BD, BioGX Announce FDA Emergency Use Authorization Submissions for New COVID-19 Diagnostics for Use in U.S.

New Diagnostics Have Potential to Increase Capacity of COVID-19 Testing in U.S. by Thousands of Tests Per Day

FRANKLIN LAKES, N.J. and BIRMINGHAM, Ala., March 16, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and BioGX Inc, a molecular diagnostics company, today announced that the companies have submitted Emergency Use Authorization requests to the U.S. Food and Drug Administration (FDA) for new diagnostic tests that, if authorized, would increase the potential capacity to screen for COVID-19 (coronavirus) by thousands of tests per day.

The tests would help fill an urgent need across the U.S. for laboratories to access an easy-to-use, rapid diagnostic test to screen patients for COVID-19. The tests will be run on the BD MAX™ Molecular Diagnostic Platform, which is already in use in nearly every state across the U.S. at hundreds of laboratories, with each unit capable of analyzing hundreds of samples per day. The system is fully automated, reducing the opportunity for human error and increasing the speed to result. Samples are capable of being analyzed start to finish in two to three hours. Each BD MAX™ System can process 24 samples simultaneously.

"The collaboration with BioGX to deliver a COVID-19 diagnostic in the U.S. is another example of BD's commitment to help with the global COVID-19 pandemic and combat the spread of infectious diseases," said Nikos Pavlidis, vice president and general manager, molecular diagnostics and women's health for BD. "Our BD MAX System is a versatile molecular platform that enables us to rapidly deliver molecular solutions across our laboratory customers and help communities in need during times of high anxiety."

BioGX developed the assay for the BD MAX™ System in their Sample-Ready™ ready-to-use format to detect the presence of the SARS-CoV-2 virus, the cause of COVID-19. The assay is based on the same viral RNA targeting sequences and real-time PCR detection method as the test developed by the U.S. Centers for Disease Control and Prevention (CDC).

"These are challenging times for all of us, more so for our laboratory partners who have an urgent need for an easy to use, reliable test to detect the SARS-CoV-2 to determine if patients have contracted COVID-19," said Shazi Iqbal, Ph.D., chief executive officer of BioGX. "The foundation of BioGX firmly stands on its team's ability to step up and address such unmet needs with speed. Authorization to use our test would increase access across the U.S. to an automated, highly reliable SARS-CoV-2 test."

The companies submitted the Emergency Use Authorization requests to FDA today. The Emergency Use Authorization authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear threats by facilitating the availability and use of medical countermeasures needed during public health emergencies.

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com.

About BioGX
BioGX, Inc., headquartered in Birmingham, Alabama, and its wholly owned subsidiary BioGX B.V., based in Amsterdam, The Netherlands, (collectively “BioGX”), develop and commercialize molecular diagnostics reagents across diverse applications. BioGX operates in a cGMP compliant environment certified to International Standard ISO 13485. The company applies its proprietary platform-agnostic reagent technology to offer products and contract services across a variety of real-time PCR and Next Generation Sequencing platforms. The Sample-ReadyTM technology is at the core of all product offerings for Clinical, Food Safety, Pharma and Water Quality molecular testing. BioGX B.V.’s 50+ molecular diagnostic products are marketed and sold in 100+ countries through its Global Distribution Network. For more information on BioGX, please visit BioGX.com.

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