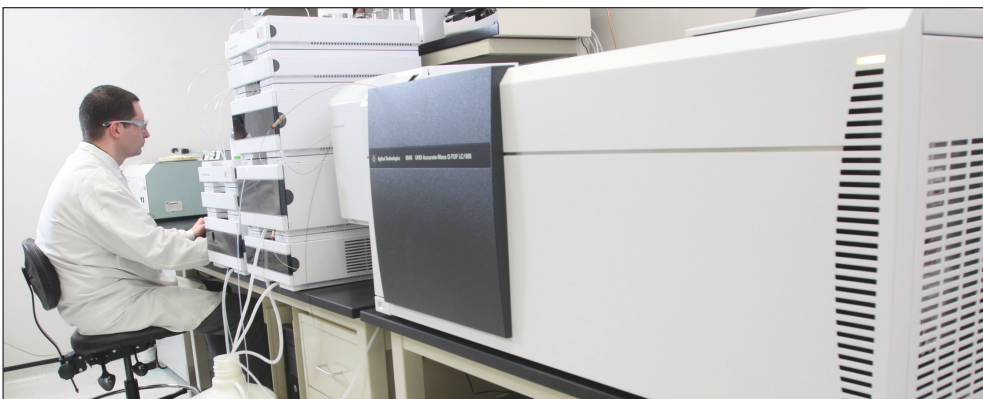


BioReliance

Analytical Services for Biologics

Comprehensive Testing Services for Recombinant Protein Therapeutic Development

BioReliance, the leader in contract safety testing services, now offers a complete range of analytical services to developers of recombinant protein and monoclonal antibody based therapeutics. Our offering spans the spectrum of laboratory methods – from basic tests, such as pH and appearance, to more demanding methods such as mass spectrometry and UHPLC. We have a team of highly experienced, industry-trained scientists who are available to support your method development, transfer and routine testing programs. Our state-of-the-art analytical laboratories, located in Rockville, MD and Glasgow, Scotland, are also supported by industry leading quality and program management systems and personnel. BioReliance has supported thousands of testing programs spanning decades of biopharmaceutical development – ranging from early development candidates to marketed products. You can rely on our quality, expertise and data to ensure the success of your biological development program.



Key Analytical Methods Offered by BioReliance*

Compendial	Mass Spectrometry	Capillary Electrophoresis	UHPLC	Immunology
pH	Intact Molecular Weight (MW) Analysis	Molecular Weight Determination (SDS Denatured)	Glycan Profiling	Host Cell Protein Contaminant Quantitation
Karl Fischer Titration			Ion Exchange Chromatography	Potency Testing (In Vitro)
Osmolarity	Antibody Subunit Analysis	Purity (SDS Denatured)	Size Exclusion Chromatography	Anti-Drug Antibody Detection & Characterization
BCA & Bradford Protein Concentration	Peptide Mapping	Isoelectric Point Determination	Reverse Phase Chromatography	
Appearance	N- and C-Terminal Sequencing	Charge Profile Determination	Amino Acid Analysis	Residual Solvents & Detergents
Residual Solvents, Detergents and other Process Components	Glycan Profiling			Western Blot
SDS PAGE				

*Does not include all methods offered. Please inquire for complete list.

BioReliance offers a complete range of analytical methods, including mass spectrometry and capillary electrophoresis

Highly experienced, industry trained scientists will work with you to design a successful analytical testing program for your recombinant protein based therapeutic

Projects are designed to meet regulatory standards while being delivered on time and within budget

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Areas of Expertise

BioReliance can design and conduct analytical studies for:

- Reference standard characterization
- Comparability and lot release testing
- Product stability
(including purposeful degradation and light exposure studies)

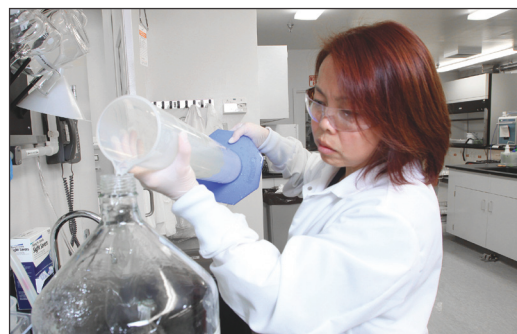
In addition, we can develop, transfer and validate methods in support of these study types. We have experience with almost every biologically derived therapeutic type; including recombinant proteins, monoclonal antibodies, biosimilars, vaccines, gene therapy and cell therapy. Our scientists collectively have >100 years of experience designing and conducting analytical testing programs, including the authoring stability protocols that are compliant with ICH Q5C. We will work with you to design a customized testing program that is best suited to your specific product - and that is delivered on-time and within budget.

Facilities, Equipment and Quality Assurance

Our recently expanded, fit-for-purpose Analytical laboratories are fully equipped and prepared to support you in your efforts to bring biopharmaceutical products to market. All instrumentation is validated in compliance with cGMP and GLP requirements. BioReliance also maintains its own dedicated suite of stability testing chambers. All documents (including validation plans) are generated, monitored and reviewed according to our document control procedures, which include IQ, OQ, PQ packages as well as SOPs for operation and maintenance of instruments.

You can rely on us to help you successfully develop and manufacture your recombinant protein therapeutic.

Contact BioReliance today to discuss your specific analytical testing requirements.



www.bioreliance.com

North America Toll Free: 800 553 5372 Tel: 301 738 1000

Europe & International Tel: +44 (0)141 946 9999 • Japan Tel: +81 (0)3 5796 7430

Email: info@bioreliance.com

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