

We are committed to provide the professional and compliant cell banking , cell line characterization and cell bank bioreposity.

## Cell Substrate Characterization In Biopharmaceuticals

Cell substrate is an important raw material in biologics production. It is categorized as primary cell, diploid cell, stem cell and continuous cell lines in accordance with the origins and characteristics. To ensure the quality of biological products, it is required the full understanding of the cell characteristic and reduction of exogenous agent presence in the cell lines. Comprehensive cell line characterization will bring the high quality and safety to biological products.



TABLE 1 CHARACTERISTICS OF DIFFERENT CELL SUBSTRATE

Cell Line Classification	Advantage	Disadvantage
Primary cell line	<ul style="list-style-type: none"> <li>✓ Easy Preparation</li> <li>✓ High Viral Susceptibility</li> </ul>	<ul style="list-style-type: none"> <li>✗ High Risk of Exogenous Factor</li> <li>✗ High Variability in Quality Stability and Sensitivity</li> <li>✗ Incomplete Testing</li> </ul>
Diploid cell line	<ul style="list-style-type: none"> <li>✓ Easy Standardization</li> <li>✓ High Production Consistency</li> <li>✓ No Tumorigenic Risk</li> </ul>	<ul style="list-style-type: none"> <li>✗ Not Easy to Scale-up Production</li> <li>✗ High Demands on Culture Condition</li> <li>✗ Not Easy to Culture in Serum-free</li> </ul>
Continuous cell line	<ul style="list-style-type: none"> <li>✓ Comprehensive Standardized Training Process</li> <li>✓ Consistency of Cell Banking</li> <li>✓ Scale-up Production Using Standard Media</li> </ul>	<ul style="list-style-type: none"> <li>✗ Risk of Endogenous Virus</li> <li>✗ Potential Tumorigenicity</li> </ul>
Stem cell line	<ul style="list-style-type: none"> <li>✓ Comprehensive Standardized Training Process</li> <li>✓ Consistency of Cell Banking</li> <li>✓ Standard Media</li> </ul>	<ul style="list-style-type: none"> <li>✗ Complex Passage Culture</li> <li>✗ Unspecified Protein Products</li> <li>✗ Difficult to Control Cell Differentiation</li> </ul>



The application of cell substrate in biopharmaceuticals includes expression system, host cell, donor cell, etc. In the cell substrate preparation, cell banking is considered to be the best solution to ensure reliable and consistent cell production. Cell bank should be fully characterized before used in manufacture. Although primary cells are not suitable for cell banking, the batch release testing is still required for product safety.



Expression System (e.g. CHO)

- > Stable Cell Line
- > Transit Transfection

Host Cell (e.g. Vero)

Donor Cell (e.g. iPSC)

- > Autologous
- > Allogenic

Feed Cell (e.g. K562)

- mAb
- Gene Therapy Vaccine
- Cell Therapy



The application of cell substrate

The cell substrate characterization should be fully considering the cell properties, product characterization and the regulatory requirements. Cell line used for biopharmaceuticals should be tested for cell identity, free of culturable bacteria, fungi, mycoplasma and infectious viruses, including potential pathogens. Animal pathogens, which is not normally found in the cell substrate, should be considered as well as endogenous retroviruses.



Cell Substrate Characterization	MCB	WCB	EOPC
Identity	●	●	●
Sterility	●	●	●
Mycoplasma	●	●	●
Mycobacterium	●	●	●
<i>in-vitro</i> virus screen	●	●	●
<i>in-vivo</i> virus screen	●		●
Specific pathogen test	●		●
Retrovirus detection	●		●

### Strategy for Cell Substrate Characterization

BRC Biotech provides comprehensive cell line characterization, raw materials, bulk harvest and drug product testing. We cover antibody products, gene cell therapy, vaccines and other applications. Providing to you:

#### Cell Bank

- ✓ GMP-Grade Cell Banking

#### Biorepository Service

- ✓ GMP-Grade Biorepository

#### Cell Line Characterization

- ✓ Cell Source
- ✓ Cell Line
- ✓ Sterility
- ✓ Mycoplasma
- ✓ Mycobacterium
- ✓ DNA Residue Testing
- ✓ *in vitro/in vivo* Adventitious Virus Screen
- ✓ Species-Specific Virus Rapid Testing
- ✓ Retrovirus Testing
- ✓ Genetic Stability

#### Testing for Drug Product

- ✓ Rapid Sterility Testing
- ✓ Rapid Mycoplasma Testing
- ✓ Rapid Mycobacterium Testing
- ✓ DNA Residue Testing
- ✓ Residual Nucleic Acid Fragmentation



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