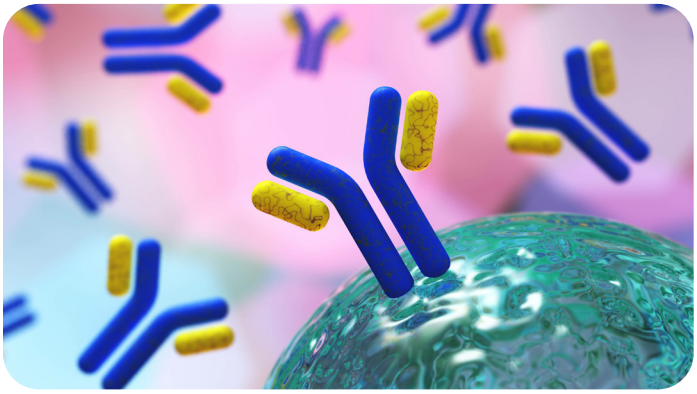
Fact Sheet

Accelerating Discovery: Your Quick Start Guide for Ligand Binding Assay Development

In the high-stakes world of drug discovery, precision and speed are everything. Ligand Binding Assays (LBAs) are the cornerstone of bioanalytical method development, enabling accurate quantification of therapeutic molecules and biomarkers.



Whether you're developing a monoclonal antibody, a biosimilar, or a novel biologic, understanding and identifying the foundational requirements that this quick start guide identifies will give your team a streamlined roadmap for what's needed for LBA bioanalysis work and ensure that your program can hit the ground running.

ESSENTIAL INFORMATION TO START WITH:

- First Patient In (FPI) date/when the assay is needed?
- Disease indication intended?
- Estimated trough level and Cmax?
- Mode of Action (MOA)?
- Required sensitivity?
- Drug: type, structure (Monoclonal Antibody [Mab], multi-specific, oligonucleotides, PEG, Antibody Drug Conjugate [ADC]), mass, formulation, extinction coefficient, and molecular weight?
- Known specificity or cross-reactivity potential?
- Matrix type?
- ETA (if reagents are being produced)?

NECESSARY MATERIALS TO PROVIDE OR PROCURE WITH IQVIA LABORATORIES:

- Biotherapeutic/drug (the lot used in the trial)
- Anti-Drug Antibody (ADA)/Neutralizing (NAb) positive control
- Capture
- Detector
- Target, concomitant drug, or other interferent

REQUIRED SUPPORTING DOCUMENTS:

- Clinical protocol (final or draft)
- Validation report/method for existing assays
- Certificate of Analysis (CoA) for client provided materials

IQVIA Laboratories leads with science, has a solid foundation in LBA best practices, and will use the information provided in this quick start guide to accelerate decision-making, minimize costly delays, and better position your program for successful submissions and long-term success.

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