BD Receives 510(k) Clearance for COVID-19, Influenza A/B, RSV Molecular Combination Test

Single Test on BD MAX™ System Identifies and Differentiates Multiple Respiratory Infectious Diseases fromOne Sample

FRANKLIN LAKES, N.J., Aug. 1, 2023 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced U.S. Food and Drug Administration (FDA) 510(k) clearance for the BD Respiratory Viral Panel (RVP) for BD MAX™ System, a single molecular diagnostic combination test that identifies and distinguishes SARS-CoV-2, influenza A, influenza B, and Respiratory Syncytial Virus (RSV) in approximately two hours.

The test, which has been available in the United States since February through an Emergency Use Authorization (EUA) from FDA, uses a single nasal swab or a single nasopharyngeal swab sample to determine if a patient has COVID-19 or the flu or RSV. The BD RVP test helps eliminate the need for multiple individual tests or doctor visits and can help clinicians implement the right treatment plan quickly. The co-testing approach also helps increase testing capacity during the busy flu season and speed up the time for diagnosis.

"Last year, we experienced a threat of a 'tripledemic' with COVID, flu and RSV circulating simultaneously, and that threat remains for the coming respiratory season," said Nikos Pavlidis, vice president and general manager for Diagnostics at BD. "As patient symptoms and clinical presentation can be nearly identical, a combined testing panel is key to enabling clinicians to quickly and efficiently diagnose, differentiate and treat patients, and help manage the spread of the infections. The advanced robotic architecture of the BD MAX™ System automates manual, time-intensive processes, which has never been more important than in today's environment of staffing shortages and laboratory scientist burnout."

The BD MAX™ System, a molecular diagnostic platform, is already in use at thousands of hospitals and medium-throughput laboratories worldwide, and each unit is capable of analyzing hundreds of samples over a 24-hour period. The BD MAX™ RVP test is an RT-PCR assay that detects and differentiates the RNA of SARS-CoV-2, flu A, flu B and RSV in approximately two hours, with the simple and automated "walkaway workflow" of the BD MAX™ System that requires minimal human interaction.

The BD Respiratory Viral Panel for BD MAX™ System was CE marked under the IVD directive 98/79/EC in May of 2022, and now with the 510(k) clearance, BD will discontinue the BD RVP EUA version and replace it with the 510(k) version, with no gaps in availability of the test.

The respiratory viral panel is an important addition to the extensive number of assays available on the BD MAX™ System across respiratory infections, sexually transmitted infections, gastrointestinal infections, women's health and health care associated infections. The BD MAX™ open system also allows customers to leverage research use only (RUO) assays and user-defined protocols (UDP) to address emerging needs quickly.

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

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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