

A Leader in Providing Innovative Contract Services

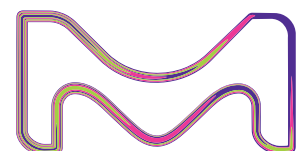
MilliporeSigma BioReliance® testing services is the leading provider of contract services in the biopharmaceutical industry, supporting every phase of the testing, development and manufacturing process and offering a comprehensive and integrated package of services. Our clients include producers of traditional pharmaceuticals, medical devices, chemicals and other products, as well as biopharmaceuticals.

Support for all phases of drug development

Service	Preclinical	Phase I	Phase II	Phase III	Commercial
Cell banking & testing	◆	◆	◆	◆	◆
Raw materials testing	◆	◆	◆	◆	◆
Lot release testing	◆	◆	◆	◆	◆
Clearance validation		◆		◆	
Virus manufacturing	◆	◆	◆	◆	◆
Genetic toxicology	◆				

Comprehensive services

- Comprehensive biosafety testing services
- Global facilities
- Technical and regulatory support
- Dedicated program management, online iNet system for real time reports



Our Services

Biosafety Testing

We test cell banks, raw materials, bulk harvest and final products for a wide range of contaminants. With over 300 molecular biology tests alone, our expertise in biologics testing is unrivalled.

Biorepository

Long & short term biorepository storage of cell banks

Bulk Lot Release Testing

Sterility Testing
Mycoplasma Detection
Adventitious Agent/Virology Testing
Residual DNA Testing
Endotoxin Testing
Electron Microscopy Services
Bioburden Testing

Final Product Release Testing

Sterility Testing
Residual DNA Testing
Comparability & Lot Release Testing
Rabbit Pyrogen

Cell Line Characterization

Sterility Testing
Mycoplasma Detection
Adventitious Agent/Virology Testing
Cell Line Authentication
Genetic Stability Testing
Oncogenicity & Tumorigenicity Testing

Immunology & Cell Based Assay Services

Biopotency Testing
ELISA Assays
Host Cell Protein Assays

Next Generation Sequencing

Virus characterization
Adventitious agent detection
Genetic stability

Raw Material Testing

Sterility Testing
Mycoplasma Detection
Adventitious Agent/Virology Testing
Residual DNA Testing
Endotoxin Testing
Bioburden Testing
Bovine & Porcine Testing

Viral Clearance Studies

Complete Clearance
Prion Detection & TSE Clearance
Viral Clearance Assays & Studies

Biomanufacturing Services

We are dedicated to meeting your manufacturing needs for the production of cell banks, viral seed stocks and viral vaccines. We specialize in biomanufacturing and provide the highest quality therapeutics. Our cGMP compliant production facilities and extensive regulatory experience provide support for product development and regulatory approval.

Production of cGMP cell banks

(human, murine, CHO & insect lines)

Production of clinical lots using viral vectors or cell therapies

Product Characterization for Biologics

Manufacturers of biologics require analytical testing to assess the quality and purity of the products for use in humans.

Stability Testing
Product & Reference Standard Characterization
Comparability & Lot Release Testing

Specialized Testing Services for Viral & Gene Therapy Products

Digital PCR
Rapid Sterility
Titer by TCID50
Residual DNA Sizing
CMV Promotor qPCR
Replication competent AAV (rcAAV)
Aggregation – Dynamic Light Scattering (DLS)

Toxicology

We have been a scientific leader in toxicology for more than 50 years—from safety testing the first polio vaccines in the 1950s to validating new transgenic mouse models for carcinogenicity testing. Our comprehensive toxicology services include a broad spectrum of in vitro and in vivo toxicology testing services designed in accordance with international guidelines and are conducted in full compliance with GLP regulations.

Genetic Toxicology

QSAR
Mutagenicity
Clastogenicity
Aneugenicity
DNA Damage

Regulatory & Technical Services

Advice on regulatory strategies
Data review and evaluations
Report writing and technical support
Response to regulatory authorities

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