BD and CerTest Biotec Announce CE Mark for Molecular Test to Detect, Identify Certain SARS-CoV-2 Variants

VIASURE SARS-CoV-2 Variant Real Time PCR Detection Kit for BD MAX™ System Identifies and Differentiates Alpha (B.1.1.7), Beta (B.1.351) and Gamma (P.1) variants

ZARAGOZA, SPAIN and FRANKLIN LAKES, N.J. (Aug. 6, 2021) –BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and CerTest Biotec, today announced the CE mark for a molecular test that can detect and distinguish between the Alpha (B.1.1.7), Beta (B.1.351) and Gamma (P.1) SARS-CoV-2 variants.

VIASURE SARS-CoV-2 Variant Real Time PCR Detection Kit for BD MAX™ can be used as a combined test with VIASURE SARS-CoV-2 (N1+N2) Real Time PCR Detection Kit for BD MAX™, or as a reflex test to run variant identification on a SARS-CoV-2 positive sample.

“The SARS-CoV-2 virus has shown rapid mutation, and the ability to monitor variants that have the potential for increased severity or transmissibility is a critical tool in the fight against this virus,” said Fernand Goldblat, vice president and general manager of Integrated Diagnostic Solutions for BD in Europe, Middle East and Africa. “Along with sequencing, diagnostic screening assays are an important part of the strategy to identify, differentiate and contain variants of concern.”

Nelson Fernandes, managing director of CerTest BioTec, added “The VIASURE SARS-CoV-2 (N1+N2) Real Time Detection Kit for BD MAX™ and VIASURE SARS-CoV-2 Variant Real Time PCR Detection Kit for BD MAX™ are available with three alternatives for specimen collection: nasopharyngeal, oropharyngeal and saliva. Since the same single specimen can be used to run both assays to detect SARS-CoV-2 and test for its variants, the system provides a comprehensive solution for SARS-CoV-2 testing.”

The test snaps into the test-specific position on the BD MAX™ ExK™ TNA extraction strip, supplied by BD.

The BD MAX™ System, a molecular diagnostic platform, is widely used in hundreds of laboratories across Europe. Each unit can return results in two to three hours and is capable of analyzing hundreds of samples over a 24-hour period. The new variant detection assay is part of a robust COVID-19 testing solution on the BD MAX™ System, which also includes the ability to run asymptomatic individuals using BD SARS-CoV-2 Reagents for BD MAX™ System and test saliva samples with both BD and VIASURE kits.

VIASURE SARS-CoV-2 Variant Real Time PCR Detection Kit for the BD MAX™ System is sold through BD’s distribution network. To locate a BD representative or request information, visit www.bd.com or www.certest.es. VIASURE Kits are not available for sale in the United States. Product availability may vary in different countries; please contact your local BD representative.

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.

About CerTest
CerTest Biotec is a European company established in 2002 for the development and manufacturing of in vitro diagnostic medical devices. Today, CerTest is a global company structured around 5 business units offering one of the widest portfolios for human In Vitro Diagnostic. The company bases its future on a strong technical knowledge and expertise in the detection of human diseases. CerTest last generation laboratories, state-of-the-art technical equipment and skilled professionals are the keys for providing reliable solutions for the medical diagnostic professional.

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https://news.bd.com/2021-08-06-BD-and-CerTest-Biotec-Announce-CE-Mark-for-Molecular-Test-to-Detect,-Identify-Certain-SARS-CoV-2-Variants