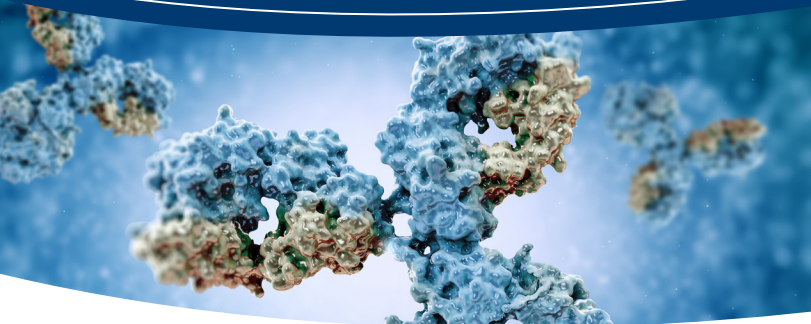


# PARTNERSHIP

It's what turns services into solutions.



## CMC (CHEMISTRY, MANUFACTURING, AND CONTROLS) CGMP ANALYTICAL TESTING FOR BIOLOGICS

**QUALITY.** *It's how you get from formulation to the pharmacy.*

Biologics or biopharmaceuticals are inherently more complex than small-molecule drugs. You need the right team to help you. Frontage has expertise and state of the art instrumentation necessary for the analytical method development, validation and transfer for complex biopharmaceutical compounds. Using bottom up, middle up/down, and top down approaches, we offer analytical support for characterization of primary, secondary and tertiary structures, post translational modifications such as glycosylation, disulfide linkage, antibody drug conjugation, or PEGylation.

### COMPREHENSIVE SERVICES

- Release
- Stability
- Reference standard qualification
- In-depth structural elucidation
- Comparability or Biosimilarity
- Forced degradation
- Support of formulation development

### ANALYTICAL METHODS FOR BIOLOGICS

- UV A280
- Extinction coefficient determination
- Peptide mapping by CE-MS/MS, LC-MS/MS
- Western Blotting
- Receptor Binding by ELISA
- Receptor Binding kinetics by SPR
- Intact mass by CE-MS, LC-MS
- Free thiol
- Secondary structure by UV CD
- Thermogram melting point by DSC
- Glycan profile by RapiFluor LC-Fluor/MS
- Drug antibody ratio by CE-MS/MS, LC-MS/MS
- HMW & LMW species by SEC HPLC
- Size by CE-SDS
- Charged Variant by cIEF, IEX
- Product purity by RP-HPLC
- Host Cell Proteins by ELISA, CE-MS/MS, LC-MS/MS
- Host Cell DNA by qPCR
- Process residuals by LC-MS/MS
- Endotoxin by LAL
- Sub-visible Particles
- Cell based assays

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## STABILITY MANAGEMENT SERVICES

Frontage offers a variety of storage conditions for test samples to meet the demands of drug development requirements in different markets throughout the world. We have the expertise and equipment to handle large scale studies and specialized studies alike.

- Six walk-in stability chamber rooms for standard storage conditions (25°C/60%RH, 30°C/65%RH, 40°C/75%RH)
- 4,000 total cubic feet of capacity Reach-in chambers (-70°C, -20°C, 25°C/40%RH, 40°C/NMT 25%RH, 30°C/75%RH) for special container requirements and complex products
- Photo-stability chamber meeting ICH stressed light exposure study requirements

## QUALITY ASSURED

With an excellent compliance history, Frontage operates under strict adherence to ICH and US FDA CGMP guidelines. Our facilities and processes undergo routine audits and inspections from sponsors and regulatory authorities. Our SOPs, while robust, have the flexibility to accommodate a variety of protocols, templates and reporting formats according to client requirements and preferences.

WE HAVE AN  
UNPARALLELED  
COMPLIANCE AND  
QUALITY TRACK  
RECORD

## 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 10 years, Frontage has earned a reputation for collaboration, responsiveness and the ability to customize service and deliverables that are aligned with the needs of our clients.

*Frontage is a full service CRO which closely collaborates with pharmaceutical and biotech companies to help them bring promising drug candidates to market.*

*We offer solutions to help our clients in analytical testing, product development, DMPK, bioanalysis, clinical, and biometrics. What sets us apart is our ability to collaborate closely with our clients to ensure a deep understanding of their drug development goals and our ability provide flexible solutions that are customized to each client's needs.*

*At Frontage, we are committed to providing rigorous scientific expertise to ensure the highest quality and compliance on each project. Frontage proudly serves innovator, generic and consumer health companies from IND enabling through late stage clinical projects. Frontage successfully assists clients to advance hundreds of molecules through development to commercial launch in global markets. This partnership with our clients is how we turn services into real solutions that get our clients ahead.*

**FOR MORE INFORMATION, CONTACT US AT:** [sales@frontagelab.com](mailto:sales@frontagelab.com) **OR VISIT US AT:** [frontagelab.com](http://frontagelab.com)

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