



## COMPANY OVERVIEW

# Evolving the Model for Partnership in Large Molecule Bioanalysis to Produce Premium Scientific Results

Led by industry experts in large molecule drug development, BioAgilytix offers industry-leading services and solutions designed to support the most complex large molecule bioanalytical needs.

With advanced laboratory facilities in Durham, North Carolina; Boston, Massachusetts and Hamburg, Germany, we are able to support all large molecule global studies through every phase of development. We are committed to working scientist-to-scientist to deliver integrated bioanalytical solutions—helping your team navigate increasingly complex scientific and regulatory demands.

### Services

Our expert services span from discovery to post-market surveillance support for:

- ✔ **Biomarkers**
- ✔ **Immunogenicity/Anti Drug Antibodies (ADA)/ Neutralizing Antibody Assays (NAb)**
- ✔ **Pharmacokinetics (PK)**
- ✔ **Cell-Based Assays/Potency Assays**

### Solutions

Our scientists are helping customers pursue the opportunities of compelling therapeutic strategies for all large molecule modalities, including:

- ✔ **Gene Therapy**
- ✔ **Cell Therapy**
- ✔ **Biosimilars**
- ✔ **Antibody-Drug Conjugates (ADCs)**

### Quality

Projects can be designed to incorporate your required regulatory compliance, including:

- ✔ **Good Laboratory Practice (GLP)**
- ✔ **Good Clinical Practice (GCP)**
- ✔ **Good Manufacturing Practice (GMP)**
- ✔ **Clinical Laboratory Improvement Amendments (CLIA)**

### Platforms

Any platform in our world-class bioanalytical platform suite can be tailored to your assay demands, including:

- |                  |                  |                         |                             |
|------------------|------------------|-------------------------|-----------------------------|
| ✔ <b>ELISA</b>   | ✔ <b>HPLC</b>    | ✔ <b>ImmunoCAP</b>      | ✔ <b>ELISPOT</b>            |
| ✔ <b>MSD-ECL</b> | ✔ <b>Gyrolab</b> | ✔ <b>LI-COR</b>         | ✔ <b>ProteinSimple Ella</b> |
| ✔ <b>qPCR</b>    | ✔ <b>Luminex</b> | ✔ <b>Flow Cytometry</b> |                             |
| ✔ <b>ddPCR</b>   | ✔ <b>Biacore</b> |                         |                             |

# Best-in-Class Services for Large Molecule Bioanalysis

**BioAgilytix is committed to upholding premium scientific, service, and quality standards, allowing us to excel in some of the most demanding areas of bioanalysis today where extensive, expert-level skill is required.**

Our commitment to solving problems through partnership leads us to pair our advanced scientific expertise and extensive technical capabilities with dedicated collaborative project management processes to produce timely, high-quality results.

## Expert Quality with On-Time Delivery

Large molecule bioanalysis projects are inherently complex —we provide quality science, quality data, and a quality partnership to ensure that we get accurate results that are right the first time, every time.

## Scientific Expertise Driving Superior Results

Our veteran scientists are key to the quality of work that BioAgilytix produces. Each member of the team is dedicated to being a true partner in your bioanalytical projects, helping you problem solve through every phase of drug development.

With an average of 10+ years of post-schooling bench experience, our team possesses deep expertise in a wide variety of current bioanalytical solutions and services including biomarkers, cell-based assays, immunogenicity, and PK. Our scientists have contributed to more than 2,500 publications and are committed to staying on the pulse of the latest scientific and regulatory developments in the biotech and pharma industries.

Between our teams in USA and Europe, we are able to support global studies for any large molecule need.

## Collaborative Partnership Drives Success

As a team, we don't just talk about quality, we embody it. Our sustainable Quality Management System (QMS) is built on four key pillars: Customer understanding, Performance and reliability, Regulatory compliance, Ownership and accountability. These foundational elements drive everything we do, allowing BioAgilytix to deliver robust, reliable results to our customers.



Scientific team averaging **10+ years of post-schooling bench experience**



Comprised of **50%+ Ph.D. and Masters-level scientists**



**Supported 35%+ of biologics** approved by the FDA in 2018-2020



Team **boasts a 90%+ employee retention rate—the highest in the industry**



**Ranked #1 by our customers** in quality and customer service\*

*\*Based on an independent customer satisfaction survey*

## The BioAgilytix Global Team

### USA Headquarters – Durham, NC

BioAgilytix's USA headquarters is a 78,685 square foot facility located in the Research Triangle Park region. This high-capacity, CLIA-certified laboratory supports discovery, preclinical, clinical and manufacturing trial phases.

### Boston Laboratory – Boston, MA

Located in the heart of the world's biotech innovation hub, this 26,453 square-foot facility also houses BioAgilytix Diagnostics, a New York State-licensed Boston laboratory that is CLIA-certified and CAP-accredited.

### Hamburg Laboratory – Hamburg, Germany

The state-of-the-art lab, at 29,902 square feet in size and growing, is one of the most technologically advanced bioanalytical laboratories in Europe and has been in operation since 1996.



#### USA Headquarters

2300 Englert Drive, Durham, NC 27713  
919.381.6097

#### Hamburg Laboratory

Lademannbogen 10, 22339 Hamburg, Germany  
+49 40 526779 0

#### Boston Laboratory

1320 Soldiers Field Road, Boston, MA 02135  
617.456.0800

 [www.bioagilytix.com](http://www.bioagilytix.com)

 [info@bioagilytix.com](mailto:info@bioagilytix.com)

© 2021 BioAgilytix Labs, All rights reserved.