

## BioAgilytix Launches Customizable Testing Packages Supporting Solutions to Treat and Prevent Spread of COVID-19

*The CRO has applied its clinical assay and diagnostics capabilities to address a breadth of sponsor and employer needs stemming from the COVID-19 pandemic*

**June 8, 2020—Durham, NC**—BioAgilytix, a leading provider of contract bioanalytical testing services with specialization in large molecule bioanalysis, has announced that it is now offering customizable COVID-19 testing packages with services to address a breadth of sponsor and employer needs stemming from the coronavirus pandemic. The services apply BioAgilytix's deep experience with clinical assays and diagnostics to viral and antibody testing for SARS-CoV-2, the virus causing COVID-19 infection. Testing includes [return-to-work screening programs](#) for immediate testing and ongoing monitoring of employees returning to the workplace, and a [suite of assays for sponsors](#) to support clinical trial decision-making for COVID-19 programs and other disease indications.

"We have all felt the impact of COVID-19 on our businesses and communities, and that is why we are driven to be part of the solution," said Jim Datin, President and CEO of BioAgilytix. "We are also in a unique position because we are a bioanalytical lab with a premier diagnostic testing facility. We have the assay expertise required, the technologies needed, and a team that is passionate about helping our customers and companies everywhere to move forward in this pandemic safely. It made sense for us to apply our resources to testing that will help manage the spread of COVID-19 as well as be integral in finding treatments and vaccines for the disease."

BioAgilytix's [COVID-19 testing services for employers](#) can be used to identify employees with active COVID-19 infections before they rejoin the workplace, and also to understand the exposure of the workforce to COVID-19. As part of these services, BioAgilytix provides guidance to define the appropriate screening approach, sample collection methods, and testing logistics for each organization in the short-term and over time. "Our goal is to provide a personalized experience that employers would not typically get from a large-scale diagnostics lab in regards to employee screening," said Linda Robbie, Ph.D., Vice President and General Manager of BioAgilytix's Boston Operations where the diagnostics facility is based. "Companies have never faced a challenge like this, and it is our duty as testing experts to guide them to an effective screening strategy that fits their needs and provides a solution for both the employer and their employees, in terms of keeping them safe. It is also important to note that we have created this capacity specifically to support employer-driven testing. Employers can feel assured that they are not tying up resources in labs that are handling much of the front line worker testing needs."

BioAgilytix's [sponsor-focused COVID-19 testing services](#) are also customizable to client need and include PCR-based viral testing and immune response assays. The lab additionally offers cytokine monitoring and Biacore assays to further characterize antibody response to better understand stage of infection, maturation of antibodies, and strength of antibody response against COVID-19. The assays can be used to provide guidance for new vaccine and therapeutic programs targeted at COVID-19, as well as support development decisions for therapeutics aimed at other diseases. "All sponsors will need to consider how patients with antibodies to the virus might impact their clinical trial strategy as they launch or restart trials that were delayed due to COVID-19 quarantines," said Jim McNally, Chief Scientific Officer – North America at BioAgilytix. "We are able to provide the breadth of testing needed to determine disease state, characterize antibody response, and assess biomarkers related to the virus. This yields robust data sets that will help us better understand the novel disease and its potential effects on patients."

“We specialize in assays for clinical trials and can perform testing under CLIA in our US labs,” added Datin. “That means we can deliver testing results that will stand up to stringent regulatory submission requirements. Data of this caliber will be needed to streamline development and approvals to get COVID-19 treatments and vaccines to market as fast as possible – while doing so safely. We’re proud to support the efforts of pharma, biotech, and all companies working to combat COVID-19. Together we’ll make an impact for patients and for people everywhere.”

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### **About BioAgilytix**

BioAgilytix is a leading bioanalytical testing laboratory specializing in large molecule bioanalysis. With laboratory locations in North Carolina’s Research Triangle area, the Cambridge area of Massachusetts, and Hamburg, Germany, BioAgilytix provides PK, immunogenicity, biomarkers, and cell-based assay services supporting the development and release testing of biologics across a number of industries and disease states. BioAgilytix offers assay development, validation, and sample analysis under non-GLP, GLP, and GCP, as well as GMP quality control testing (i.e. product release testing, stability testing, etc.). BioAgilytix also offers diagnostic testing services at its CLIA-certified, CAP-accredited Boston laboratory.

BioAgilytix’s team of highly experienced scientific and QA professionals ensures high quality science, data integrity, and regulatory compliance through all phases of clinical development, and is a trusted partner to many of the top global pharmaceutical and biotech companies. For more information, visit [www.bioagilytix.com](http://www.bioagilytix.com).

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