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BD, CerTest Biotec Announce US Commercial Launch of Monkeypox Assay

Research Use Only (RUO) assay now globally available for BD MAX™ System

FRANKLIN LAKES, N.J., Sept. 26, 2022 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, and CerTest Biotec today announced their newly developed molecular polymerase chain reaction (PCR) assay for monkeypox virus is now commercially available globally, including in the United States, for research use only applications by laboratories.



The teams leveraged the BD MAX™ System open architecture reagent suite to develop the CerTest VIASURE Monkeypox molecular research use only assay. BD is working to submit a clinical test for monkeypox virus for emergency use authorization (EUA) as soon as possible, based on the guidance issued by the FDA on September 7.

"Even before the U.S. Department of Health and Human Services and Food and Drug Administration declared the ongoing monkeypox outbreak in the United States a public health emergency, we were working with CerTest to quickly develop a molecular assay to help better understand and track the disease," said Nikos Pavlidis, vice president of Molecular Diagnostics at BD. "Due to the COVID-19 pandemic, the installed base of our BD MAX™ System experienced explosive growth, providing greater access to this unique, open-architecture system that enables rapid response to emerging health threats like monkeypox."

The BD MAX™ System family 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.

"This new test boosts capacity for monkeypox research and surveillance of this global health emergency," said Nelson Fernandes, managing director of CerTest Biotec. "The value of the BD MAX™ open systems architecture and its ability to speed research and development continues to be critical."

As with all CerTest assays, the CerTest VIASURE Monkeypox virus PCR Detection RUO 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 75,000 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](https://twitter.com/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.

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