



Bioanalytical Services & Solutions

Bioanalytical Expertise

- ✓ **Advanced Method Development**
 - Expertise in hybrid LC-MS, and ligand-binding technologies.
 - Experience with complex matrices (i.e. CSF).
- ✓ **Expertise 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



- 2,400+ validated assays covering plasma, serum, CSF, and synovial fluid matrices.
- Adherence to FDA (21 CFR), European Clinical Trials Directive, and MHRA standards.
- Co-located with Worldwide CPU.
- High-throughput capabilities for faster timelines without accuracy compromise.
- Expertise in unstable analytes, multi-analyte assays, and quantitation limits down to sub pg/mL.

State-of-the-Art Bioanalytical Laboratory & Industry Leading Experts



- 60,000 sq. ft. laboratory building located in Austin, TX
- Successful FDA inspection history: No findings from numerous audits in the past 5 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



Partner with Worldwide Clinical Trials

With a proven history of delivering timely, high-quality bioanalytical data, the Bioanalytical Lab at Worldwide is your trusted partner to accelerate your drug development programs.

Want to Learn More? We are here to help! [Visit our website](#) to discover our comprehensive services and how we can support your research or connect with us on [LinkedIn](#).

