

## Expert Partnership Contract Testing Services

Choosing the right partner for your analytical and biosafety testing is critical in the race to approval. We offer best-in-class, risk-mitigating solutions with technical and regulatory expertise to help you bring life-changing drugs to market. Our testing and manufacturing services span the product cycle from early pre-clinical development to licensed production. Partner with us to meet your needs for biosafety testing, analytical development, and biomanufacturing services.

### Comprehensive services support the development journey

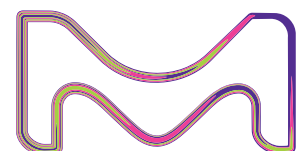
Testing and manufacturing services span the product cycle

Innovative Methods	Services	Preclinical	Phase I	Phase II	Phase III	Commercial
	Analytical Development and Product Characterization	✓	✓	✓	✓	✓
	Raw and Ancillary Materials Testing*	✓	✓	✓	✓	✓
	Plasmid DNA Characterization	✓	✓	✓	✓	✓
NGS and Blazar® platform	Cell Banking, Cell Line Characterization, and Biorepository	✓	✓	✓	✓	✓
	Virus Banking, Virus Bank Characterization, and Biorepository	✓	✓	✓	✓	✓
	Viral Clearance Testing**		✓		✓	
NGS and Blazar® platform	Bulk Harvest Release Testing	✓	✓	✓	✓	✓
NGS	Drug Substance, Drug Product Release Testing, and Stability Testing	✓	✓	✓	✓	✓

\* Microbiology assays and other methods for adventitious agent detection  
 \*\* Support for IND and BLA enabling studies



Dedicated program management,  
online iNet system for  
real time reports



# Our Services

## Analytical Development for Biologics

It is imperative to understand product and process consistency and mitigate risk as related to safety and efficacy. We employ both classic and progressive techniques.

- Biophysical characterization
- Cell-based potency
- Molecular assays
- Product & process impurities

## Biosafety Testing

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

## Raw & Ancillary Material Testing

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

## Cell Line Characterization

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

## Biorepository

- Long & short term biorepository storage of cell banks

## Viral Clearance Testing

- Provide™ Clearance
- Viral Clearance Assays & Studies

## Bulk Harvest, Drug Substance and Drug Product Release Testing

- Sterility Testing
- Mycoplasma Detection
- Adventitious Agent/Virology Testing
- Residual DNA Testing
- Endotoxin Testing
- Electron Microscopy Services
- Bioburden Testing
- Comparability & Lot Release Testing
- Rabbit Pyrogen

## Stability Studies

- Short term
- Long term
- Accelerated

## Immunology & Cell Based Assay Services

- Biopotency Testing
- ELISA Assays
- Host Cell Protein Assays

## Next Generation Sequencing or High Throughput Sequencing

- Virus characterization
- Identity Testing
- Adventitious agent detection
- Genetic stability

## 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 production facilities are certified according to GMP. Our extensive regulatory experience provide support for product development and regulatory approval.

## Production of GMP cell banks

(human, murine, CHO & insect lines)

## Production of clinical lots using viral vectors or cell therapies

## Specialized Testing Services for Viral & Gene Therapy Products

- Digital Droplet PCR
- Rapid Sterility
- Infectious Titer by TCID50
- Residual DNA Sizing
- CMV Promotor qPCR
- Detection of replication competent virus (RCL, RCA, rcAAV)
- Aggregation – Dynamic Light Scattering (DLS)

## Regulatory & Technical Services

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

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