



PAREXEL® CLINICAL RESEARCH SERVICES: EARLY PHASE

BIOANALYTICAL AND BIOMARKER SERVICES

Bioanalysis is the discipline that allows the quantitative determination of chemical entities and biomarkers in biological matrices. Analytical methods must generate reproducible and reliable data to allow valid interpretation of the studies for which they support. This science bridges the gap between the administration of a drug during preclinical or clinical trials and the interpretation of the analytical data for pharmacokinetic or pharmacodynamic purposes.



BIOANALYTICAL AND BIOMARKER SERVICES TO HELP YOU MEET YOUR GOALS SOONER

PAREXEL'S LABORATORY
IN BLOEMFONTEIN,
SOUTH AFRICA
— processes —
120,000+
SAMPLES EVERY YEAR



PAREXEL can support your trials, providing well characterized and fully validated analytical methods to yield the reliable results that you need. With more than 30 years of experience in bioanalysis and hundreds of validated assays, PAREXEL has the expertise, experience and resources to help you reach milestones faster—within budget, and with better information to help you make the right decisions.

Partnering with PAREXEL provides you access to our dedicated bioanalytical laboratories in Bloemfontein, South Africa, supported by a specialized network of strategic partners. You benefit from one simple partnership for fast and accurate analysis of drugs, metabolites and biomarkers including assay development and validation services across the full continuum of drug development.

As the demand for generic medicines has grown we have partnered with many companies specializing in the development of these products.

We have a sound understanding of the unique needs of generics development and have developed a dedicated supersite within our network to provide the optimal environment for bioequivalence (BE) studies:

- A fast regulatory start-up environment for BE studies (typically 4 weeks)
- Best of both worlds; a low-cost location with the high-quality service and expertise you'd expect from one of the world's leading CROs
- More than 30 years of hands-on clinical research experience
- Specialist generics expertise and project management
- Clinic and bioanalytical laboratory services under one-roof
- Ready access to target patient populations and healthy volunteers

PAREXEL LABORATORIES—FAST FACTS

- ISO 17025 accredited and GLP compliant
- Fully validated software systems including LIMS (Watson)
- Extensive knowledge of chromatography and mass spectrometry
- Automated, high throughput assay methods
- High capacity for large batches of pre-clinical & clinical PK samples
 - Act as a central PK laboratory for multi-site trials conducted across the globe
- Clinical laboratory services available (clinical chemistry, hematology and serology)
- Immunoassay/biomarker services for biomarkers and biologics using immunoassay techniques (ELISA and RIA)
- Pharmacogenetics services
- Immunogenicity testing

BIOMARKERS FOR CRITICAL THERAPEUTIC DISEASE CATEGORIES

We are working hard to anticipate your next request. Understanding your pipelines and knowing how time is of critical importance to your industry, we are proactively adding to our validated assay list to help ensure a faster start-up for your studies. We share your determination to get your products to market faster—to the patients who need them.

STATE-OF-THE-ART TECHNOLOGY FOR RELIABLE RESULTS

PAREXEL's laboratories are equipped with the latest technology to provide fast, reliable results. Our technology includes the Applied Biosystems (AB) API LC-MS/MS 5500™ system, a spectrometer chosen for its high sensitivity and robustness for even the most complex and demanding matrices.

Other instruments include:

- AB Sciex API 5500, API 4000 and API 3200 triple quadrupole LC-MS/MS systems with ESI, APCI and APPI inlet systems
- Automated HPLC Systems with UV and fluorescence detectors
- Robotic sample processors
- Flow Cytometry
- Cytometric Bead Array
- MALDI TOF mass spectrometry
- PCR

ACCESS TO THE BIOMARKERS EXPERTISE YOU NEED

PAREXEL is committed to providing you all of the services you need from one convenient partnership. Through our network, we can provide additional in-depth cellular and soluble biomarker analysis expertise to give you access to deep scientific insight and an extensive portfolio of biomarkers and non-routine laboratory analysis to help you better understand your therapy's activity and safety profile. PAREXEL can help you select and interpret the right biomarkers to equip you with the knowledge you need to make decisions with confidence and understand the implications of your therapy.

PAREXEL gives you access to key biomarkers in most major disease categories. These include:

- Oncology
- Neurology
- Cardiovascular
- Infectious diseases
- Endocrinology
- Respiratory
- Gastroenterology
- Urology
- Immunology
- Hematology



**We are always available
for a conversation.**

Hendrik Theron

Director, Bioanalytical Services

T +27 51 410 3179

M +27 71 674 8460

hb.theron@PAREXEL.com

*WHEREVER YOUR
JOURNEY TAKES YOU,
WE'RE CLOSE BY.*

CORPORATE HEADQUARTERS

195 West Street
Waltham, MA 02451
USA
+1 781 487 9900

Offices across Europe, Asia and the Americas

www.PAREXEL.com

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