BD Supports U.S. Government Efforts to Increase COVID-19 Testing Capacity with Point-of-Care Tests

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Government committed to use of BD Veritor™ Plus System and 15-minute SARS-CoV-2 test kits

FRANKLIN LAKES, N.J., July 15, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, announced today a commitment from the U.S. Department of Health and Human Services (HHS) to purchase BD diagnostic solutions in expanding access to rapid point-of-care testing for COVID-19 through a broad, decentralized network of testing instrumentation.

HHS has committed to purchase 2,000 BD Veritor™ Plus Systems and 750,000 SARS-CoV-2 antigen test kits for use on the system. Distribution is set to begin next week.

"The BD Veritor™ Plus System for rapid detection of SARS-CoV-2 is the latest point-of-care testing advance that will significantly expand testing in distributed locations for the benefit of all Americans," said Admiral Brett P. Giroir, M.D., assistant secretary for Health and COVID-19 testing coordinator. "This development will help identify community spread of the virus by further enabling rapid diagnosis of COVID-19."

The U.S. Food and Drug Administration (FDA) granted BD an Emergency Use Authorization (EUA) for its BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 earlier this month. The test leverages BD Veritor™ Plus Analyzers, portable instruments that are slightly larger than a cell phone, which are already in use in 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 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.

"The ongoing pandemic has been devastating for individuals, families and businesses around the world," said Dave Hickey, president of Integrated Diagnostic Solutions for BD. "Until there is an effective treatment or vaccine, rapid diagnostic testing is fundamental to controlling the spread of the disease. The BD Veritor™ Plus Analyzers, SARS-CoV-2 antigen test kits, and BD Synapsys™ Informatics Solution will play a critical role in helping clinicians identify individuals with COVID-19 while helping public health officials track COVID-19 incidence and identify emerging outbreaks in real-time."

BD began shipping limited quantities of its BD Veritor™ Plus SARS-CoV-2 antigen test kits to distributors last week as it ramps up production capacity. 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 expects to produce up to 10 million tests from July through September.

In addition to a SARS-CoV-2 antigen assay for the BD Veritor™ Plus System, BD and a network of partners offer a portfolio of COVID-19 testing solutions including highly sensitive molecular diagnostic tests on the BD MAX™ System. All BD COVID-19 diagnostic products have EUA and BD intends to pursue 510(k) clearance with 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 Veritor™ Plus System for Rapid Detection of SARS-CoV-2 Assay has not been FDA cleared or approved. The test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and, the test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics 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.

Contacts:

Gwen Gordon	Monique N. Dolecki
BD Public Relations	BD Investor Relations
858.352.8462	201.847.5378
gwen.gordon@bd.com	monique_dolecki@bd.com

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