

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.

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.



USA Headquarters


2300 Englert Drive, Durham, NC, 27713
919.381.6097

European Headquarters

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

Boston Location

1320 Soldier's Field Road, Boston, MA 02135
617.456.0800

 www.bioagilytix.com

 info@bioagilytix.com

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