

# Scientific Focus: Immunogenicity

With an expert team that includes pioneers and world-leading authorities in the field of immunogenicity, BioAgilytix brings deep experience to support anti-drug antibody (ADA) and neutralizing antibody (NAb) assay development and validation to support the development of biologics.

Specifically, our immunogenicity services include labeling of reagents, oversight of surrogate positive control antibody generation, and development, qualification, and validation of assays to assess humoral and cellular immunogenicity. Our scientists are experienced in supporting immunogenicity studies in a variety of species including rodents, humans, and non-human primates.

## Benefit from Our World-Leading Immunogenicity Expertise

BioAgilytix's scientists were involved in characterizing some of the first documented cases of immunogenicity to biotherapeutics, and today our team is comprised of world-leading authorities on the subject. We leverage this highly specialized expertise to support our customers' immunogenicity projects through every phase of small and large molecule drug development.

## Measure Adverse Immune Reactions with the Utmost Accuracy

The selection of an appropriate assay and assay strategy in immunogenicity depends on many drug-and disease-specific aspects. Our experts understand the complexities that must be addressed in isotyping, ADA, NAb analysis, and more, and will help you determine the optimal platform to yield high-quality data results. We also offer these services under GxP, as well as CLIA.

## Immunogenicity Expertise:

- ✓ ADA
- ✓ Screening Assays
- ✓ Confirmatory Assays
- ✓ Titer Assays
- ✓ Characterization Assays
- ✓ NAb
- ✓ Cellular immunogenicity Assays
- ✓ Cytokine Quantitation
- ✓ Oversight of Antibody Generation

## Our Immunogenicity Platforms Include:

- ✓ ELISA
- ✓ MSD-ECL
- ✓ Gyrolab
- ✓ Biacore
- ✓ ImmunoCAP
- ✓ Flow Cytometry
- ✓ ELISpot

## Setting the Global Standard for Scientific Excellence in Bioanalysis

Quality science, quality data, and a quality partnership — it's how we ensure your small and large molecule bioanalytical needs are met with accuracy, high performance, and timely results.

### Overall Support for All International Bioanalytical Services

With advanced laboratories in Durham, Boston, San Diego, Hamburg, Germany, and Melbourne and Brisbane, Australia, BioAgilytix can support all global studies through every phase of development, from discovery through Phase IV trials and post-market surveillance.

### A Leader and Partner in Drug Development

BioAgilytix is comprised of true experts in bioanalysis, with a veteran team averaging over 10 years of bench experience and comprised of approximately 50% Ph.D. and Master's-level scientists.

### Totally Committed to On-Time Delivery of Quality Results

We deliver our bioanalytical services by pairing our unique scientific capabilities, extensive QA expertise, and collaborative project management processes to ensure reliable, timely, high-quality results.

## Discuss Your Program with Our Scientists Today

Let's talk scientist-to-scientist about the bioanalytical needs of your small and large molecule projects.



### Services

- ✓ Pharmacokinetics (PK) / Pharmacodynamics (PD)
- ✓ Immunogenicity / Anti-Drug Antibodies (ADA) / Neutralizing Antibody Assays (NAb)
- ✓ Biomarkers
- ✓ Cell-Based Assays (CBA) / Potency Assays



### Platforms

- ✓ ELISA
- ✓ MSD-ECL
- ✓ LC/MS
- ✓ qPCR/ddPCR
- ✓ HPLC
- ✓ Gyrolab
- ✓ Luminex
- ✓ Biacore
- ✓ ImmunoCAP
- ✓ LI-COR
- ✓ Flow Cytometry
- ✓ ELISpot
- ✓ ProteinSimple
- ✓ Ella



### Quality

- ✓ GLP
- ✓ GCP
- ✓ GMP
- ✓ CLIA

**BioAgilytix** 

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