BD Receives FDA Emergency Use Authorization for COVID-19, Influenza A/B, RSV Combination Test

Single Test on BD MAX™ Molecular Diagnostic System Identifies and Differentiates Multiple Respiratory Infectious Diseases

FRANKLIN LAKES, N.J., Feb. 8, 2023 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that it has received Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) for a new molecular diagnostic combination test for SARS-CoV-2, Influenza A + B and Respiratory Syncytial Virus (RSV) to help combat illness in the current and future respiratory virus seasons.

The test, for use on the BD MAX™ Molecular Diagnostic System, uses a single nasal swab or a single nasopharyngeal swab sample to identify and distinguish if a patient has COVID-19, the flu, RSV or some combination of the three, with results available in as little as two hours. The test helps eliminate the need for multiple tests or doctor visits and can help clinicians implement the right treatment plan quickly. The co-testing approach also helps to increase testing capacity during the busy flu/RSV season and speed time to diagnosis.

"While fears of a 'tripledemic' this respiratory season have largely diminished, accurately differentiating influenza and RSV from COVID-19 and providing appropriate treatment remains a challenge for our customers," said Nikos Pavlidis, vice president of Molecular Diagnostics at BD. "This diagnostic test provides the ability to identify multiple pathogens using a single sample and can quickly pinpoint the causative virus or viruses and enable clinicians to administer appropriate treatment early in the course of infection."

The BD MAX™ System is already in use at thousands of hospitals and laboratories worldwide, and each unit is capable of analyzing hundreds of samples over a 24-hour period. The Respiratory Viral Panel for BD MAX™ System is an RT- PCR assay that detects and differentiates the nucleic acid of SARS-CoV-2, flu A, flu B and RSV in as little as two hours for the first result, with the simplified and automated workflow of the BD MAX™ System.

Development of this combination test has been funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number 75A50121C00025.

The BD Respiratory Viral Panel assay for BD MAX™ System was CE marked under the IVD directive 98/79/EC in May of 2022. It is an important addition to the extensive number of assays available on the system across respiratory infections, sexually transmitted infections, gastrointestinal infections, women's health and health care associated infections. The BD MAX™ open system allows customers to leverage research use only (RUO) assays and user-defined protocols (UDP) to address emerging needs quickly.

About BD Respiratory Viral Panel for BD MAX™ System

- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under EUA for use by authorized laboratories.
- This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus, not for any other viruses or pathogens.
- 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is 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 77,000 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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