



Scientific Focus: **PHARMACOKINETICS (PK)**

BioAgilytix understands that when it comes to pharmacokinetic (PK) assays, it is of highest priority that the applied bioanalytical method is well characterized, fully validated, and documented in order to yield reliable results.

We offer high-quality PK assay procedures and results strictly in compliance with GLP / GMP and CLIA regulations, and in accordance with international regulatory standards (FDA, EMEA, ICH).

Benefit from Our Deep and Diverse PK Expertise

Our scientists are experienced in supporting PK analysis in a variety of species including rodents, humans, and non-human primates, and in multiple matrices such as serum, plasma, urine, and saliva.

We have proven our expert ability to interpret this assay data to gain an accurate understanding of the absorption, distribution, metabolism, and excretion characteristics of the product.

Make the Right Bioanalytical Method Selection with Our Help

Our veteran scientists are well-versed in the factors that could influence the validity of PK assay data, and take these complexities into account during method validation to ensure optimal results. We'll help you select the best-fit platform for your project, based on both sensitivity and regulatory requirements.

PK Expertise:

- ✓ Preclinical and Clinical Support
- ✓ Assay Development
- ✓ Assay Validation
- ✓ Sample Analysis

Our PK Platforms Include:

- ✓ ELISA
- ✓ MSD-ECL
- ✓ Gyrolab
- ✓ Luminex
- ✓ Flow Cytometry
- ✓ qPCR

Setting the Global Standard for **Scientific Excellence in Large Molecule Bioanalysis**

Quality science, quality data, and a quality partnership—it's how we ensure your large molecule bioanalytical needs are met with accuracy, high performance, and timely results.

Global Support for All Large Molecule Bioanalytical Needs

With advanced laboratory facilities in North Carolina and Boston, as well as in Hamburg, Germany, BioAgilytix is able to support all phases of large molecule global studies, from discovery through Phase IV trials and post-market surveillance.

A Global Leader in Large Molecule Drug Development

BioAgilytix is comprised of true experts in large molecule bioanalysis, with a veteran team averaging over 10 years of bench experience and comprised of over 50% Ph.D. and Masters-level scientists.

Globally Committed to On-Time Delivery of Quality Results

We deliver our bioanalytical services by pairing our unique scientific capabilities, extensive QA expertise, and collaborative project management processes to ensure reliable, timely, high-quality results.

Discuss Your Project with Our Scientists Today.

Let's talk scientist-to-scientist about the bioanalytical needs of your large molecule program.



Services

- ✓ Pharmacokinetics (PK) / Pharmacodynamics (PD)
- ✓ Immunogenicity / Antidrug Antibodies (ADA) / Neutralizing Antibody Assays (NAb)
- ✓ Biomarkers
- ✓ Cell-Based Assays (CBA) / Potency Assays



Platforms

- ✓ ELISA
- ✓ MSD-ECL
- ✓ qPCR
- ✓ ddPCR
- ✓ HPLC
- ✓ Gyrolab
- ✓ Luminex
- ✓ Biacore
- ✓ ImmunoCAP
- ✓ LI-COR
- ✓ Flow Cytometry
- ✓ ELISPOT
- ✓ ProteinSimple Ella



Quality

- ✓ GLP
- ✓ GMP
- ✓ GCP
- ✓ CLIA



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