

Human Derived Cell Substrate Characterization

Flyer

Recommended Testing Panel for Human Cell Banks

Robust cell line characterization ensures the safety, quality, and consistency of biopharmaceutical products manufactured using human-derived cell substrates. Compared with rodent cell lines such as CHO, human cell banks require additional considerations related to donor eligibility, human pathogen risk, tissue traceability, and in some cases where tumorigenic potential is deemed to be a risk (e.g. primary cells, stem cells) tumorigenicity and genomic integrity.

A well-defined testing strategy across the cell banking lifecycle—from Master Cell Bank (MCB) to Working Cell Bank (WCB) and End-of-Production Cells (EOP)—is essential to demonstrate cell identity, purity, genetic stability, and freedom from adventitious agents.



Regulatory Expectations

Human cell banks require testing for relevant communicable diseases (e.g., HIV, HBV, HCV), and full traceability from donor to final bank. For human cell-based MCB, WCB, and EOP characterization, regulatory expectations are defined by a broad set of global standards including guidelines from ICH Q5D, Q5A(R2) and Q7, 21 CFR 1271, EMA and WHO.



cGMP Cell Bank Manufacturing

In addition to comprehensive cell bank characterization testing, Minaris also manufactures and characterizes cGMP-compliant cell banks to support both clinical and commercial programs. With more than 20 years of experience in cell bank manufacturing, integrated services include cell expansion, harvest and fill, and cryopreservation using controlled-rate freezers. Banks are delivered fully released, characterized, and ready for use. Minaris provides a dedicated program manager, the same highly trained team from verification run to manufacturing, flexible shift models to support variable expansion and doubling times, and daily readouts and full transparency throughout your program. For human cell substrates, we also support viral safety strategy development, and regulatory-facing data packages tailored to your product classification.



Requirements for Different Stages of Cell Banking

Testing requirements should be risk-based and lifecycle-appropriate. The MCB is the foundational human cell substrate and requires the most extensive testing and comprehensive characterization, including:

- Cell identity confirmation
- Purity and sterility
- Expanded adventitious agent testing, including human-specific viral panels
- Genetic stability assessment
- Tumorigenicity testing, where applicable
- Phenotypic characterization

The WCB is derived from the MCB and requires a reduced, confirmatory testing panel to demonstrate derivation from the qualified MCB (identity confirmation), no contamination introduced during expansion, and retention of key phenotypic and functional characteristics. EOP cells represent the maximum population doubling level or passage number used in manufacturing and the purpose of testing these cells is to demonstrate that the cell line remains genetically stable, phenotypically consistent, free from adventitious agents and functionally suitable for production.

Attribute	Full Assay Name	MCB	WCB	EOP	Test Code	Minimum Sample Requirements	TAT (days)
Safety	Isolator Sterility Testing by Direct Inoculation USP<71> (GMP) - (Up to 100mL TA or 20 Vials)	✓	✓	✓	3000004994	Per USP guidelines	21
Safety	Bacteriostasis and Fungistasis (Direct Method) (GMP) ¹	✓		✓	3000004996	Varies depending on fill/volume	21
Safety	EP, JP, and USP Mycoplasma Detection (GMP)	✓	✓	✓	3000005147	1x15mL & 1e6 cells/mL	35
Safety	EP, JP, and USP Mycoplasma Detection with MycoplasmaStasis (GMP)	✓		✓	3000007121	1x45mL & 1e6 cells/mL	35
Safety	Mycobacterium Tuberculosis DNA Detection by qPCR (GMP)	✓		✓	3000005638	1e7 cells frozen	9
Safety	In Vitro Assay for Adventitious Viral Contaminants - (3 Cell Lines) in Plates - Extended Duration (GMP)	✓	✓	✓	3000004805	2x6mL at 1e7 cells/mL	35
Safety	AgentSCREEN™ Adventitious Virus Detection in Cell Bank Sample by NGS (GMP)	✓		✓	3000008512	> 5e6 cells/mL	28
Safety	TEM - Ultrastructural Evaluation of Cell Culture Morphology, with Characterization and Tabulation of Retrovirus-like Particles (GMP)	✓		✓	3000005236	2e7 viable cells	35 ²
Safety	GalV Detection - Co-Cultivation of Test Article with HEK 293 Cells - 5 passes (GMP)	✓		✓	3000007382	1% or 1e8 cells (whichever is less)	35 ²
Safety	F-PBRT Assay using AMuLV as a Positive Control (GMP)	✓		✓	3000007535	1 mL supernatant	12
Safety	Panel for Detection of Human Viral Adventitious Agents by qPCR - Automated (B19, EBV, SV40, CMV, HHV-6, HHV-7, HSV I, HSV II, HHV-8, HCV, HTLV-1, HTLV-2, HAV, HBV, HIV-1 and HIV-2) (GMP)	✓		✓	3000005021	1e7 cells frozen or 7 mL	21
Safety	Human Polyomaviruses JCV and BKV DNA Detection by qPCR using TaqMan (GMP)	✓		✓	3000005410	1e7 cells frozen	14
Safety	HPV-18 DNA Detection by qPCR using Taqman (GMP)	✓		✓	3000005415	1e7 cells frozen	12
Safety	9 CFR Porcine Viruses Detection - 21 day (GMP) ³	✓		✓	3000007387	1x500mL serum or 2x8mL cell lysate	31
Safety	9 CFR Bovine Viruses Detection in Bovine Serum or Other Products - 21 day (GMP) ³	✓		✓	3000007314	1x500mL serum or 2x8mL cell lysate	31
Safety	Discriminatory Detection of PCV 1 and PCV 2 by qPCR using TaqMan - Automated (GMP) ³	✓		✓	3000005134	1e7 cell pellet or suspension or 1 mL	12
Safety	BPyV DNA Detection by qPCR using Taqman (GMP) ³	✓		✓	3000005445	1x10e7 cells	12
Identity	Human Cell Line Identification using STR DNA Fingerprinting (GMP)	✓	✓	✓	3000007574	1e6 cells in frozen pellet or frozen cell suspension	10

¹Ingress Study may need to be conducted if the container has not been previously validated.

²Additional time may be needed if cell bank expansion needs to be performed first.

³Optional dependent upon risk assessment.



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