ALTASCIENCES

BIOANALYTICAL SOLUTIONS FOR

# IMMUNOGENICITY TESTING

**Testing new therapeutics for their immunogenicity potential is a critical part of drug development**, for many types of drugs, such as immunomodulators. Altasciences performs nonclinical and clinical validations in accordance with the EMA guideline on Immunogenicity Assessment and the 2019 FDA guidance *Immunogenicity Testing of Therapeutic Protein Products—Developing and Validating Assays for Anti-Drug Antibody Detection*.

The immunogenicity testing requirements vary depending on the specifics of your development program, and **our experts have the vast knowledge and flexibility** to ensure that every program is designed with the appropriate and necessary assessments in mind.

## IMMUNOGENICITY TESTING—TIERED APPROACH


We have **robust experience with all necessary assays** for your program, with a wide range of characterization assays, including assessment of cross reactivity to endogenous proteins. In addition to titration of your samples, we have **expertise in assessment of binding specificity, isotyping, and NAb assays**, like competitive ligand binding or NAb cell-based assays, depending on the mechanism of action of your drug.

# IMMUNOGENICITY TESTING SOLUTIONS

Our scientists have decades of expertise with a wide array of assay types, and they can provide all the necessary guidance to help select the best approach for your unique program.

**Experience with:**

- drug–mAb, PEGylated proteins, endogenous analogues, peptides, fusion proteins, oligonucleotides, gene therapy, ADCs, PDC, bispecifics, and more
- interference issues from drug, drug target and/or binding components, and various mitigation strategies
- pre-existing antibodies—the appropriate cut-point approach will be determined based on prevalence and magnitude of responses
- positive control generation and characterization, mAb, and polyclonal sera

Watson LIMS is used for all sample analysis and validation projects, and statistical analyses are performed by a biostatistician.

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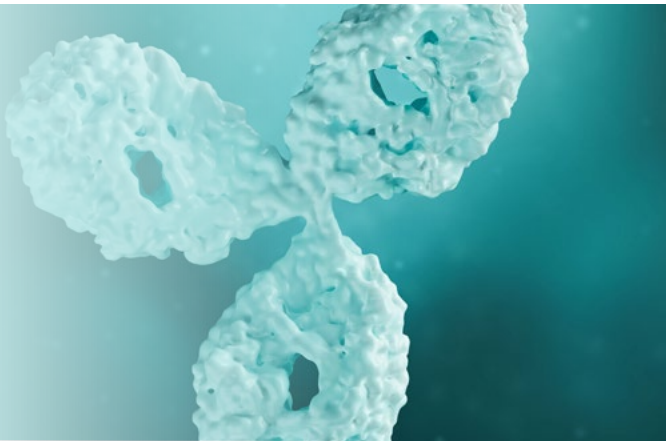
### Study Populations

- Healthy normal volunteers
- Asian populations for ethnobridging studies
- Patients
  - Immuno-oncology
  - Oncology
  - Malabsorption disorders
  - HBV
  - Pediatric enzymology
  - Influenza
  - HIV



# ASSAY TYPES

| | | |
|---|---|---|
| Bridging and indirect immunoassay (ELISA or ECLIA), with or without acid dissociation | SPEAD | ACE |
| PandA | BEAD | BEAD-AGL |
| HISDA | PABAB | |

**Platforms:** MSD, Gen5, Flow cytometry, Luminex

For higher throughput and reproducibility, we offer automation for BEAD assays or any immunodepletion requirement using the King Fisher. We also offer in-house labeling of antigen with biotin and sulfo-TAG (or others as needed). We have expertise in large-scale critical reagent preparation, and well-defined processes for life-cycle management and qualification of critical reagents.

# INTEGRATED PRECLINICAL TO CLINICAL SOLUTIONS

Our **fit-for-purpose assays are developed and validated for your specific program**, with progression from preclinical to clinical at the forefront. Altasciences' integrated preclinical to clinical solutions ensure seamless transition through the phases of development, supported by proactive communication and timely responses.

Altasciences is **ideally positioned to advance your program from preclinical to early phase clinical trials**, and to support your bioanalytical needs up to Phase IV .

Our integrated services ensure that preclinical data is available without delay to inform downstream clinical analyses. Taking into consideration the specifics of your molecules, our experts will verify how assays developed for preclinical studies can be adapted and validated for use in clinical trials. Having comprehensive and early understanding of challenges experienced during preclinical studies can set the stage for addressing those issues during the clinical phase.

For a deeper dive into Altasciences' approach to validating immunogenicity assays for both nonclinical and clinical studies, refer to ***The Altascientist*** on the topic.

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