

## BIOANALYTICAL ASSAYS FOR VACCINES

**BioAgilytix supports robust, compliant bioanalytical assessments for the diverse range vaccine varieties in development today.**

This includes pathogen-derived vaccines, recombinant proteins and virus-like particles (VLPs), nucleic acid- or vector-based vaccines, and emerging virus neutralization approaches such as monoclonal antibodies directed at the target virus.

Leveraging a long, successful track record supporting diverse and complex biologics in combination with our broad platform capabilities, we will **apply the optimal, phase-appropriate method to meet your unique vaccine program needs**, including:

### Flow Cytometry

- ✓ T Cell, B Cell & NK Panels
- ✓ T and B Cell Activation Markers & Tetramer Staining
- ✓ Specific Cell Population Isolations
- ✓ Vaccine-Induced T Cell Enumeration

### ELISA

- ✓ Antibody Titers
- ✓ Anti-drug Antibodies (ADA)
- ✓ Seroconversion
- ✓ Host Cell Proteins

### Cell-Based Assays

- ✓ Neutralizing Antibodies (NAb)
- ✓ Potency Assays

### ELISPOT

- ✓ Enumeration of Antigen-Specific Cellular Response
- ✓ Immune Response Monitoring

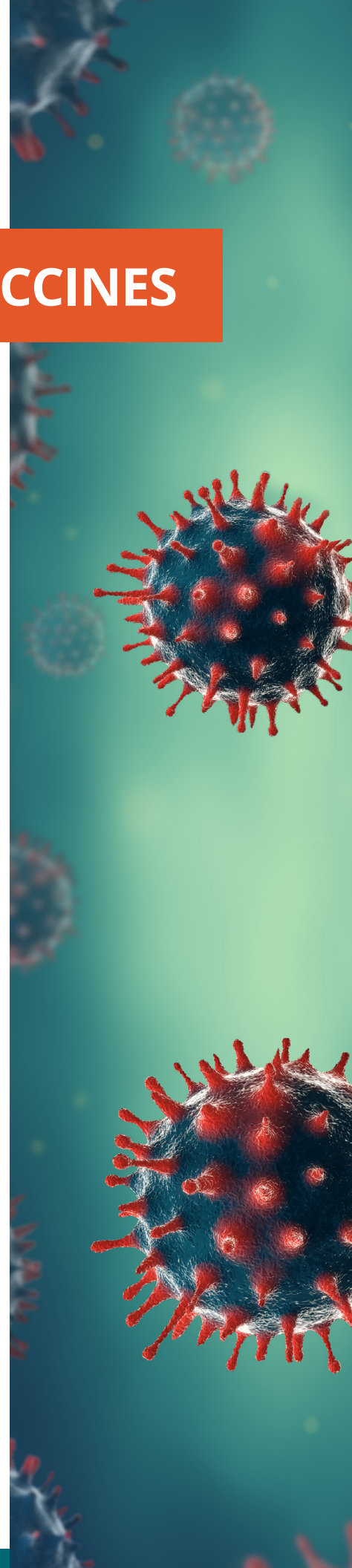
### Meso Scale Discovery (MSD)

- ✓ Validated Cytokine/Chemokine Panels
- ✓ Vaccine Antigen Detection

### Real-Time PCR (qPCR) & Digital Droplet PCR (ddPCR)

- ✓ Viral Load
- ✓ Genotyping
- ✓ Gene Expression
- ✓ Immune Response Monitoring
- ✓ Host Cell DNA

**Our experience is deep across the range of assays above performed under GLP, GCP, and GMP regulations.** Our specialization in immunology and with ADA and NAb assays ensures your vaccine products are well-positioned to successfully advance down the development and approval pathways.



# 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
- ✓ Gyrolab
- ✓ Luminex
- ✓ Biacore
- ✓ ImmunoCAP
- ✓ Western Blot (LI-COR)
- ✓ Flow Cytometry
- ✓ ELISPOT
- ✓ ProteinSimple Ella



## Quality

- ✓ GLP
- ✓ GMP
- ✓ GCP
- ✓ CLIA



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