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Bioanalytical Services

Testing Services for Large Molecule Drug Development

Our mission is to extend our clients' capabilities by combining scientific knowledge, capacity, regulatory expertise and flexibility to provide the trusted, relevant information required for the drug approval process.

Eurofins Bioanalytical Services is a powerhouse large molecule biotherapeutic-focused, bioanalytical contract research organization. Since its formation in 2003, we have actively supported the evolving needs of companies that develop biotherapeutics.

Founded by industry leaders, Eurofins Bioanalytical Services has grown and shaped the current state of the art in large molecule bioanalysis through contributions in industry working groups and collaborations with our clients. Continuing to develop this understanding, our team of over 130 service staff focuses only on large molecule bioanalysis and is dedicated to meeting the needs of our customers.

Flexible and customer-oriented, Eurofins Bioanalytical Services is uniquely positioned to meet the needs of clients. As a specialty provider, we are ideally placed to ensure that the needs of each project are addressed—from the specific needs of emerging and virtual clients through adoption of the latest technologies for exploratory studies. As a market leader, we also possess industry-leading capacity to handle large and late-stage projects with professionalism, proven commitment to quality, and focus on meeting deadlines and budgets.

We continue to shape and are shaped by our rapidly changing field and invite you to discuss your project needs with our team.

Large molecule bioanalytical specialists

Flexibility and focus on client needs

Comprehensive assay platform capabilities

Headed by industry leaders with decades of bioanalytical experience

Dedicated program management

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Eurofins Bioanalytical Services. St Charles, MO USA.

Eurofins Bioanalysis. Oxford, UK.

Immunogenicity Testing

Biopharmaceuticals, such as antibodies, peptides and recombinant proteins, have the potential to induce an anti-drug antibody (ADA) response. In non-clinical studies, development of ADA can affect drug exposure and impact on data from toxicity, pharmacokinetic (PK) or pharmacodynamic (PD) studies. In clinical studies, development of ADA can be associated with a variety of potentially serious clinical side effects as well as a loss of drug efficacy. Eurofins Bioanalytical Services adheres to current FDA and EMA guidelines for immunogenicity testing and our scientists routinely contribute to industry meetings and workshops. We continue to follow and refine a stepwise approach to measure ADA responses using the leading instrumentation platforms and latest methodologies.

- Screening assay
- Confirmatory assay
- Titer
- Characterization assays (isotype, affinity)
- Neutralizing antibody (NAb) assays

Our senior scientific staff oversees method development, transfer, reagent development and GLP-compliant validation to ensure that robust assays are in place for studies of any scale. State–of-the-art facilities in St. Charles, MO, USA and Oxford, UK house industry-defining global capacity and capabilities including GLP-compliant development and implementation of NAb bioassays.
Meeting the needs of both our clients and regulators, we can develop or transfer NAb assays in our dedicated GLP-compliant cell-based assay laboratories. We offer Ready-To-Assay™ cell technology to ensure consistency in NAb assay testing.

Platforms
ELISA
RIA
ECL (MSD)
Gyrolab™ Assays
Cell-based Assays

Pharmacokinetics Assays

Pharmacokinetic /Toxicokinetic (PK/TK) analysis of biopharmaceutical requires different solutions from those traditionally employed in the analysis of small molecules. We have industry-leading experience in the development and validation of PK/TK assays for large molecules and peptides.

To provide the best analytical solution for the broadest range of matrices and species, we:

- Develop and validate assays that have analytical ranges appropriate for the study samples
- Develop assays that are both specific and sensitive
- Provide support for critical reagent generation and purification including the generation of antibodies to be used for capture or detection reagents
- Assess method feasibility in multiple technology platforms

We routinely perform large-scale sample analysis for pre-clinical (GLP-compliant) and clinical (GCP-compliant) studies, employing automation where appropriate. Studies not claiming GLP/GCP compliance are still performed to the same high standards under our comprehensive quality system.

