

# Bioanalysis For Gene Therapies

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

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 therapy 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:

## Immunogenicity

- ✔ Ligand Binding Assays
- ✔ Neutralizing Antibody Assays (NAb)
- ✔ Cellular Immunogenicity Functional Assays
- ✔ Immunophenotyping
- ✔ Total Antibody Assays (NAb)
- ✔ Cytokine Quantitation Assay

## Pharmacodynamic (PD) Markers

- ✔ Ligand Binding Assays (including multiplex)
- ✔ Flow Cytometry
- ✔ Quantitative PCR (qPCR)
- ✔ Droplet Digital PCR (ddPCR)
- ✔ Immunohistochemistry
- ✔ Western Blot
- ✔ ELISpot

## Good Manufacturing Practices (GMP)

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

## Viral Shedding (Safety)

- ✔ qPCR
- ✔ ddPCR
- ✔ Cell-based Infectivity Assays

## Pharmacokinetics (PK)

- ✔ Ligand Binding Assays
- ✔ qPCR
- ✔ ddPCR

## Biodistribution

- ✔ qPCR
- ✔ ddPCR
- ✔ Ligand Binding Assays

## 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
- ✓ GMP
- ✓ GCP
- ✓ CLIA



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