BD Announces Emergency Use Authorization, CE Mark for Combination Molecular Diagnostic to Detect SARS-CoV-2, Influenza A+B in Single Test

New single test for the BD MAX™ System also shows ability to detect U.K., South African Variants

FRANKLIN LAKES, N.J., Feb. 12, 2021 /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) has granted Emergency Use Authorization (EUA) for a new molecular diagnostic test for both SARS-CoV-2 and Influenza A+B that can return results in two to three hours. The new test also has been CE marked to the IVD Directive (98/79/EC).

The new EUA includes updated information in the test's instructions for use that addresses variants of the SARS-COV-2 virus, including variants from the U.K. and South Africa. A computer analysis showed that 99.9% of the genetic sequences of the these variants are an identical match to at least one of the two molecular targets for the test[i]. This ability to detect these new variants also applies to the standalone SARS-CoV-2 test for the BD MAX™ System.

The BD® SARS-CoV-2/Flu assay is run on the BD MAX™ System and distinguishes between SARS-CoV-2 and Influenza A+B, providing a positive or negative result for each virus using a single specimen. The BD MAX™ System, a molecular diagnostic platform, is already in use at thousands of laboratories worldwide, and each unit is capable of analyzing hundreds of samples over a 24-hour period.

"The guidelines from the U.S. Centers for Disease Control and Prevention (CDC) recommend testing for both Flu and SARS-CoV-2 for all patients who are hospitalized and for patients who will not be hospitalized but for whom a positive result will change clinical management," said Dr. Charles K. Cooper, vice president of Medical and Scientific Affairs for Integrated Diagnostic Solutions at BD. "Since COVID-19 and Flu often present with similar symptoms, such as fever and dry cough, having a single specimen for accurate diagnosis speeds time to results and helps clinicians determine the right care more quickly to help prevent community transmission."

The BD® SARS-CoV-2/Flu for BD MAX™ System kits are now available for order inthe United States and Europe. The test is the latest addition to the company's comprehensive COVID-19 diagnostics response. In October 2020, BD announced the CE mark for the CerTest Biotec VIASURE SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit, which allows BD MAX™ System users to combine as a single test the VIASURE Flu A, Flu B & Respiratory Syncytial Virus (RSV) Real Time PCR Detection Kit and report concurrently.

"Our diagnostic solutions for COVID-19 and Flu will help inform timely diagnosis and, ultimately, may contribute to faster and clinically appropriate patient management and treatment," said Dave Hickey, president of Life Sciences for BD. "In addition, the new information provided on the test's ability to detect the U.K. and South African variants provides helpful guidance to health care practitioners as we look to identify and contain these new strains."

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories; this product has been authorized only for the detection of nucleic acid from SARS CoV-2, influenza A virus and influenza B virus and not for any other viruses or pathogens; and the emergency use of this product 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 declaration is terminated or authorization is revoked sooner.

U.S. customers interested in BD diagnostic solutions for COVID-19 should visitBD.com/covid19, or contact IDS.CovidTests@bd.com. Customers outside the United States should visit https://lp.bd.com/diagnosticisnow

About the BD MAX™ System and BD® SARS-CoV-2 Reagent Kits
The BD MAX™ System is a molecular diagnostic platform already in use at thousands of laboratories worldwide. The system is fully automated, reducing the opportunity for human error and increasing the speed to result, and can process 24 samples simultaneously, and up to several hundred samples per 24-hour period. Each unit is capable of performing assays for respiratory infections, enterics, hospital acquired infections, and sexually transmitted infections.

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 70,000 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 or connect with us on LinkedIn at www.linkedin.com/company/bd1/ and Twitter @BDandCo.

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[i] The N1 and N2 primers and probes utilized for SARS-CoV-2 detection within the BD SARS-CoV-2/Flu for BD MAX System are identical in sequence to those reported in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. An in silico comparison of the N1 and N2 primer sets was performed using all available high quality SARS-CoV-2 sequences submitted to the GISAID EpiCoV database6 by January 13, 2021 (n=329,434). Alignments against the N gene showed that both N1 and N2 primer/probe sets are a perfect match to 93.8% of sequences in the database, 96.8% of the sequences were a perfect match to the N1 primer set region, and 97.0% were a perfect match to the N2 primer set region. In total, 99.9% are a perfect match to either the N1 or the N2 region primer sets. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

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Additional assets available online: Photos (1)

https://news.bd.com/2021-02-12-BD-Announces-Emergency-Use-Authorization-CE-Mark-for-Combination-Molecular-Diagnostic-to-Detect-SARS-CoV-2-Influenza-A-B-in-Single-Test