BD Launches Portable, Rapid Point-of-Care Antigen Test to Detect SARS-CoV-2 in 15 minutes, Dramatically Expanding Access to COVID-19 Testing

- Simple new assay leverages more than 25,000 BD Veritor™ instruments already used across the U.S. to immediately increase access to COVID-19 testing in frontline health care settings
- BD will begin shipping the new test this week and expects to ramp-up manufacturing capacity to 2 million tests per week by the end of September
- This is the company's third diagnostic test to receive Emergency Use Authorization by U.S. FDA for detecting COVID-19

FRANKLIN LAKES, N.J. , July 6, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that the U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for a rapid, point-of-care, SARS-CoV-2 diagnostic test for use with its broadly available BD Veritor™ Plus System. The launch of this new assay that delivers results in 15 minutes on an easy-to-use, highly portable instrument is critical for improving access to COVID-19 diagnostics because it enables real-time results and decision making while the patient is still onsite.

The BD Veritor™ System, which is slightly larger than a cell phone, is currently in use at more than 25,000 hospitals, clinician offices, urgent care centers and retail pharmacies in all 50 U.S. states. Its one-button functionality, workflow flexibility, and ease-of-use make it an ideal solution for settings without laboratory personnel. It also offers customers real-time reporting capabilities through the BD Synapsys™ informatics solution providing them with the ability to easily report data for disease monitoring and surveillance purposes.

BD is leveraging its global manufacturing network and scale and expects to increase capacity to be able to produce 2 million tests per week by the end of September. The company already expects to produce up to 10 million tests from July through September.

"This will be a game-changer for frontline health care workers and their patients to be able to access a quick diagnostic test for COVID-19, offering results in real-time at convenient locations like retail pharmacies, urgent care centers and doctors' offices," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "Such tests will also help communities be more informed and better prepared to help prevent new spikes and additional waves of COVID-19 by enabling public health workers to quickly identify infectious individuals and trace their contacts. The highly portable, easy-to-use, point-of-care format of this test, large quantity of test kits available and existing, expansive footprint of BD Veritor™ Plus instruments will help bring widespread access to COVID-19 testing in the United States and around the world as additional country-specific regulatory requirements are met."

The launch of the BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 Assay is the latest effort in the company's comprehensive response to address critical health needs related to the global pandemic. The new immunoassay test joins a portfolio of three molecular solutions for COVID-19 testing that have been registered for use with the BD MAX™ Molecular System, including two with EUAs and two with CE mark. So far this year, the company has provided health care providers globally with approximately 48 million swabs for flu and COVID-19 testing, more than 2.85 million COVID-19 rapid

molecular diagnostic tests on the BD MAX™ System, and millions of products used in the treatment of COVID-19 patients, including infusion pumps, infusion sets and catheters.

All BD COVID-19 diagnostic products have regulatory authorizations in the markets where they are sold. BD intends to pursue 510(k) clearance for the BD Veritor™ Plus SARS-CoV-2 assay from the FDA at a later time. U.S. customers interested in BD diagnostic solutions for COVID-19 should contact IDS.COVIDtests@bd.com.

About the BD Veritor™ SARS-CoV-2 Assay
The BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 Assay is deemed to be a CLIA-waived immunoassay designed to be used in health care settings to provide an aid to rapid diagnosis of COVID-19 in symptomatic individuals. BD clinical studies performed at more than 20 sites across the U.S. demonstrated that the test is capable of achieving 84% sensitivity and 100% specificity, which is in line with the performance from similar immunoassay tests for Flu A/B, RSV and Strep A on the BD Veritor™ Plus System — all of which are widely-used, highly relevant and clinically valid. Similar to all immunoassay tests, FDA recommends that negative test results be confirmed by a molecular method to confirm the result, if necessary, for patient management.

The BD point-of-care test has not been cleared or approved by FDA. The test has been authorized by FDA under an EUA only for the detection of SARS-CoV-2 nucleocapsid antigens to aid in the diagnosis of SARS-CoV-2 virus infection. It has not been authorized for use to detect any other viruses or pathogens. The test is authorized in the United States 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.

Forward Looking Statements
This press release contains forward-looking statements regarding the use of BD's point-of-care test and BD's manufacturing capacity. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements, many of which are beyond the company's control, including risks relating to market acceptance of the test, events that could impact our manufacturing capabilities, and other challenges inherent in manufacturing and commercially launching new products. Further information on these risks and uncertainties is included in the company's most recent Annual Report on Form 10-K and other SEC filings. BD expressly disclaims any undertaking to update any such statements set forth herein to reflect events or circumstances after the date hereof, except as required by applicable laws or regulations.

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