

Altasciences leverages decades of immunoassay expertise to deliver **reliable data** across all phases of **assay development, validation, and testing**—helping to bring innovative therapies to market faster. Our scientists are equipped to handle **complex methods** and **diverse therapeutic areas**, including metabolic, neurologic, oncology, genetic, and autoimmune diseases.

We can also develop **custom immunoassay solutions** by leveraging our extensive experience in a wide range of animal model sample types, including plasma, serum, cerebrospinal fluid, and tissues.

KEY LBA APPLICATIONS AND OFFERING

Whether you're evaluating early-stage candidates or advancing toward regulatory approval, we offer **tailored solutions** to meet your program's needs.

Pharmacokinetic (PK) and Pharmacodynamic (PD) Studies

- Measure drug concentration over time
- Assess biological responses to treatment

Immunogenicity Testing

- Detect anti-drug antibodies (ADAs)
- Determine if immunogenicity against the drug impacts safety and efficacy

Biomarker Discovery and Validation

- Quantify disease-related biomarkers
- Evaluate treatment response

Biopharmaceutical Development

- Support nonclinical and clinical development of monoclonal antibodies, gene therapy products, and other biologics
- Evaluate product efficacy and safety

Clinical and Translational Research





- Investigate receptor-ligand interactions



We work alongside you to generate the insights needed to advance your program, utilizing our decades of scientific expertise and regulatory knowledge to ensure we meet your goals, while remaining adaptable.

COMPREHENSIVE LBA ASSAYS

Our laboratories offer a comprehensive **suite of validated assays** to support diverse research requirements, from early-stage development to Phase III clinical trials. Each assay is optimized to deliver **maximum sensitivity** and **consistent performance**.

Category	Key Features
 Immunogenicity Assays	<ul style="list-style-type: none">• Validations aligned with 2019 FDA guidance for clinical studies• Leaner validation for nonclinical studies• Characterization for clinical studies can include titration, NAb cell-based and non-cell-based assays and domain specificity, and isotyping
 Quantification Methods	<ul style="list-style-type: none">• ELISA and ECLIA (ligation and dual hybridization)• Matrix optimization and interference testing• High sensitivity and precision across a wide dynamic range
 Functional Cell-Based Assays	<ul style="list-style-type: none">• Flow cytometry-based analysis• Receptor occupancy and cytokine release assays• Cell proliferation studies• Standardized protocols for reproducibility
 Biomarker Analysis	<ul style="list-style-type: none">• Pharmacodynamic assessments• Multiplexed analysis for multiple target detection• Supports exploratory and validated biomarker measurements

TAILORED LBA SERVICES

We deliver **precise, reproducible LBA solutions** across all phases of development, with flexibility to support a single study or full program.

All assays are developed under GLP and GCP guidelines and rigorously validated to ensure data integrity and compliance with FDA, EMA, and ICH requirements.

Our customized strategies are designed to meet the specific needs of your biologic and novel therapeutic modalities, with optimized processes to accelerate timelines and support faster decision-making.

We work as an extension of your team to design the most suitable strategies for your project. Partner with us for a full program, a single study, or a service—we're flexible.

