BD Announces CE Mark of Portable, Rapid Point-of-Care Antigen Test to Detect SARS-CoV-2 in 15 minutes

SARS-CoV-2 Assay for BD Veritor™ Plus System to be available in Europe by end of October

FRANKLIN LAKES, N.J., Sept. 30, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced its rapid, point-of-care, SARS-CoV-2 antigen test for use on the BD Veritor™ Plus System has been CE marked to the IVD Directive (98/79/EC).

The new test delivers results in 15 minutes on an easy-to-use, portable instrument, which is a critical improvement in turnaround time for COVID-19 diagnostics, because it provides real-time results and enables decision-making while the patient is still onsite. The company expects commercial availability of this new assay at the end of October for countries in Europe that recognize the CE mark.

"Availability of the SARS-CoV-2 assay on the BD Veritor™ Plus System in Europe builds on our molecular test on the BD MAX™ System that has been available since March," said Roland Goette, president of BD EMEA Region. "The addition of a truly portable, point-of-care test that can deliver results while the patient waits will be welcomed by health care providers and patients alike to help protect against additional waves of COVID-19."

The test, which has been available in the United States since July through an Emergency Use Authorization by the U.S. Food and Drug Administration (FDA), uses the BD Veritor™ Plus System, which is already in use across Europe to test for conditions such as Group A Strep, influenza A+B and Respiratory Syncytial Virus (RSV). The BD Veritor™ Plus System, which is slightly larger than a mobile phone, offers an easy-to-use workflow that makes it an ideal solution for point-of-care settings. It also offers customers traceability and reporting capabilities through the optional BD Synapsys™ informatics solution.

The European Centre for Disease Prevention and Control (ECDC) recently released guidance that all patients with acute respiratory symptoms should be tested for both SARS-CoV-2 and influenza A+B in parallel during flu season[1]. The BD Veritor™ Plus System can test for both infections on the same platform.

BD is leveraging its global manufacturing network and scale to produce 8 million SARS-CoV-2 antigen tests per month by October and expects to produce 12 million tests per month by March 2021.

For Product Enquiries and How to Order:
All BD SARS-CoV-2 diagnostic products have regulatory authorizations in the markets where they are sold. European customers interested in BD diagnostic solutions for SARS-CoV-2 should visit bd.com/VeritorSystem-EU or contact BD's local customer service.

About the BD Veritor™ System for Rapid Detection of SARS-CoV-2 Assay
The BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 Assay has been CE marked to the IVD Directive (98/79/EC), but has not been cleared or approved by FDA. The test has been authorized by FDA under an EUA for use by authorized laboratories. The 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. The BD Veritor™ Plus System for Rapid Detection of SARS-CoV-2 Assay is not authorized for use by consumers or for at-home use.

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.

[1] https://www.ecdc.europa.eu/en/covid-19/surveillance/testing-strategies

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