



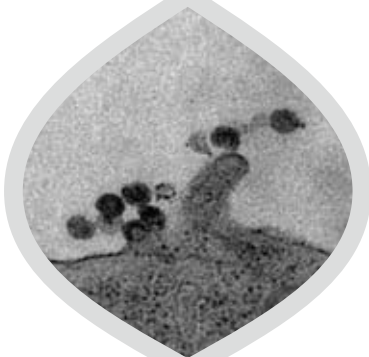
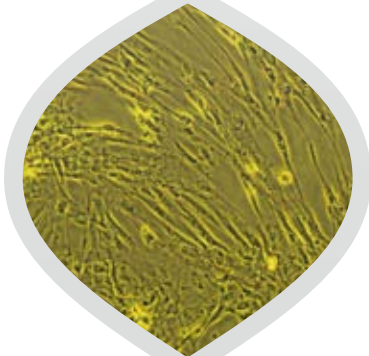
# Testing Facility for Biological Safety (TFBS)

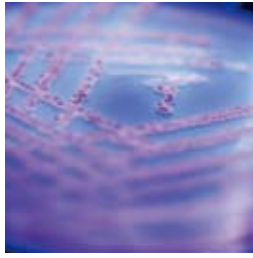
## Cell Bank Characterization

The pivotal step to ensure the safety of the biopharmaceutical product is to perform characterization and biological safety testing of the cell line. The international regulatory guidelines such as ICH (Q5A, Q5B, Q5D), EP, USP and JP for the characterization of a cell line are focused on 3 major aspects: 1. The source history and generation of the cell line; 2. Characterization and testing to establish Identity, Purity and Genetic Stability of the cell line; and 3. The banking procedures of the cell line. Through well-controlled development and characterization of the cell bank, manufacturer can effectively address the quality and safety concerns originated from the presence of adventitious contaminants or the uncertain property of the cell line.

Characterization of cell bank is essential to ensure the safety and production yield of cell-derived biopharmaceutical products. The objective is to confirm the identity, purity, genetic stability and tumorigenicity of the cell bank. Cell banks must be extensively characterized to confirm the cell identity and eliminate the presence of undesired cell lines and adventitious agents such as bacteria, fungi, mycoplasma, mycobacteria and virus. Generally, Master Cell Bank, Working Cell Bank, End of Production Cell, Unprocessed Bulk, Purified Bulk and Final Product at different stage of production all requires a regime of different tests to ensure its safety.

TFBS works closely with clients to develop and design cost effective, scientifically sound, and validated testing methods for the characterization of cell bank. At TFBS, we offer our client accurate, prompt, convenient, and most efficient assays for your time-sensitive projects. From preliminary testing of seed stocks to rigorous Cell Bank Characterization, TFBS can meet your requirement and execute tests with compliance to GLP and international regulatory guidelines.





## Eukaryotic Cell Bank Characterization

## Prokaryotic Cell Bank Characterization

<b>Identity Assays</b>	<ul style="list-style-type: none"> <li>&gt; Isoenzyme Analysis</li> <li>&gt; Karyology Services</li> <li>&gt; DNA Fingerprint Assays</li> <li>&gt; RAPD Assays (Random amplified polymorphic DNA)</li> </ul>	<ul style="list-style-type: none"> <li>&gt; API 20</li> <li>&gt; Bacteriophage Test</li> <li>&gt; Gram Stain</li> <li>&gt; Culture</li> <li>&gt; RAPD Assay</li> </ul>
<b>Purity Assays</b>	<ul style="list-style-type: none"> <li>&gt; Electron Microscopy Services</li> <li>&gt; Sterility Testing</li> <li>&gt; Mycoplasma Testing</li> <li>&gt; Specific Virus Assays</li> <li>&gt; In Vivo / In Vitro Virology Assays</li> <li>&gt; Retrovirology Assays</li> <li>&gt; Mycobacterium Assays</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Antibiotic Resistance Test</li> <li>&gt; Plasmid Sequencing</li> <li>&gt; Restriction Enzyme Mapping and Copy No.</li> <li>&gt; Retention of Expression Construct</li> </ul>
<b>Stability Assays</b>	<ul style="list-style-type: none"> <li>&gt; Nucleic Acid Sequencing Services</li> <li>&gt; Genetic Stability Assays</li> </ul>	
<b>Other Assays</b>	<ul style="list-style-type: none"> <li>&gt; Tumorigenicity</li> <li>&gt; Oncogenicity</li> <li>&gt; Immunogenicity</li> <li>&gt; Customized Assays</li> </ul>	

### Contact Us

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