designed to detect microbial and viral contaminants, verify cell line identity and confirm genetic stability of the Master Cell Banks (MCBs) and Working Cell Banks (WCBs).

## Characterization for a Typical Mammalian Cell Bank



Actual schedules may vary due to the differences in individual cell banks, and the time to completion may be shortened depending upon the testing regimen selected.

## Service Areas

- Identity testing
- Purity testing
- Stability testing
  - Copy number determination
  - DNA and RNA sequencing
  - Restriction map analysis
- Virological safety testing

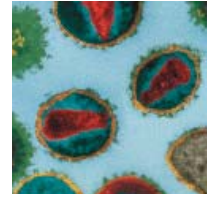
## Cell Banking Experience

- Mammalian
- Insect
- Avian
- Stem Cell



The BPS group provides clients with a wealth of experience in cell bank characterization. Our cell bank characterization programs include testing of MCBs, WCBs, and End-of-Production Cells (EOPCs), which are cells at the limit of *in vitro* age as designated by the International Conference on Harmonisation (ICH). BPS concentrates on developing client-focused project designs tailored to the product, its stage of development, and the required regulations.

A list of potential assays associated with the characterization of mammalian and other eukaryotic cell banks is outlined below. While many of the key aspects of testing are similar across the industry, our team of experts and dedicated programs aim to ensure an appropriate testing plan is developed for your specific cell line.



## Assays for Testing Cell Banks

<ul style="list-style-type: none"> <li>- Bacteriostasis and fungistasis</li> <li>- Sterility</li> <li>- Mycoplasma (cultivable and non-cultivable strains or by PCR)</li> <li>- Mycobacterium</li> </ul>	Determines the presence of contaminating organisms
<ul style="list-style-type: none"> <li>- Isoenzyme analysis/DNA fingerprinting and karyology</li> <li>- Copy number determination</li> <li>- Restriction map analysis</li> <li>- DNA/RNA sequencing</li> </ul>	Cell line identification and genetic stability
<ul style="list-style-type: none"> <li>- Transmission electron microscopy</li> <li>- Reverse transcriptase PCR assay (PBRT)</li> <li>- Retroviral infectivity assays</li> <li>- <i>In vitro</i> and <i>in vivo</i> adventitious virus testing</li> <li>- PCRs for species-specific viruses</li> </ul>	Determines the presence of contaminating organisms
<ul style="list-style-type: none"> <li>- Mouse, rat and hamster antibody production assays</li> </ul>	Antibody production assays