

BIOANALYTICAL LARGE MOLECULE

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

Gain access to comprehensive biologics services in support of advanced development programs

WE PROVIDE SCIENTIFIC INPUT TO INFLUENCE THE DECISION MAKING PROCESS with Frontage's bioanalytical laboratory. We have the capabilities to analyze virtually any peptide, protein or antibody, 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 antidrug 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 Disicovery S600)
- Spectromax/Smax L plate reader
- Flexstation



PARTNERSHIP

It's what turns services into solutions.

- Quanterix Simoa HD-1 Analyzer
- Ella Protein Simple System
- Magpix Luminex
- BIORAD CHEMI-Doc (quantitation of SDS-PAGE/
- 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:

- ELISA (single analyte)
- MSD
- SIMOA
- FIIA
- · 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.

FRONTAGE'S COMMITMENT

Our extensive list of validated biomarker assays and capacity offered by two global laboratories - equipped with the latest analytical equipment for efficiency and precision – are supported by robust quality systems, one of the largest teams of expert scientists and a stellar track of compliance and data integrity.

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: sales of frontagelab.com OR VISIT US AT: frontagelab.com

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