CHO Cell Line Characterization

Minaris Advanced Testing

Flyer

Recommended Testing Panel for CHO Cell Banks

Robust cell line characterization ensures the safety, quality, and consistency of biopharmaceutical products manufactured using CHO (Chinese Hamster Ovary) cells. 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 line identity, purity, genetic stability, and freedom from adventitious agents.

This flyer outlines the recommended testing panel at each stage of cell banking based on regulatory expectations and industry best practices. The testing strategy is designed to ensure that cell substrates remain suitable, stable, and compliant throughout their intended use and therefore support manufacture of a consistent product with respect to quality, potency and efficacy.

Regulatory Expectations

For CHO-based MCB, WCB, and EOP/Limit of In Vitro Cell Age (LIVCA) characterization, ICH Q5B, ICH Q5D and ICH Q5A(R2) serve as the primary global standards, supplemented by regional guidance (FDA, EMA) and WHO recommendations.

These documents collectively define expectations for:

- Cell substrate characterization
- Viral safety
- Expression construct analysis

Referencing these guidelines ensures alignment with current global regulatory expectations for biologics manufactured in CHO cells.

Requirements for Different Stages of Cell Banking

Testing requirements should be risk based and lifecycle appropriate. The MCB is the foundational cell substrate and therefore requires the most extensive and comprehensive testing including identity, purity, genetic, and cell characterization. The WCB is derived from the MCB and requires a reduced, confirmatory testing panel to confirm that it is derived from the qualified MCB, that no contamination occurred during expansion, and key characteristics remain unchanged.

Finally, EOP cells represent the maximum population doubling level or passage number used in manufacturing. The purpose of testing these banks is to demonstrate that the cell line remains genetically and phenotypically stable through the maximum in vitro cell age used for production. Once confirmatory and design studies are completed, Minaris can complete full cell bank characterization.

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.

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 Virus Contaminants - MRC-5, VERO, and CHO Cells with Hemadsorption and Hemagglutination Endpoints (GMP) - Extended Duration	✓	✓	✓	3000005092	2x6mL at 1e7 cells/mL	35
Safety	AgentSCREEN™ Adventitious Virus Detection in Cell Bank Sample by NGS (GMP)	✓		✓	3000008512	> 5e6 cells/mL	28
Safety	Co-Cultivation of Test Article Cells with *Mus dunni* Cells and PG4 S+L- Endpoint - 2 Passes (GMP)	✓		✓	3000007304	1e7 viable cells and 2x2mL supernatant	35[2]
Safety	TEM - Ultrastructural Evaluation of Cell Culture Morphology, with Characterization and Tabulation of Retrovirus-like Particles (GMP)	✓		✓	3000005236	2e7 viable cells	35[2]
Safety	MVM DNA Detection by qPCR using TaqMan (GMP)	✓		✓	3000005740	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	12
Safety	BPyV DNA Detection by qPCR using Taqman (GMP) [3]	✓		✓	3000005445	1e7 cells	12
Safety	F-PBRT Assay using AMuLV as a Positive Control (GMP) [4]	✓			3000007535	1mL supernatant	12
Safety	Calicivirus RNA Detection by RT-qPCR using TaqMan (GMP)	✓			3000007833	1e7 cells frozen	12
Safety	Hamster Antibody Production (HAP) (GMP)	✓			3000007683	1x5mL & 10e7 cells/mL	65
Safety	Mouse Antibody Production (MAP) (GMP)	✓			3000007681	1x8mL & 10e7 cells/mL	65
Identity	Non-Human Cell Line Identity using Ion Torrent Genexus Sequencers - CHO (GMP)	✓	✓	✓	3000004958	1e6 cells	10
Stability	Sanger Sequencing of Genomic DNA for Targeted Region (GMP)	✓		✓	3000007779	5e6 cells	18
Stability	Determination of Genetic Stability by Gene Copy Number Analysis Using TaqMan (GMP)	✓		✓	Varies[5]	2e7-6e7 frozen cell suspension or pellet	21
Stability	DNA Restriction Enzyme Digest Analysis (Southern Blot) Utilizing Chemiluminescence Detection (GMP)	✓		✓	Varies[5]	2e7-6e7 frozen cell suspension or pellet	21

[1] Ingress Study may need to be conducted if the container has not been previously validated.
[2] Additional time may be needed if cell bank expansion needs to be performed first.
[3] Optional dependent upon risk assessment.
[4] PBRT PCR testing is likely to provide a positive result due to endogenous Type A/C particles inherently in CHO cell lines.
[5] Depends on number of targets and samples.

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