WORLDWIDE
CLINICAL TRIALS

MAKE INFORMED DECISIONS, FASTER

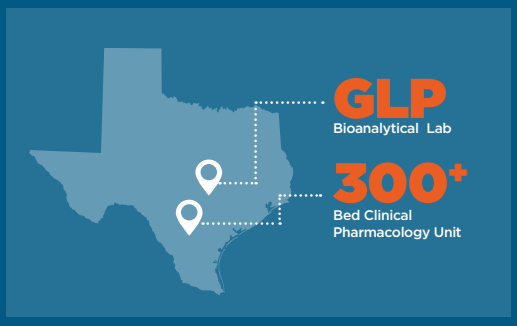
WITH WORLDWIDE CLINICAL TRIALS' BIOANALYTICAL LABORATORY

Last Update: 21042020

WORLDWIDE CLINICAL TRIALS

OUR AREAS OF SCIENTIFIC EXPERTISE INCLUDE:

- Peptides/proteins
- Steroids
- Retinoids
- Biomarkers
- Multi-analyte assays, including metabolites
- Unstable analytes, including prodrugs
- Enantioselective assays
- Low-level (sub pg/mL) quantitation
- Derivatization
- Immunocapture and enzymatic hydrolysis
- Microsampling, including plasma microcapillaries and dried blood spot analysis. Exploratory bioanalysis (tissues, CSF, synovial fluid) for site-of-penetration and target organ studies



WHAT SETS OUR BIOANALYTICAL LAB APART?

We deliver uncommon value. From discovery to post-marketing, we partner with your team to develop a custom method, transfer/optimize and validate an existing method, identify liabilities and de-risk a regulated assay, or adapt a method to increase efficiency and cost-effectiveness. The keyword here is partnership – you're more than a molecule to Worldwide! We know your early phase development comes with high stakes, and we take that seriously.

One way we demonstrate our commitment to customers is by focusing on quality. Our inspection history from 2011 to present-day has consistently resulted in no observations, attesting to our focus to provide the highest quality data possible.

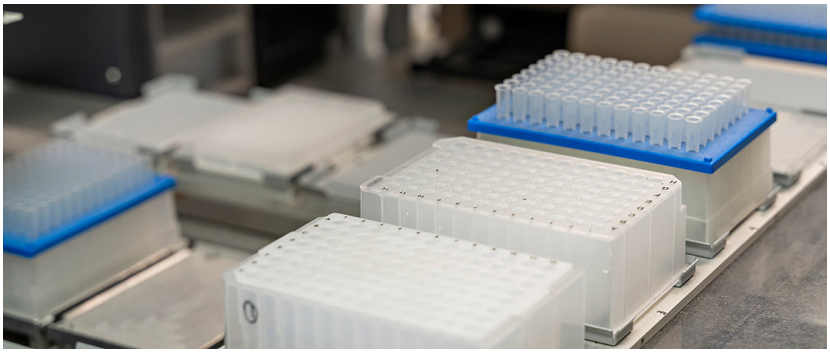
We know that cost will always be a factor for your organization – but not at the risk of quality. Our team provides quality service with rapid turnaround at a competitive cost. You can rely on strong scientific expertise at our Bioanalytical Laboratory in Austin, TX. Our scientists routinely analyze more than 30,000 samples per month and have demonstrated capability up to 45,000 samples per month.

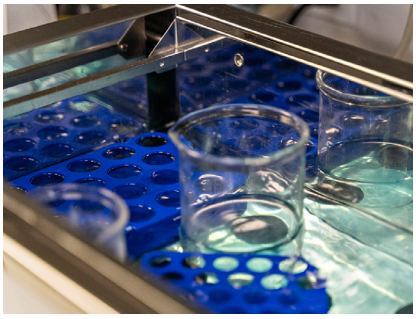
With state-of-the-art instrumentation and more than 2,400 validated assays, we are at the forefront of the industry in the development of bioanalytical methodology.

Our bioanalytical work meets all regulatory standards, including:

- FDA Regulations (US Code of Federal Regulations, 21 CFR) for Good Laboratory Practice, Good Clinical Practice (GCP), Bioavailability and Bioequivalence Requirements, conduct of clinical trials, and human subject protection.
- European Clinical Trials Directive 2001/20/EC and Commission Directive 2005/28/EC.
- UK Medicines and Healthcare Products Regulatory Agency (MHRA) requirements.

Our quality assurance and quality control processes add another level of oversight. Let us demonstrate our excellence!





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WORLDWIDE CLINICAL TRIALS

BIOANALYTICAL SUPPORT SERVICES FOR YOUR PEACE OF MIND INCLUDE:

- Method development, feasibility, and validation
- Drug discovery
- Nonclinical toxicokinetic studies
- Pharmacokinetic (PK) screening
- Pre-clinical animal and clinical sample analysis
- Dose-escalating studies
- Clinical PK/bioavailability studies
- Bioequivalency studies
- Bioavailability studies
- First-to-file studies
- Drug-drug interaction studies
- AME and protein-binding studies
- Metabolite profiling; and
- Pharmacogenomics screening

EXPERIENCE MATTERS. WORK WITH A PROFICIENT, TRUSTWORTHY PARTNER.

