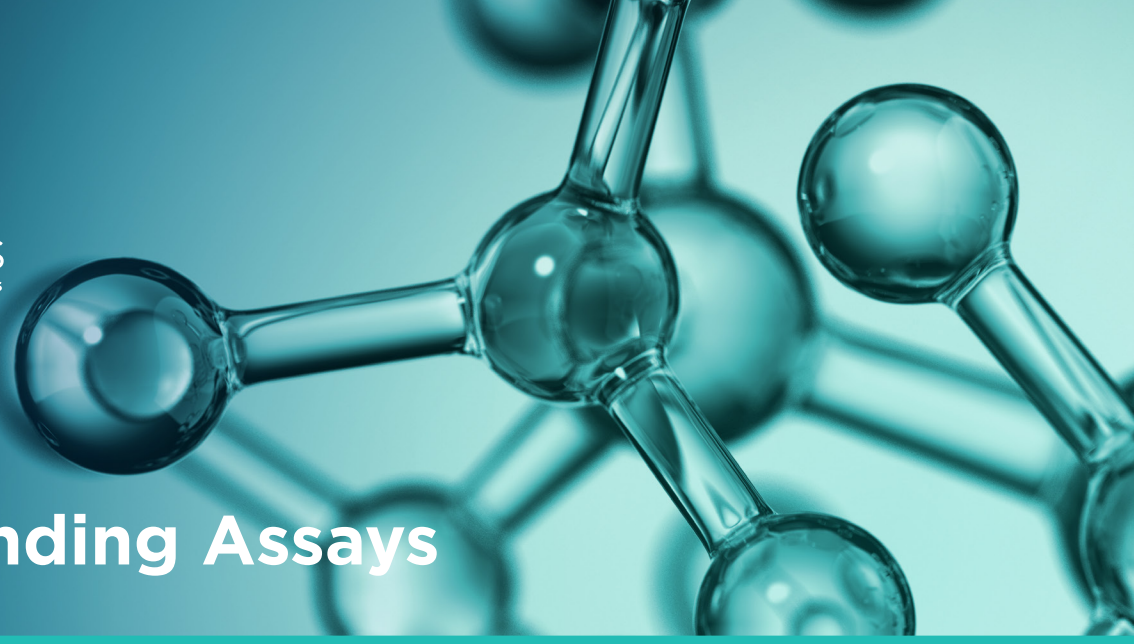
ALTASCIENCES
BIOANALYSIS & RESEARCH SERVICES



Bioanalysis
Ligand Binding Assays

Altasciences is a forward-thinking, mid-size, early phase contract research organization with a unique company focus on supporting drug development from lead candidate selection to proof of concept.

With over 25 years of industry experience, we provide preclinical and clinical solutions to an international customer base of biopharmaceutical companies.

Altasciences' full-service offering includes program management, preclinical safety testing, clinical pharmacology services, medical writing, biostatistics, data management, and bioanalysis services tailored to specific research requirements.

Assay Development and Validation

We work with you, in a collaborative approach, to develop, transfer, optimize and validate assays using customized designs and the latest platforms, including:

- Mesoscale Electrochemiluminescence Sector Imager for sensitive PK measurements, Immunogenicity assays and Multiplexed Biomarker assays
- BioTek Synergy H4 Multimode Plate Reader using Absorbance, Fluorescence or Luminescence reading modes for added flexibility in designing sensitive and customized spectrophotometric ELISA assays
- Hybridization technology to accurately quantify oligonucleotides, in circulation and in their targeted tissues
- Luminex 200 System for performing multiplexed assays
- BioTek EL406 Microplate Washer/Dispenser to increase assay throughput
- Precellys Evolution Homogenizer for efficient tissue sample homogenization

Our experts will oversee your project, from method development to sample analysis.

Services Available

- Quantitative assays
- Immunogenicity assays
- Biomarkers: single or multiplexed
- Biosimilarity

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altasciences.com

Quantitative Assays

Altasciences uses innovative and cost-effective approaches when developing or customizing ligand binding assays for the quantitative determination of your biologic therapeutic products. We are highly experienced with preclinical and clinical samples from healthy or patient populations, as well as working with multi-site studies.

Biomarker Assays

Our scientific team stays up to date with the most recent approaches. We have a panel of validated biomarker assays available for analysis, covering several disease indications, such as oncology, metabolic disease, neurology and inflammation.

Immunogenicity Assays

To ensure that immunogenicity screening and characterization assays have sufficient sensitivity and minimal drug/target interference to detect clinically relevant levels of Anti-Drug-Antibodies (ADAs), we compare and apply different assay formats and technology platforms:

- ELISA or ECLIA
- Bridging or direct binding assays
- Neutralizing antibody assays (NAb)

Statistiscal analysis is completed by Altasciences' biostatisticians using SAS®.

Support Services

Sample Managemeant and Storage

- Controlled storage units
- Activities and traceability performed using Watson
- Back-up generators for critical equipment
- Three walk-in -20 °c freezers (capacity of approximately 1,430,000 samples)
- 39 stand-up -80 °c freezers (capacity of approximately 1,076,000 samples)
- Sample shipment kit services for multi-site studies

Medical Writing

- Team with over 20 years of experience
- Study design in line with current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- Team with over 20 years of experience
- Electronic Data Capture
- CDISC standards fully integrated in workflow
- Medical coding using latest version of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last participant's final visit

Biostatistics

- All programming done using SAS®
- Randomization list
- Statistical analysis plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data (e.g. safety lab)
- Creation of CDISC-compliant FDA submission-ready package

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