

BioReliance

Overview of Services

A Leader in Providing Innovative Contract Services

Founded in 1947, BioReliance Corporation is one of the world's leading contract services organizations, offering scientific and laboratory services related to safety testing for the biopharmaceutical and pharmaceutical industries. With nearly 700 employees around the world, BioReliance has the scientific expertise and depth of regulatory knowledge to support our clients' products through clinical development and commercial testing.

Over the years, BioReliance has led the industry in first-to-market testing protocols, including the first safety testing for the polio vaccine (1955), the first commercial mammalian-derived biologic (1981), and the first gene therapy to enter clinical trials (1990). Today BioReliance continues to invest in time-saving methods such as faster mycoplasma testing for biologics and new genetic toxicology applications for small molecules. In addition, our focus on operational excellence initiatives has resulted in lower turnaround times for many of our services.

BioReliance has performed work on behalf of thousands of clients, including the majority of the major biopharma, biotech and pharmaceutical companies around the world. Every client with ongoing testing has a primary point-of-contact within our global program management group to monitor timelines and convey testing results. Our commitment at BioReliance is to ensure that your overall goals remain on track.

BioReliance's services support 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	◆	◆	◆	◆	◆
Genomics	◆	◆	◆	◆	◆
Genetic toxicology	◆				
Mammalian toxicology			◆		

Comprehensive services

Full range of biologics testing, cGMP cell bank and virus manufacturing, toxicology, and clearance validation services

Global facilities

Locations in Rockville, Maryland; Glasgow and Stirling, Scotland to support a broad range of global testing requirements

Technical and regulatory support

Program management and scientific teams that design and monitor compliant testing and manufacturing programs tailored for each client's product

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List of Services

BioReliance offers over 1000 protocols for biologics safety, toxicology and genomic services. You can inquire about a service, including custom assay development, by sending us an email at: info@bioreliance.com or by visiting our website, www.bioreliance.com.

Biologics Safety Testing

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

Analytical Methods (including Mass Spec)

Amino acid analysis
Carbohydrate analysis
Comparability testing
N-terminal sequencing
Peptide mapping
Purposeful degradation
Stability storage

Cell Biology

Biorepository
Cross-reactivity testing
Electron microscopy
Fluorescence in situ hybridization
Histology
Karyology
SKY Karyotyping

Clearance Validation and Cleaning Studies

Clearance studies for viruses, bacteria, DNA
Cleaning validation studies
Column re-use studies
TSE studies by Western blot and bioassay

Genomics

Adventitious agent testing (AAT)
Advanced mammalian genetic stability (Q5B) analysis
Advanced residual DNA testing
Advanced viral genetic stability analysis
Bioreactor contamination remediation
Custom Assay Development and Validation
Data Analysis and Bioinformatics
DNA Methylation Analysis
Infectivity assays
In-process testing
MCB characterization

Microbial genetic stability analysis
Microsatellite & STR services
Novel cell line characterization for FDA submission
Nucleic Acid Extraction
RNA Expression Analysis
Targeted genotyping
Virus stock characterization

Immunology

ADA (Anti-drug Antibody)
Bioprocess Contaminant Testing
Custom ELISAs
Detection of expressed recombinant protein
Detection of cytokine response
Detection of neutralizing antibodies
Host Cell Protein Assays
Immunogenicity
Immunohistochemistry
Neutralization Antibody Assays
PK/PD
Potency assays

In Vitro and In Vivo Virology

Biodistribution studies
Detection of adventitious viruses
Detection of specific mammalian viruses
Detection of viral vectors and infectivity
Immunoassays
Retrovirology assays
Tumorigenicity assays

Microbiology

Mycoplasma testing
Sterility testing

Molecular Biology

Detection of human viruses
Detection of retroviruses
Detection of rodent viruses
Detection of other species-specific viruses
Q-PCR services
Residual host cell DNA testing

cGMP Manufacturing

We offer mammalian and insect cell banking, as well as viral manufacturing.

Production of cGMP cell banks for human, murine, CHO and insect lines
Production of clinical lots using viral vectors or cell therapies
Long-term biorepository storage of cell banks

Toxicology

Genetic Toxicology

Assessment of hemolytic property
Chromosome damage
Gene mutation
Mammalian S9 microsome preparations
Primary DNA damage

Mammalian Toxicology

Analytical chemistry services
Contract pathology services
Custom vaccine toxicology studies
Repeated-dose studies
Studies for nucleic-acid based therapeutics
Transgenic carcinogenicity studies

Regulatory & Technical Services

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

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