

LC-MS/MS Capabilities and Expertise

Helping our customers apply liquid chromatography tandem-mass spectrometry (LC-MS/MS) techniques to the development of biologics.

PPD® LABORATORIES

We understand that the development and validation of **LC-MS/MS methods for biologics** is different. **PPD Laboratories' bioanalytical lab** leverages **extensive development and validation expertise** to support your program at any stage of pharmaceutical development.

Our team works with you to understand your program.

We can design and validate custom assays, or adapt existing assays, to quickly generate meaningful data to help inform your project decisions.



30 years of experience developing and validating bioanalytical assays



Broad biologics capabilities



High-quality scientific talent supporting customer programs



Leading-edge LC-MS/MS instrumentation

Wide-ranging biologics capabilities

- LC-MS/MS of macromolecules, including but not limited to:
 - Peptides
 - Conjugated toxins
 - Lipids
 - Polysaccharides
- Atypical peptides
- Monoclonal antibodies (mAbs)
- Antibody drug conjugates (ADCs)
- Fab fragments
- Fusion products
- Unusual matrices (variety of tissues)
- Difficult compounds (reactive, endogenous)

Key instrumentation

- More than 125 LC/MS systems
 - 121 Waters and SCIEX triple quadrupoles, including 50 SCIEX Triple Quad™ 6500 instruments
 - 10 Waters Xevo® TQ-S systems
 - Six SCIEX API 7500 (1 6500) Tandem Mass Spectrometers QTRAP® Ready
 - One Waters Xevo G2 QToF (HRMS)
 - One Thermo Scientific™ Q Exactiv™ Plus (HRMS)
- 10 Thermo Scientific Aria® multiplexing systems
- 50+ UHPLC systems
 - 32 Waters Acquity systems
 - Six Shimadzu Nexera systems with 2-D capabilities
- Hamilton® MICROLAB® STAR and STARlet automatic pipetting workstations

PPD Laboratories partners closely with customers to drive development with well-defined assays backed by our extensive experience with traditional LC-MS/MS techniques that we apply to the analysis of biologics

Our biologics development team has experience with a range of sample preparation approaches, from simple protein denaturation and digestion to complex affinity capture enrichment techniques. While the majority of applications will utilize LC-MS/MS to indirectly measure one or more surrogate peptides produced by proteolytic digestion, our team also has experience with the semiquantitative analysis of intact proteins and ADC characterization using high-resolution mass spectrometry.

Proteins

- Methods
 - Extracted by protein precipitation, SPE or affinity-based methods
 - Smaller proteins (<10KDa) analyzed intact
 - Larger proteins (>10KDa) analyzed following denaturation, reduction, alkylation and digestion
- Experience
 - Human IGF-1
 - Somatropin (recombinant hGH)
 - mAbs (various IgG and IgM including ADCs); universal preclinical and specific approaches (anti-ID, target capture)
 - 63+ assays, including multiplexed mAb assay
 - 51+ antibody conjugated assays
 - 29+ unconjugated toxin assays from five toxin families; auristatins, purrolobenzodiazepines (PBD), maytansines, tubulysins and calicheamicins

Peptides

- Methods
 - Extracted by selective PPT or μ Elution SPE
 - Analyzed by 2D-UHPLC-MS/MS
- Experience
 - Salmon calcitonin (MW-3400; 5.00 to 500 pg/mL; 0.3 mL aliquot)
 - Somatropin (recombinant hGH)
 - Exenatide (MW-4200; 10.0 to 1000 pg/mL; 0.3 mL aliquot)
 - Liraglutide
 - PEGylated peptide, phosphopeptide
 - Amyloid- β biomarker peptides
 - Peptidyl-Gd3-DOTA+- imaging agent
 - Teraparotide (PTH [1-34])
 - 40+ customer proprietary assays

PPD Laboratories

PPD Laboratories provides high-quality scientific expertise with industry-leading technologies supported by a commitment to exceptional quality. Our customers benefit from comprehensive lab services spanning bioanalytical, GMP, central lab testing, vaccine sciences and biomarkers. Our laboratory services accelerate pharmaceutical development for small molecules, biologics, vaccines, and cell and gene therapies allowing customers to make faster decisions about their compounds.

