



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 antibody reagents, ADA purification, and oversight of surrogate positive control antibody generation. 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 scientists were involved in some of first cases of immunogenicity, 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 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 analytical equipment platform to yield high-quality data results. We also offer these services under GLP, GMP, GCP, and GCLP, as well as CLIA.

Immunogenicity Expertise:

- ✓ ADA
- ✓ NAb Assays
- ✓ Screening Assays
- ✓ Confirmatory Assays
- ✓ Characterization Assays
- ✓ Antibody Generation
- ✓ Isotyping

Our Immunogenicity Platforms Include:

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

Setting the Global Standard for **Scientific Excellence in Large Molecule Bioanalysis**

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

Global Support for All Large Molecule Bioanalytical Needs

With advanced laboratory facilities in North Carolina and Boston, as well as in Hamburg, Germany, BioAgilytix is able to support all phases of large molecule global studies, from discovery through Phase IV trials and post-market surveillance.

A Global Leader in Large Molecule Drug Development

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

Globally 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 Project with Our Scientists Today.

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



Services

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



Platforms

- ✓ ELISA
- ✓ MSD-ECL
- ✓ qPCR
- ✓ ddPCR
- ✓ HPLC
- ✓ Gyrolab
- ✓ Luminex
- ✓ Biacore
- ✓ ImmunoCAP
- ✓ LI-COR
- ✓ Flow Cytometry
- ✓ ELISPOT
- ✓ ProteinSimple Ella



Quality

- ✓ GLP
- ✓ GMP
- ✓ GCP
- ✓ CLIA



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