

## BIOANALYSIS FOR GENE THERAPIES

BioAgilytix has a proven 10+ year track record successfully supporting gene therapy programs through all phases of development and to market approval.

Our experience spans *in vivo* and *ex vivo* gene therapies, with specialized expertise developing robust and novel bioanalytical methods to understand the distribution, function, efficacy, and immunogenicity of innovative gene therapeutic candidates in line with regulatory requirements.

We are equipped with a premier suite of bioanalytical platforms to ensure delivery of precise, robust, and reliable results for a wide range of assessments including:

### Pharmacokinetics (PK)

- ✓ Quantitative PCR (qPCR)
- ✓ Digital Droplet PCR (ddPCR)
- ✓ Ligand Binding Assays
- ✓ Branched DNA

### Biodistribution

- ✓ qPCR
- ✓ ddPCR
- ✓ Ligand Binding Assays
- ✓ Branched DNA

### Immunogenicity

- ✓ Ligand Binding Assays
- ✓ Cell-based Assays (NAb)

#### Subject Selection/Enrollment – CLIA

- ✓ TAB
- ✓ Cell-based Assays (NAb)

#### Against the Transgene – GxP

- ✓ Ligand Binding Assays
- ✓ Cell-based Assays (NAb)

#### Viral Vector (In Study) – GxP

- ✓ TAB
- ✓ Cell-based Assays (NAb)

### Pharmacodynamic (PD) Markers

- ✓ Ligand Binding Assays (including multiplex)
- ✓ qPCR
- ✓ ddPCR
- ✓ Flow Cytometry
- ✓ Immunohistochemistry (IHC)
- ✓ Western Blot
- ✓ ELISPOT

### Chemistry, Manufacturing, & Control (CMC)

- ✓ Flow Cytometry
- ✓ qPCR
- ✓ ddPCR
- ✓ ELISA
- ✓ LI-COR Odyssey
- ✓ Western Blot
- ✓ Cell-based Assays (potency)

### Viral Shedding (Safety)

- ✓ ddPCR
- ✓ qPCR
- ✓ Cell-based Infectivity Assays



# 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 gene therapy 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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