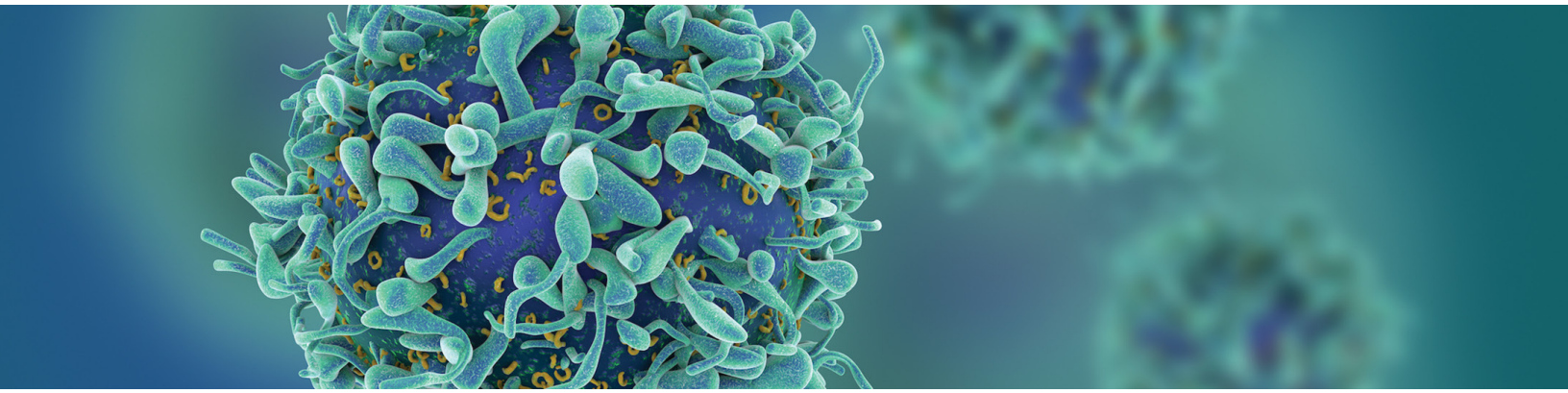


BIOANALYTICAL BIOMARKERS

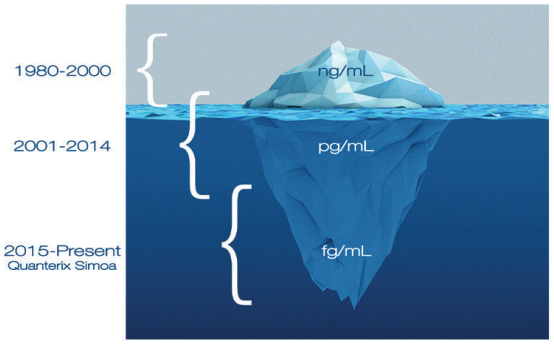
Frontage's Bioanalytical Team is highly experienced in developing, qualifying and validating Biomarker assays. We have expertise in ELISA, ECL based platforms as well as ultra-sensitive detection capabilities (Quanterix Simoa™) for quantitation in the femtogram/mL range, including single and multiplex analysis in various disease categories (e.g. Inflammation, Oncology, Neuroscience, Infectious Diseases, Respiratory, etc.).

Ultra-Sensitive Biomarker Quantification – Frontage Is First

Frontage Laboratories is the first CRO to validate multiple Simoa™ (Single Molecule Array) instruments in a GLP regulated environment. Simoa™ technology provides a novel and ultrasensitive method for detecting and quantifying biomolecules in biological specimens at femtogram concentrations. This very low level detection is difficult or impossible to measure on other instrument platforms. When biomarkers are present at extremely low levels in early stages of physiological abnormalities (i.e. well before the onset of disease symptoms) or when they are down regulated by therapeutic intervention, detection and quantification can enable early diagnosis and prediction of therapeutic effectiveness. However, too often traditional assay platforms cannot meet the required assay sensitivity needed. The sensitivity of Quanterix Simoa™ analyzer makes it the instrument of choice for ultra-sensitive analysis of biomarkers.

Comprehensive Suite of Platforms

Our Biomarker assay platforms include both singleplex and multiplex formats in various biological matrices from preclinical and clinical development programs. For exploratory and preclinical studies, our biomarker assays are useful to demonstrate the validity of a novel biomarker; for clinical trial studies, our assays can monitor the activity of a biopharmaceutical through analysis of therapeutic targets.



ICP-MS for trace elements as the biomarkers
GC-MS for small molecule biomarkers
LC-MS/MS for small molecule and protein biomarkers
ELISA Assay Kits (single analyte)
Meso Scale Discovery (single or multiplex)
Quanterix Simoa™ HD-X and SP-X (single or multiplex, fg/mL sensitivity)
Ella Protein Simple System (single or multiplex, high throughput)
Magpix Luminex (multiplex, biomarker screening)
Gyros Workstation (nano-liter sample volume, large dynamic range)
qPCR, ddPCR Platforms
Flow Cytometry
SMC Pro for High Sensitivity Assays

Broad Range Of Capabilities and Experience

Our biomarker scientists have developed, qualified and validated a large number of biomarker assays for major pharmaceutical companies in the US. We are proud to become a benchmark in the field and have a significant contribution to the pharmaceutical industry with our clients who can rely on our expertise and state-of-the-art technology to advance their drug development. We have also published novel biomarker assays developed in-house to share our expertise with the industry. With the addition of new technologies such as ELLA and Luminex, we will continue as a top-notch provider of biomarker assays in the years to come.

Areas of expertise include:

- Fit-for-Purpose (FFP) and Exploratory Biomarkers
- Validation differences depending on study purpose and method categories
- Method validation to support Labeling Claims, Safety and Efficacy
- Significant endogenous levels of biomarker(s) of interest
- Parameters of validation and level of "compliance" (fit-for-purpose), methodology and SOPs
- A variety of platforms available (based on amount of endogenous biomarker in the matrix)
- Shared samples for many biomarkers
- Complexity around analysis of "multiplex" data
- Healthy vs. Diseased performance differences
- Potentially different locations, labs, companies and instrumentation
- Sample collection, processing and shipping inconsistencies
- Matrix selection & volumes

THE FRONTAGE COMMITMENT

We are committed to meeting this growing need in the biopharmaceutical industry and delivering high-quality bioanalytical services in a timely fashion to global clients in compliance with applicable FDA guidance and ICH guidelines. Our extensive list of validated biomarker assays and capacity offered by two global laboratories (US and China) – 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 record of compliance and data integrity.

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 CLIA Certified Laboratory. Our audit history with regulatory authorities and client inspections is virtually spotless. In addition to our stringent SOPs, Watson LIMS, e-Notebook and 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 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*