BIOANALYSIS SUPPORT

Large Molecules (Ligand Binding Assays)

ACM BIOANALYTICAL SERVICES

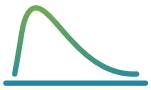
Introducing ACM Global's Bioanalytical Services state of the art ligand binding assay service line, specifically designed to cater to your dynamic drug development program. Our scientists have the expertise and flexibility to assist you with your complex method development, validation and sample analysis needs. Specialists in the quantification of drugs/biomarkers and qualitative analysis of anti-drug and neutralizing antibodies in biological samples, we ensure you have the technical insight needed to successfully complete your bioanalytical studies. Compliant with GLP and GCP regulations, our custom-built bioanalytical laboratory has built a strong reputation by meeting the highest analytical standards.

Your Partner in Bioanalysis to Support Analysis

ACM Bioanalysis services include:

- Method Development and Validation
- Assay Feasibility Studies
- Analysis of Innovators and Biosimilars
- Bioanalytical Method Transfer
- Anti-Drug Antibody and Neutralizing antibody analysis
- Bioanalysis of samples originating from first in human clinical studies with quick turnaround times of results
- Preclinical Research and Development and Clinical Research

Pharmacokinetic (PK) and Toxicokinetic (TK) Analysis



Our bioanalytical scientists are experts in ligand binding assays using both ELISA and MSD platforms. Our custom method development and validation programs support both preclinical drug development and clinical trials programs, providing bioanalytical PK/TK data, which is vital for the assessment of the absorption, distribution, metabolism and excretion of your drug. With extensive experience in a wide range of large molecule therapeutics including monoclonal antibodies, fusion proteins, anti-body drug conjugates, bi/tri specific antibodies, oligonucleotides and more, we provide solutions whatever your project's needs.

Pharmacodynamic (PD) Biomarker Analysis

PD biomarker data is a great tool in drug development - from establishing the therapeutic proof of concept, to being used as a surrogate endpoint in clinical trials indicating the pharmacological effect of a drug.

At ACM Bioanalytical Services we can help you establish the "Context of Use" requirements for a biomarker and support the associated required analysis; from exploratory clinical biomarkers used as supporting information in a non-regulated space, to fully validated methods determining primary end-points ready for regulatory submission. Our bioanalytical scientists can develop highly sensitive methods for measuring the up/down-regulation of biomarkers in serum and other biological matrices depending on your requirements.

Anti-Drug Antibody (ADA) and Neutralizing Antibody (nAb) Analysis

Information on any immune response observed during clinical trials, particularly the incidence of ADA responses that could affect pharmacokinetics, pharmacodynamics, safety, or efficacy, is crucial for any therapeutic protein development program. We provide expertise and support for the screening, confirmation, titre and further characterization of anti-drug antibodies to meet your projects needs, from pre-clinical to Phase I-IV clinical. Specializing in advanced ADA assay techniques such as ACE, SPEAD and PanDa in addition to excelling in the industry standard MSD bridging format we can meet your sensitivity and drug tolerance requirements. Our in-house reagent conjugation capabilities ensure quality critical reagents are generated for use throughout your study lifecycle without the need for 3rd party vendors.

Your bioanalytical requirement is our top priority. Therefore, exceptional service is at the core of everything we do. We believe this philosophy is the differentiating factor that allows us to be a trusted and valuable partner to our clients.

To learn how we can meet your testing needs, please contact us at **acmglobalab.com/bioanalytical-services**.

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