Does your CRO partner have the experience to back up its claims? With an early phase focus for over 20 years, we currently conduct approximately 100 clinical trials annually.

ISR reports

RATED OVERALL TOP PERFORMER FOR:

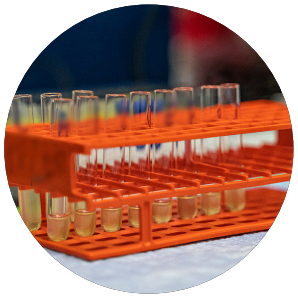
- Budget Factors
- Delivery Factors
- Staff Characteristics
- Accessibility
- Services
- Customer Loyalty

24/7 SPECIMEN CONTROL

We are dedicated to maintaining the integrity of your specimens by providing a 24/7 call list and accommodating emergency retrieval on nights and weekends. We ensure that every biological sample is properly collected and handled to avoid pre-analytical errors. We can provide custom labels to minimize sample discrepancies, which is especially helpful for multi-site studies.

Upon receipt of samples:

- Containers are opened to ensure all samples are frozen and intact.
- Samples are logged into our Watson Laboratory Information Management System (LIMS) database and given a unique identification number to track them through all stages of preparation and analysis.
- The temperature of each -20°C or -70°C freezer is monitored by both Tyco Integrated Security as well as a Vaisala continuous data logger.



WORLDWIDE RANKS AS A TOP PERFORMER FOR EARLY PHASE SERVICES

The latest Early Phase CRO Quality Benchmark Report, conducted annually by Industry Standard Research, notes Worldwide Clinical Trials is a Top Performer, based on customer feedback and scoring for accessibility, services and ability to meet customer expectations. Let us partner with you on your next project and celebrate its successful outcome!

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THERE'S NO SUBSTITUTE FOR UNCOMMON EXPERTISE. MEET YOUR PARTNERS.

Karin Keller

Associate Director, Head of Method Development and Validation

As an Associate Director, the Head of Method Development, Dr. Keller directs and manages the Method Development department to ensure high quality and efficiency in bioanalytical assay development and validation and non-clinical sample analysis. Dr. Keller is responsible for advancing bioanalytical technologies to extend our laboratory capability and capacity, and for developing streamlined processes and fostering strong collaboration for high productivity. She is responsible for promoting scientific development within Worldwide and providing technical support to Business Development. Other responsibilities include providing expertise in assay development, preparing and reviewing analytical methods, regulatory audits, SOP's or other guidelines, ensuring staff compliance with SOPs, GLP and safety guidelines.

Dr. Keller earned a PhD in Analytical Chemistry at The University of Texas at Austin, and has over 10 years' experience developing bioanalytical assays for pharmaceuticals and their metabolites or biomarkers in biological matrices. She also has experience with acquisition, qualification, maintenance, and operation of a wide variety of analytical instrumentation, including multiple MS and LCMS platforms. She participates regularly in client meetings to ensure clear communication of project requirements and timelines, and supervises the conduct of validation studies to ensure timely delivery of GLP-compliant analytical procedures.

Michele Malone

Senior Director, Head of Laboratory Operations

Michele serves as the Senior Director of Laboratory Operations at Worldwide's bioanalytical facility located in Austin, Texas. She has over 24 years' experience in the CRO industry and has served in a variety of roles ranging from bench chemist, quality assurance, project management to operations. Prior to joining Worldwide, she served 5 years as a research scientist in academia. Michele has participated in numerous regulatory inspections and ensures compliance and quality are at the forefront of daily operations. In addition to overseeing operations, Michele is certified as the Radiation Safety Officer for the Austin facility. Michele received her Bachelor of Science degree from the University of Houston – Clear Lake.

Jeffrey G. Stark, Ph.D.,

Director, Pharmacokinetics, Worldwide Clinical Trials

Dr. Stark holds degrees in chemistry (BS, University of Texas at Austin), theoretical chemistry (MS, University of Florida/Quantum Theory Project), and pharmaceutical sciences (PhD, University of Florida/College of Pharmacy). He has a background in molecular structure, drug design, and pharmacokinetic and pharmacodynamic (PK/PD) modeling. His doctoral research focused on the PK/PD modeling of corticosteroids and systemic effects, specifically the suppression of lymphocytes and endogenous cortisol. Throughout his post-graduate education, he was active in preparing course material and teaching general chemistry, pharmacokinetics, and chemistry and pharmaceutical compounding laboratory techniques. He has authored or co-authored 1 book chapter and over 60 manuscripts or abstracts, primarily in the field of pharmacokinetics and drug development. Dr. Stark is currently the Director of Pharmacokinetics at Worldwide Clinical Trials and has been with the organization for 16 years.