

# Large Molecule Bioanalytical and ADME Solutions

IQVIA Laboratories leads with science and offers complete large molecule bioanalytical and ADME laboratory services for testing around the globe and across the product development spectrum. We combine knowledge from the collective services provided by our central labs, bioanalytical and ADME labs network. The result is timely, high-quality, regulatory-compliant data that supports the insights you need to make more informed decisions and instill confidence in your regulatory filings.

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## Experience with the following modalities

MULTI-DOMAIN  
PROTEINS

ANTIBODIES

OLIGONUCLEOTIDES

ANTIBODY-DRUG  
CONJUGATES

PEPTIDES

## Biologics by LC-MS

Formed in 2008, the LC-MS biologics team at IQVIA Laboratories is one of the few bioanalytical laboratories successfully employing both triple quadrupole and high-resolution mass spectrometry (HRMS) for biological analyte LC-MS quantitation. We lead the regulated bioanalysis CRO industry in HRMS capacity with 11 validated Quadrupole-Orbitrap instruments. Extensive nano-LC capabilities together with a highly automated bead-based immunoprecipitation extraction processes deliver unparalleled sensitivity and proven reproducibility. These advanced technologies and our depth of experience combine with a collaborative approach to solve your large molecule bioanalytical challenge.

- Hybrid immunocapture-LC-MS for improved selectivity and sensitivity over either platform alone for specific bioanalytical challenges
- Advanced techniques and technologies to measure:
  - » Low-abundance protein biomarkers for drug development
  - » Low concentration bioanalysis of potent, targeted, protein therapeutics in biological matrices
  - » Peptide therapeutics and oligonucleotides/siRNAs
- Selective and sensitive quantitation of advanced therapeutic constructs (multi-specific mAbs, fusion proteins, antibody-drug conjugates)
- Breakthrough technologies:
  - » Nano- and micro-LC capabilities for enhanced sensitivity
  - » HRMS for sensitive targeted quantitation
  - » Automated bead-based immunocapture
  - » Online, column-based immunoaffinity chromatography

- Industry-leading scientific team:
  - » Dedicated large molecule LC-MS team, led by 6 PhD scientists
  - » Combining skills of molecular biology, proteomics, peptidomics, analytical chemistry and biochemistry towards mass spectrometry and ligand binding-based assay experience

## Large Molecule Immunoassay Services

IQVIA Laboratories offers a full range of services for the development or technical transfer and validation of custom-designed assays and application to study sample testing for PK concentration, immunogenicity and biomarker testing. Ligand binding assays (LBA), typically in the format of immunoassays, are the standard for bioanalytical testing of large molecule drugs. Formats can include use of target, anti-idiotypic antibodies, anti-conjugate, enrichment approaches, and competitive assays depending on drug design and characteristics of the drug and reagents. Platforms including chromogenic ELISA, chemiluminescence, fluorescence and electrochemiluminescence that provide the standard basis for macromolecule drug testing.

### Quantitative concentration assays

- PK concentration (Free, Total, Complex)
- Biomarker for analytes that will be used to make regulatory decisions and for label instructions
- Immunogenicity (anti-drug antibody)
  - » Screen/confirm/end point titer
  - » Domain specificity/isotyping
  - » Neutralizing (competitive LBA and cell-based)

Additional services include critical reagent conjugation and characterization, immunogenicity cut point statistical reports.

## ADME Services

IQVIA Laboratories helps customers evaluate *in vitro* properties and *in vivo* plasma/tissue exposures to optimize ADME characteristics for potential drug candidates and assess risk associated with metabolism and drug-drug interactions (DDI).

- *In vitro* permeability of peptides (MDCK II cell line)
- Drug-antibody ratio (DAR) estimation for antibody-drug conjugates (ADCs)
- *In vitro* drug-drug interaction (DDI) risk assessment of oligonucleotides and payload from ADCs
- Discovery level LC-MS bioanalysis of peptides for PK or pharmacology studies
- Biotransformation of peptide and oligonucleotide therapeutics using HRMS

## Why IQVIA Laboratories?

We deliver a full suite of innovative technologies and deep scientific assets to enable solutions for your large molecule bioanalysis and the successful outcome you seek.