

# BIOANALYTICAL SERVICES

## **EXPERTISE.** It's how you get from the molecule to the market.

Frontage Laboratories provides bioanalytical services to help support your full drug development. Our state-of-the-art equipment and experienced personnel will quickly and efficiently provide you with the data to support your programs. We provide the resources of a highly skilled, client-focused staff with extensive academic, scientific and pharmaceutical industry experience.

## **CORE SERVICES**

 $\operatorname{GLP} \& \operatorname{Non-GLP}$  Bioanalysis support of Discovery, Pre-Clinical and Clinical

Large & Small Molecule Programs including Biomarkers

- Method Development/Optimization/Transfer
- Method Validation
- Sample Analysis

LC-MS/MS, Ligand Binding, Real-time PCR capabilities in CLIA-Certified, GLP-Compliant Labs:

- TK/PK
- ADA
- Nab
- Biomarker
- Genotyping

## **INSTRUMENTATION AND EQUIPMENT**

- Global Bioanalytical Mass specs capacity 65 instruments
- Includes API 6500+, API 6500, 5500, 5000, 4000, 6600
  TripleTOF, QTrap, ICP-MS, Waters TQS
- Shimadzu NEXERA UHPLC systems
- Tecan and Hamilton Liquid Handling Systems
- Quanterix Simoa HD-1 Analyzers
- MSD's (Sector S600)
- Spectromax/Smax L plate readers, Flexstation
- Ella Protein Simple Systems, Magpix Luminex
- WATSON LIMS
- IDBS eNotebook





## **PARTNERSHIP**

It's what turns services into solutions.

#### **EXPERIENCE WITH:**

- Methods developed from scratch or transfer validated/ qualified method/kit
- Method validation/qualification per industry guidance
- Small molecules, peptides, proteins, ADC's, oligonucleotides & metals
- Various biological matrices including tissues
- Critical Reagent Labeling
- Expertise in Labile Compound Methods
  - Enzymatic instability
  - Physical/chemical instability
  - Liposomal formulations
- Nonclinical toxicokinetic/pharmacokinetic screening
- Clinical PK/bioavailability studies
- Bioequivalence studies
- Therapeutic drug monitoring studies
- Drug-drug interaction studies
- · Protein binding studies
- CLIA assays
- Immunogenicity ADA, NAB assays
- Cell-Based Assays Functional in vitro assays, Toxicity & Viability
- PD/Biomarker Assays
- Micro-sampling techniques
  - Dried blood spot (DBS)
  - Capillary (CMS)
- Analyte stabilization
- Analyte binding

- ·Bioanalytical Expertise in Large Molecule Quantification by LC-MS/MS
  - •Bioanalysis of Liposomal drug (free, encapsulated drug, and total drug in plasma and tissue)
  - •Bioanalysis of PEG-lated drug (small molecule and peptide)
  - •Bioanalysis of Oligonucleotide (ASO)
  - Monoclonal antibody (mAb) /protein PK
  - •Antibody drug conjugate analysis (ADC) (PK and ADA)

Frontage employees have one goal in mind – to meet your next milestone on time with quality. We are always on the cutting edge of innovation in Bioanalysis.

### Why Frontage?

- ✓ Science: Science driven bioanalytical lab
- ✓ Quality: Quality and Compliance Excellence
- ✓ Efficiency: Bioanalysis of small and large molecule in one team
- ✓ Global: Bioanalytical support for US and China submission
- ✓ Diagnostics: GLP-Compliant, CLIA Certified Laboratory
- ✓ One Stop Shop: Comprehensive related services including Toxicology, DMPK, Phase 1 Clinic, BioStats for early and late phase & CMC

Frontage Laboratories, Inc. is a CRO providing integrated, scientifically-driven research, analytical and development services throughout the drug discovery and development process to enable biopharmaceutical companies to achieve their drug development goals. We offer our clients comprehensive services in analytical testing and formulation development, drug metabolism and pharmacokinetics (DMPK), bioanalysis, preclinical safety and toxicology and early phase clinical studies. We have enabled many innovator, generic and consumer health companies of all sizes to file IND, NDA, ANDA, BLA and 505(b)(2) submissions in global markets allowing for successful development of important therapies and products for patients. We have successfully assisted clients to advance hundreds of molecules through development to commercial launch in global markets. We are committed to providing rigorous scientific expertise to ensure the highest quality and compliance.

FOR MORE INFORMATION, CONTACT US AT: salesofrontagelab.com OR VISIT US AT: frontagelab.com

## Headquarters, Bioanalytical GMP Manufacturing Clinical Services and DMPK Services

700 Pennsylvania Drive Exton, PA 19341 P: +1 610.232.0100 F: +1 610.232.0101 SALES@FRONTAGELAB.COM and CMC Services

75 East Uwchlan Ave. Suite 100 Exton, PA 19341

200 Meadowlands Parkway Secaucus, NJ 07094 Suite 102

Princeton Office 101 Carnegie Center Princeton, NJ 08540

Safety, Toxicology and **Agrochemical Services** 10845 Wellness Way Concord, Ohio 44077

