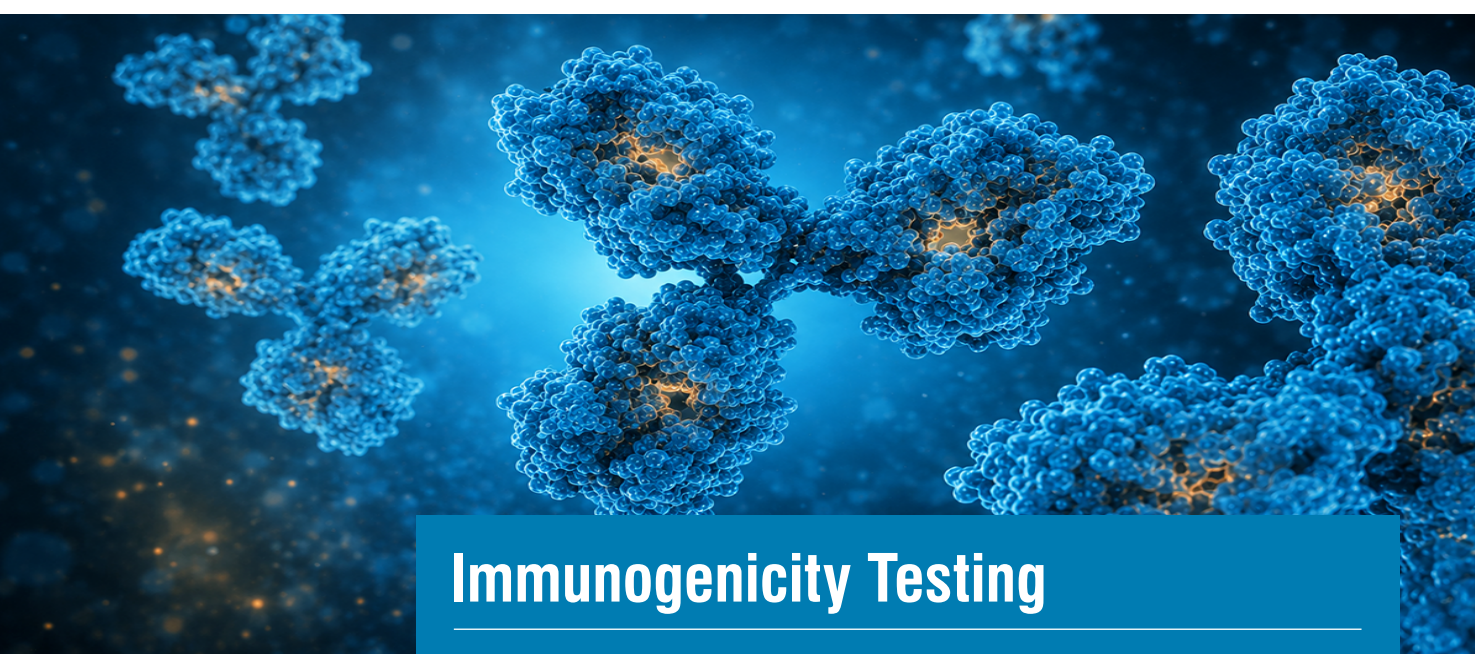




Immunogenicity Testing

At Avance Biosciences, we specialize in comprehensive immunogenicity testing to support preclinical and clinical anti-drug antibody (ADA) studies. Our expert team uses cutting-edge technology to assess how the body's immune system reacts to biologic therapies, helping you navigate the complexities of drug development and meet stringent regulatory standards.

Why Immunogenicity Testing?

Immunogenicity testing is essential to determine if a biologic therapy elicits an immune response in the body. This response can impact drug safety and effectiveness, potentially leading to adverse reactions or therapeutic failure. FDA recommends adopting a risk-based approach to evaluating and managing immune responses to — or immunologically related adverse clinical events associated with — therapeutic protein products that affect their pharmacokinetics, pharmacodynamics, safety, and efficacy. Immunogenicity tests should be designed to detect ADA that could mediate unwanted biological or physiological consequences such as neutralizing activity or hypersensitivity responses.

Our state-of-the-art services are designed to detect, quantify ADAs, including neutralizing antibodies (NABs), providing critical data for regulatory submissions and market approval.

Multi-tiered Testing Approach

Avance Biosciences uses a multi-tiered approach for ADA assessment. We can customize ADA assay tailored to your study requirements throughout all phases of drug development. To increase drug tolerance, we employ methods such as acid dissociation, affinity capture and elution, as well as solid phase extraction and acid dissociation.

Screening Assay

- Early detection of low- and high- affinity ADAs using sensitive methods
- Reactive samples will be evaluated in a subsequent confirmatory assay



Confirmatory Assay

- To confirm specific binding of ADA to the therapeutic protein
- Eliminates potential false-positive results from unspecific binding in the initial screening assay
- ADA confirmed samples will be further characterized by titration and neutralization assays



Titration Assay

- Relative level of ADA in a positive sample is assessed by titration
- Perform serial dilution on the sample and report the reciprocal of the highest dilution factor where the sample still tests positive



Neutralization Assay

- NABs are a subset of ADAs that inhibit the therapeutic activity of the product
- Selection of NAB assay type is dependent on MoA of the drug and the nature of its target
- NAB assay could be cell-based assay or competitive ligand binding assay

Our Immunogenicity Testing Services

- Assay development and validation
- Tech transfer of validated assays
- Preclinical study sample analysis
- Clinical study sample analysis
- GLP compliant services

State-of-the-Art Platforms

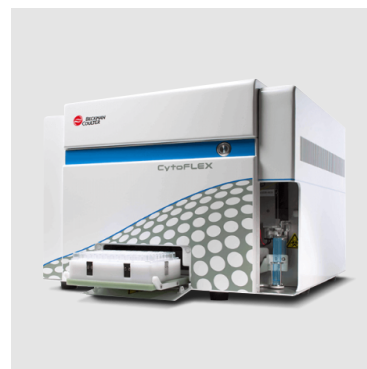
Avance Biosciences is dedicated to delivering top-tier bioanalysis services for our clients' Anti-Drug Antibody (ADA) assessments, utilizing a range of cutting-edge technology platforms. Our experienced scientific team adeptly optimizes these platforms to tailor them to the unique requirements of each client's testing. Below are the technology platforms we commonly utilize:



ELISA



MSD



Flow Cytometry

Technique	Principle	Advantages
ELISA (Enzyme-Linked Immunosorbent Assay)	Detects and quantifies antibodies through antigen-antibody interactions	• High sensitivity and specificity • Well-established and widely used. • Suitable for high throughput screening
MSD (Meso Scale Discovery) Assay	Electrochemiluminescence-based immunoassay	• Enhanced sensitivity and dynamic range. • Multiplexing capability • Low sample volume requirement
Flow Cytometry	Measures fluorescence or light scatter properties of individual cells	• Provides information on ADA specificity and cell-mediated immune responses. • Enables characterization of ADA-positive cells based on cell surface markers.