

Cell Bank Preparation

Eurofins BioPharma Product Testing offers expert capabilities for the preparation and characterization of a wide variety of mammalian (including human stem cells) and insect cell banks. We offer GMP production master and working cell banks, GMP non-production (reagent or bioassay banks) master and working cell banks and R&D cell banks, as well as banking for end of production cells upon request. We perform all GMP production cell banking in our Animal Origin Free (AOF) and non-Animal Origin Free clean room suites, in accordance with EMA and or FDA requirements, and prepare all other banks in clean cell culture labs where no work with adventitious agents occurs.

Why Choose Eurofins BioPharma Product Testing?

Our cell banking capabilities and comprehensive characterization services provide you with a single-source solution for all of your cell line needs.

Our cell banking experts have over 50 years of combined experience offering constant oversight and monitoring, as well as continual troubleshooting and status updates during expansion.

We offer long-term storage options with ample capacity for LN2 Vapor Phase.

Services Available

Cell Bank Characterization

- Identification
 - CO1 Sizing/Barcoding
 - KaryologyBullet point list
- Microbial
 - Sterility



- Mycoplasma/Spiroplasma
- Adventitious Viruses
 - *In vitro* viral testing
 - *In vivo* viral testing
- Specific Viruses
 - Bovine Viruses
 - Porcine Viruses
 - qPCR for specific viruses
 - Full human Panel
 - Rodent Viruses (MAP, HAP, RAP)
- Retroviruses
 - XC Assay for Ecotropic Retroviruses
 - S+L- Assay for Xenotropic Retroviruses
 - Electron Microscopy for Evaluation of Cell Banks and Culture Harvests
 - Co-Cultivation
 - PERT
- Stability
 - Copy number by qPCR
 - Restriction enzyme digestion mapping using Southern and Northern Blot methods
 - GMP DNA Sequencing



- Next Generation Sequencing services are available at Eurofins BioPharma Product Testing Munich, Germany.

Cell Bank Preparation

- Preparation of mammalian and insect cGMP master and working cell banks
- Preparation of non-production and re-search banks
- Pilot studies

Cell Bank Storage

In addition to LN2 cryogenic freezers dedicated to cell banking production and short-term storage, we also have additional LN2 vapor phase storage capacity for long-term cell bank storage, including LN2 Cryogenic Freezers that are:

- Housed in secured areas
- Continuously monitored by our validated monitoring systems

- Equipped with redundant controls, 24-hour monitoring and back-up generators
- Supported by a fully-validated computerized stability laboratory information management system (LIMS).

Facilities and Instrumentation

- Grade A/B cell banking suites (two are AOF)
- ISO5/7 Clean Rooms (both non-AOF)
- BSL2 Cell Culture Laboratory
- Qualified Controlled Rate Freezers
- Qualified CO2 Incubators
- Automated Cell Counting
- Quarantine Laboratory

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Outsourcing Solutions®



**BioPharma
Product Testing**

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