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BD, CerTest Biotec Announce Emergency Use Authorization for Mpox Diagnostic Test

Assay for Research and Clinical Use Now Globally Available for the BD MAX™ System

FRANKLIN LAKES, N.J., Jan. 9, 2023 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and CerTest Biotec have announced Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for a molecular polymerase chain reaction (PCR) assay for Mpox virus detection.

The VIASURE Monkeypox Virus Real Time PCR Reagents for BD MAX System* is now available for BD MAX™ System users.

"The Mpox outbreak continues to be designated as a global health emergency — the World Health Organization's highest level of alert," said Nikos Pavlidis, vice president of Molecular Diagnostics at BD. "The large installed base of the BD MAX™ System in hospital labs provides broad access to testing for a wide range of infectious diseases, now including the mpox virus. EUA for the assay enables it to be used for timely diagnosis and may help avert further global spread of the disease."

The BD MAX™ System is a fully integrated, automated platform that performs nucleic acid extraction and real-time PCR providing results for up to 24 samples across multiple syndromes in less than three hours. BD offers an extensive menu of tests on the system covering health care associated infections, respiratory infections, sexually transmitted infections, gastrointestinal infections and women's health.

"We were able to quickly develop the VIASURE mpox molecular test by leveraging the BD MAX™ System's open system reagent suite," said Nelson Fernandes, managing director of CerTest Biotec. "The EUA for the assay enables use for clinical diagnosis of the disease, in addition to surveillance and the research and development of vaccines and treatments."

As with all CerTest assays, the VIASURE Monkeypox Virus PCR Detection assay for the BD MAX™ System is offered in a lyophilized format. Accordingly, the assay will come in a tube that snaps into the test-specific position on the BD MAX™ ExK™ TNA extraction strip, which is supplied by BD.

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.

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 seven business units offering one of the widest portfolios for human In Vitro Diagnostic and Pharma. 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.

*This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratories; this product has been authorized only for the detection of nucleic acid from monkeypox virus, 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 infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, 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.

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