

BIOANALYSIS FOR CELL THERAPIES

BioAgilytix is expert in the contemporary methods, regulations, and platforms involved in the bioanalysis of cell therapies.

For over 10 years, we have been successfully supporting development programs involving TIL, TCR, CAR, and other innovative modalities across a variety of delivery mechanisms and matrices. We are able to offer deep GxP regulatory knowledge and proven capabilities to support your study from preclinical phases through clinical trials and post-marketing surveillance.

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)

- ✓ Flow Cytometry
- ✓ Quantitative PCR (qPCR)
- ✓ Digital Droplet PCR (ddPCR)

Biodistribution

- ✓ Flow Cytometry
- ✓ qPCR
- ✓ ddPCR
- ✓ Immunohistochemistry (IHC)

Immunogenicity

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

Pharmacodynamic (PD) Markers

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

Chemistry, Manufacturing, & Control (CMC)

- ✓ Flow Cytometry
- ✓ qPCR
- ✓ ddPCR
- ✓ Cell-based Potency 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 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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