

BIOANALYTICAL: LARGE MOLECULE

Expertise: Bringing your drug into the market.

Gain access to comprehensive biologics services in support of advanced development programs with Frontage's bioanalytical laboratory. We have the capabilities to analyze a wide variety of molecules including antibodies, peptide, and oligonucleotides, and have built a reputation for solving technical challenges related to assay development and validation.

OUR BIOLOGICS SERVICES INCLUDE:

- Method development, transfer and validation
- PK/TK Pharmacokinetics assays
- Macromolecule PK/TK (hybridization and immunoassays)
- Immunogenicity assays (vaccine and anti-drug antibody assays)
- Cell-based assays
- · Functional in vitro assays
- · Toxicity & viability
- · Biomarker services for drug development



OUR SPECIALTIES INCLUDE:

- · Esoteric and complex assay development
- Labile compounds
- Tissue sample analysis
- Antibody Drug Conjugates (ADC)
- · Determination of drug/antibody ratio (DAR) for ADC projects

Our expertise extends to projects that combine small and large molecule bioanalytical activities, such as ADC and biomarker analysis for small and large molecules.

KNOWLEDGE FROM EXPERIENCE

Frontage's senior scientists average 10 - 15 years in complex drug development and have worked with large molecule applications throughout its evolution in product development. The majority of our scientific teams hold advanced degrees.

INSTRUMENTATION

Frontage offers the latest, state-of-the-art instrumentation for large molecule analysis.

Some of our systems include:

- MSD (MesoScale Discovery S600)
- · Spectromax/Smax L plate reader
- Flexstation
- Quanterix Simoa HD-1 Analyzer
- Ella Protein Simple System
- Magpix Luminex
- BIORAD CHEMI-Doc (quantitation of SDS-PAGE/WB)
- Abbott AxSYM System
- PCR (AB 7900HT-Real Time PCR System)
- Tecan and Hamilton Liquid Handling Systems
- Triple Quad LC-MS/MS for protein, antibody, ADC quantitation
- Triple TOF 6600
- Dedicated tissue culture room



BIOMARKERS

Frontage offers capabilities in regulated, fit-for-purpose or CLIA-certified biomarker assay development and analysis.

Our biomarker assay capabilities include:

- MSD
- SIMOA
- ELLA
- Real time PCR
- LC-MS/MS
- · Western Blot

QUALITY ASSURED

Frontage's experience and performance metrics translate into the highest quality, reproducible bioanalytical data. Since its implementation, our incurred sample reanalysis track record includes zero failures.

Frontage's bioanalytical labs are compliant with internal Standard Operating Procedures (SOP), Good Laboratory Practice (GLP) and World Health Authority guidances. Our audit history with regulatory authorities and client inspections is virtually spotless.

In addition to our stringent SOPs, Watson LIMS, a validated freezer temperature monitoring system, central security alarm monitoring and 24-hour card-controlled facility access ensures the highest levels of data integrity.

THE FRONTAGE COMMITMENT

For many sponsors who rely on service partners to help develop and commercialize their products, good science is not enough. For more than 20 years, Frontage has earned a reputation for collaboration, responsiveness and the ability to customize services and deliverables that are aligned with the needs of our clients.

Frontage Laboratories, Inc. is a contract research organization (CRO) that provides integrated, science-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Frontage has enabled many biotechnology companies and leading pharmaceutical companies of varying sizes to advance a myriad of molecules through development and file regulatory submissions in the United States, China, and other countries.

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