

## **SARS-CoV-2 TESTING:**

# Specific Methods to Detect & Characterize Responses to the Virus Causing COVID-19

Leveraging premier platforms and specific methods, BioAgilytix offers **the complete suite of assays and services necessary** to determine disease state, characterize antibody response, and assess biomarkers related to COVID-19.

### **Viral Testing via Real-Time PCR (RT-PCR)**

BioAgilytix is able to implement the **RT-PCR assay with Emergency Use Authorization (EUA) by the FDA** to specifically detect the RNA of the SARS-CoV-2 virus to identify active or recent infections.

PCR testing can be applied under CLIA for:

- ✔ Diagnostic/ Screening Tests
- ✔ Assisting in Starting & Restarting Clinical Trials

### **Immune Response Testing via ELISA**

BioAgilytix's **highly specific immune response assays detect IgA, IgM, and IgG antibodies** to identify individuals who were infected and have already recovered from COVID-19.

Testing can include patients who were never diagnosed by providing not only qualitative (yes/no) assessment but also semi-quantitative measurements (titer) to assess a patient's relative levels (magnitude of the response) which indicate stage of infection and strength of antibody response.

Detection of antibodies to SARS-CoV-2 to support:

- ✔ Diagnostics
- ✔ Immunosurveillance
- ✔ Patient Stratification for Clinical Trials
- ✔ Vaccine Clinical Trials Support

### **Cytokine Assays for CRS Monitoring**

BioAgilytix can utilize our validated three 10-plex cytokine/chemokine panels from Meso Scale Discovery (MSD) **to detect cytokine release syndrome (CRS) in COVID-19 patients.**

### **Biacore Assays to Further Characterize Immune Response**

**We are also able to assess immune response as well as characterize isotype switching** to distinguish fresh infection from later infection and determine antibody affinities to define antibody maturation.

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As experts in clinical assays, we deliver robust data sets and comprehensive data interpretation beyond what a typical diagnostic lab can offer. **Speak to our scientists today to get your testing underway.**

# Why Work with BioAgilytix? To Ensure Compliant, Timely, Useful Results

We're committed to **applying our specialized expertise and proven processes** to help our customers test for and understand the impacts of the novel COVID-19 disease.

## Delivering Robust Data Sets

We are experts in assays for clinical trials, and can go beyond positive/negative results with **robust data sets that stand up to stringent regulatory submission requirements.**

## CLIA-Certified Labs

Our laboratories in Boston, MA and Durham, NC are able to provide individualized data needed **to support patient enrollment in clinical trials and immunosurveillance.**

## Ensuring Availability of Reagents

BioAgilytix is working closely with our supply chain partners to **ensure reagents and kits for immune response testing remain stocked** in our labs for your immediate access.

## A Personalized Approach

Our team of experts works closely with customers to help them **craft appropriate testing strategies,** and we can support development and validation of de novo assays as needed.



## Speak to Our Scientists Today

Addressing the immediate threats of COVID-19 with new vaccine and anti-viral therapeutic programs is critical, but we must also look ahead at how patients with antibodies to SARS-CoV-2 might impact and change clinical trial strategies moving forward.

**BioAgilytix is your partner for comprehensive SARS-CoV-2 testing to support these development decisions, and our labs are open and fully operational to support your immediate requirements.**

## Discuss Your Project

with us today by calling  
**919-381-6097.**



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