Our experience, flexibility and capacity enable us to manage specialized project needs, including:

- Lead optimization studies in multiple species
- Rapid turnaround studies
- Pediatric studies
- Dose escalation
- Toxicokinetic studies

Biomarker Assay Services

Eurofins Bioanalytical Services offers a range of biomarker services for all stages of research, from ready-to-run assays through to assay development and validation—for both protein and nucleic acid targets. Our St. Charles, MO, USA and Oxford, UK locations are fully equipped with the latest technologies and experienced staff to analyze your samples.

Protein Immunoassays

Research Services:

Choose from the largest portfolio of kits including RIAs, ELISAs, and Luminex® assays for exploratory analyses. Ship us your samples and we'll run the assay, sending you back validated, high quality data you can count on to advance your research. We can also run your samples on any commercially available assay that you specify, from any vendor. We offer support for pre-clinical and translational studies.

Regulatory Compliant Laboratory Services:

Our GxP-compliant, CLIA-licensed laboratories can transfer assays, validate existing kits and perform sample analysis from a single plate to Phase 3 clinical trial projects. We are equipped to handle variable sample numbers and large volumes.

Platforms

ELISA
RIA
ECL (MSD)
Luminex® Assays
Gyrolab™ Assays
Cell-based Assays

Genomics Services

Our genomic biomarker analysis services are coordinated with our other biomarker platforms to give our clients a unique, cross-sectional view of their systems, enabling confident pipeline decisions.

- Sample preparation cells, tissue or blood samples.
- Expression profiling of mRNA or miRNA
- Genotyping by Pyrosequencing® or qRT-PCR (Taqman®)
- Methylation analysis by bisulfite Pyrosequencing®
- Exploratory through GxP-compliant and CLIA studies

Platforms
ABI ViiA™ 7 (qPCR)
Qiagen Q24 Pyrosequencer

Flow Cytometry

Eurofins Bioanalytical Services has a wide range of experience in applying flow cytometry to exploratory studies through to GLP-compliant sample analysis for clinical trials. Our highly trained and knowledgeable staff is available to assist with experimental design, provide training and sample collection materials, and develop and validate assays to meet client-specified criteria. We also analyze and interpret flow cytometry data to enable our clients to obtain the best insights from large, complex data outputs.

Platforms
BD FACSCanto™ II
Beckman FC500

Capabilities include:

- Pharmacodynamics – intracellular phospho-targets
- Neutralizing antibodies
- Th17 analysis
- Immunophenotyping
- Neutralizing antibody (NAb) assays
- Biomarker analysis
- Drug characterization
- Fc receptor binding assays
- Potency assays

Biopharmaceutical Analysis

Biological drugs provide novel challenges for the design of characterization and potency assays for batch release, stability testing and impurity profiling. Batch release may involve developing an assay to directly measure the biological activity of the drug, a surrogate assay (e.g., ligand-binding assay) to indirectly measure biological activity, or a multi-assay approach. The assay must be designed specifically for the drug in question and be a biologically relevant measure of its potency. Cell-based assays may be prone to inherent variability due to the use of living material in the assay. Therefore, effective assay design, execution and statistical analysis are vital for successful batch release assays.

Eurofins Bioanalytical Services is the leader in applying specialized testing methodologies for the biotherapeutic characterization and potency assays. Our GMP-compliant laboratories perform batch release and stability studies for clinical trial material and can contribute to the batch release testing of marketed large molecule therapies.

Our ligand binding and cell-based assays for target antigens include:

- Receptor-binding assays
- Proliferation assays

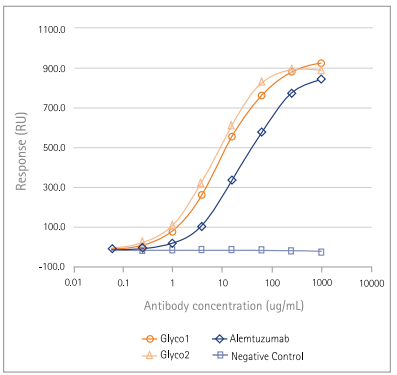
Surface plasmon resonance (SPR) and flow cytometry assays to characterize FcR binding:

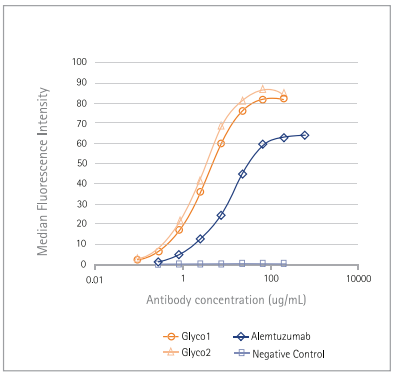
- FcγRI (CD64)
- FcγRII (CD32a)
- FcγRIII (CD16a)
- FcRn binding by SPR assay
- C1q by ELISA assays
- ADCC and CDC

Platforms

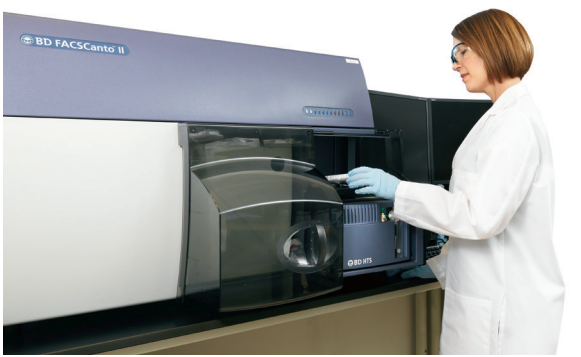
SPR (Biacore®)
ELISA
RIA
ECL (MSD)
Gyrolab™ Assays
Cell-based Assays
Flow Cytometry

Comparability Assessment by Multiple Assay Formats





Shown is a comparison of CD16A (FcγRIIIa) binding to alemtuzumab glycosylation variants by surface plasmon resonance (SPR, left) and flow cytometry (right).



Biosimilars

Eurofins Bioanalytical Services has years of experience supporting innovator and biosimilar programs, making us the ideal development partner. Following the latest regulations and guidance, we tailor bioanalytical and characterization packages to meet the distinct needs of our biosimilars clients. We use the latest technologies and procedures to ensure accuracy, adherence to standards and on-time delivery of critical data, no matter the size of project.

Non-clinical / Clinical Services

- Pharmacokinetics
- Tiered immunogenicity testing
- Biomarker analysis

Biological Characterization Services

- Ligand-binding and cell-based assays for target proteins
- CD64, CD32, CD16 binding by surface plasmon resonance and flow cytometry
- C1q binding by ELISA
- Proliferation, neutralization and receptor binding assays
- ADCC and CDC assays

Expertise In Both Simple and Complex Biosimilars

Biologic Type	Generic name	Product Characterization	PK	IMM	Stability / Potency
Small, non-glycosylated protein	Filgrastim		✔	✔	
	Exenatide			✔	
	Insulin Lispro		✔	✔	
	Insulin Glargine		✔	✔	
Small, glycosylated protein	Epoetin alpha		✔	✔	
Monoclonal antibody	Trastuzumab	✔	✔	✔	✔
	Infliximab	✔	✔	✔	
	Alemtuzumab	✔	✔	✔	
	Bevacizumab	✔			
	Rituximab	✔			

Eurofins Bioanalytical Services is a unique, large molecule-focused bioanalytical and biomarker service organization. With over ten years of experience supporting all sizes of studies from both small and large sponsors, Eurofins offers industry-leading capacity together with client-focused flexibility. Mirror sites in St. Charles, Missouri, USA and Oxford, UK provide bioanalytical / biomarker services with regulatory expertise across multiple geographies, including GxP and CLIA capabilities. We support your projects at every phase, from exploratory through to regulated studies, with client-focused project management groups and oversight by experienced scientific staff.

Our unmatched resources include a dedicated reagent development team, long-term sample storage capabilities, and a dedicated GLP-compliant cell-based assay laboratory. Our clients deeply value our broad platform base, which includes:

- ELISA
- RIA
- Gyrolab™Workstation
- Sequencing
- Flow Cytometry
- Luminex® Systems
- MSD
- qPCR
- ELISpot
- Automation
- LIMS

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Contact our Scientific Development group to discuss your drug development testing requirements and see how Eurofins Bioanalytical Services tailors our services to meet your requirements.

For more information about Eurofins Bioanalytical Services team please contact

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