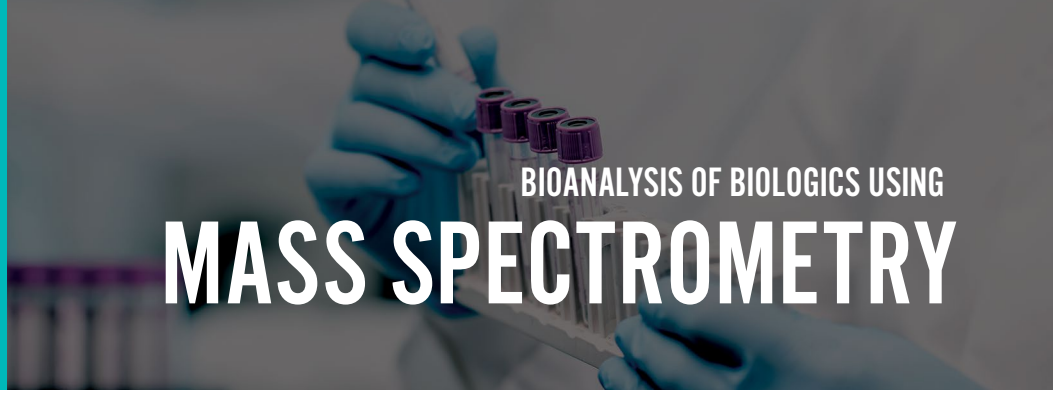
ALTASCIENCES



BIOANALYSIS OF BIOLOGICS USING MASS SPECTROMETRY

Altasciences' industry-recognized quantitation of therapeutic proteins by mass spectrometry is supported by experienced and dedicated scientists. We develop, transfer, and optimize methods with innovative workflows to meet your needs through a tiered approach of selecting a screening, qualified, fit-for-purpose, or validated assay.

We conduct sample analysis in accordance with GLP and current FDA/EMA guidelines. We are flexible and responsive. Our teams work closely with our clients to ensure the optimal path forward.

Capabilities

- Quantitative (surrogate peptide) analysis Tandem MS supporting biologic quantitation and achieving low quantitation limits with limited sample volume
- Automated immunoaffinity sample preparation producing high-throughput assays with impressive sensitivity
- HRMS workflows provide the advantages of accurate mass measurement and the allowance for both efficient qualitative (peptide mapping, and characterization of biosimilars) and quantitative analysis
- Biotherapeutics
  - Monoclonal antibodies (mAb)
  - Fusion proteins
  - Antibody-drug conjugates (ADC)
- Biomarkers and endogenous analytes
- Biological matrices
  - Serum
  - Plasma
  - Blood
  - Urine
  - Feces
  - Animal tissues
  - Cerebrospinal fluid
  - Vitreous humor
  - Tears
  - Saliva
  - Human tissue biopsies

State-of-the-Art Laboratory

Altasciences' bioanalytical capabilities are supported by over 260 highly trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories. Analysts are available 24/7, depending on program needs, and are able to process as many as 60,000 study samples per month. We have designated containment Level 2 (CL2) areas for work with Risk Group 2 (RG2) pathogens.

contact@altasciences.com
altasciences.com

Instrumentation

- Over 30 LC-MS/MS instruments, including SCIEX API 5000, 5500, 6500+, and SelexION with Nexera UHPLCs
- HRMS including the SCIEX API 6600, and ThermoFisher Q-Exactive
- Microflow and nanoflow capabilities for the front end of our HRMS systems
- SPEX Geno/Grinder® 2010 and MP Biomedicals FastPrep-96™ for Tissue Extraction
- Thermo Scientific KingFisher™ Flex for High-throughput Immunoaffinity Extraction
- Hamilton® ID STARlet Liquid Handlers

Research Support Services

Sample Management 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)
- 47 stand-up -80 °C freezers (capacity of approximately 1,076,000 samples)
- Sample shipment kit services for multi-site studies

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

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)

Data Management

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

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables, from preclinical to clinical
- 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

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

contact@altasciences.com
altasciences.com