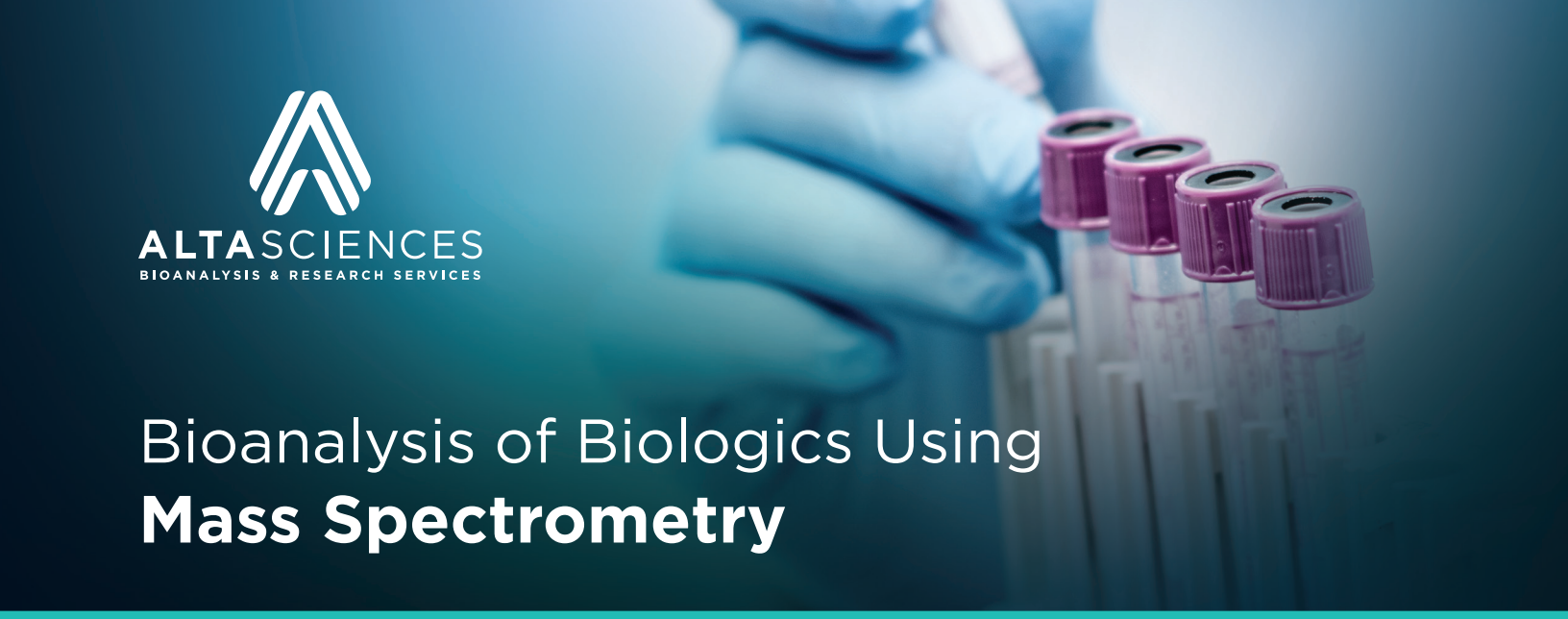
ALTASCIENCES
BIOANALYSIS & RESEARCH SERVICES



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, or validated assay.

We conduct sample analysis in accordance with GLP and current FDA/EMA guidelines. Flexibility, responsiveness, and working closely with our clients allow us to leverage our expertise and capabilities to ensure the optimal path forward.

Highlights

- 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

Capabilities

- Biotherapeutics
  - Monoclonal Antibodies (mAb)
  - Fusion Proteins
  - Antibody-Drug Conjugates (ADC)
- Biomarkers and Endogenous Analytes
- Biological Matrices
  - Serum
  - Plasma
  - Blood
  - Urine
  - Feces
  - Tissues
  - Cerebrospinal Fluid
  - Vitreous Humor

State-of-the-Art Laboratory

Bioanalytical capabilities are supported by over 100 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories. Analysts are available to work 24/7, depending on program needs, and are able to process as many as 60,000 study samples a month. We have designated containment Level 2 (CL2) areas for work with Risk Group 2 (RG2) pathogens.

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Instrumentation

- Shimadzu Nexera UHPLC with Sil 30 AC MP Autosamplers
- Thermo Scientific™ Vanquish™ UHPLC+ focused
- Thermo Scientific™ Dionex UltiMate™ 3000 RSLCnano System
- Thermo Scientific™ Q Exactive™ Plus and SCIEX
- TripleTOF™ 5600+ High Resolution Accurate Mass MS Systems
- SCIEX API 5500 and 6500+ triple-quadrupole MS with SelexION® Ion Mobility Technology
- 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

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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