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

New Test Immediately Available to Increase Capacity of Rapid, On-Site Testing of COVID-19 at Hospitals Across the U.S.

FRANKLIN LAKES, N.J. and BIRMINGHAM, Ala., April 3, 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 U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for a new diagnostic test that will enable hospitals to screen for COVID-19 (coronavirus) on site and get results in under three hours.

The test helps fill an urgent need across the U.S. for hospitals to access an easy-to-use, rapid diagnostic test to screen patients and health care workers for COVID-19. The test will be run on the BD MAX™ System, a molecular diagnostic platform already in use at hundreds of laboratories in nearly every state across the country. Each unit is capable of analyzing hundreds of samples per day.

"The BioGx molecular test for the BD MAX™ System and our recently announced serology test that can help detect current and past exposure to COVID-19 are part of BD's approach to give health care workers choice and access to the right test for the right situation," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "We continue to work diligently on an antigen test for our point-of-care BD Veritor™ System that would complete a full portfolio of COVID-19 tests."

The majority of BD MAX™ Systems are installed in hospital laboratories, reducing the added time and complexity of needing to send samples to a reference lab. The system is fully automated, reducing the opportunity for human error and increasing the speed to result. The BD MAX™ System can process 24 samples simultaneously. The tests are expected to add capacity for 50,000 tests per week nationwide.

"The collaboration with BD, combined with the new emergency use authorization process from FDA, enabled our companies to bring a new test to the BD MAX™ System quickly and efficiently," said Shazi Iqbal, Ph.D., chief executive officer of BioGX. "The development and launch speed was critical to ensure hospitals and laboratories can have additional options and capacity for an automated, highly reliable SARS-CoV-2 test for their patients."

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).

Hospitals and laboratories that use a BD MAX™ System can order tests through their BD sales representative.

The BioGX SARS-CoV-2 Reagents for the BD MAX™ System has not been cleared or approved by FDA. However, it has been authorized by the FDA under an EUA. The test has been authorized only for the detection of RNA from SARS-CoV-2 virus to aid in the diagnosis of SARS-CoV-2 virus infection, not for any other viruses or pathogens. The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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 inAmsterdam, 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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