



Integrated capabilities for bioanalytical needs



Bioanalytical services and solutions

Bioanalytical experience

Advanced method development

- Experience in hybrid LC-MS and ligand-binding technologies
- Experience with complex matrices (i.e. CSF)

Experience in complex biologics

- Extensive assay experience for mAbs, ADCs, bispecifics, fusion proteins and gene analytes

Biomarker analysis proficiency

- Capabilities in biomarker testing for inflammation, neurology, oncology and immunology
- Multiplexed approach for pharmacodynamic assessments and disease-specific profiling

Automation in bioanalysis

- Fully automated ligand-binding systems for consistent quality and faster timelines

Pharmacogenomics integration

- Developed assays targeting drug metabolism, transport and target genes
- Integrated pharmacogenomics with PK/PD data for enhanced trial success

Integrated bioanalysis in clinical trials

- One-stop service through clinical facility and central lab collaboration

Bioanalytical services

- LC/MS development, validation and sample analysis
- Large molecule development, validation and sample analysis
 - Pk, ADA, Nab
- Pharmacogenomics
- Biomarkers
- AME study support
- Central lab, PK kitting and bio-storage
- PK data analysis
- Small molecule development, validation and sample analysis

Key differentiators

- 1,400+ validated assays covering plasma, serum, CSF and synovial fluid matrices
- Adherence to FDA (21 CFR Part 11 Compliant Systems), European Clinical Trials Directive and MHRA standards
- Co-located with Fortrea Clinical Research Units
- High-throughput capabilities for faster timelines without accuracy compromise
- Knowledgeable in unstable analytes, multi-analyte assays and quantitation limits down to sub pg/mL

State-of-the-art bioanalytical laboratory and industry leading experience

- 60,000 sq. ft. laboratory building located in Austin, TX
- Regulated GLP/GCLP Bioanalytical Operations
- Successful FDA inspection history: No findings from numerous audits in the past five years
- End-to-end bioanalytical service as our lab assists with critical reagents generation, labeling and characterization, TK/PK data analysis and report preparation
- Strong scientific leadership across small and large molecule bioanalysis and biomarker development

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