CerTest Biotec and BD Announce COVID-19 Diagnostic Test

CerTest Biotec launches CE Marked COVID-19 diagnostic test for the BD MAX™ System

ZARAGOZA, Spain and FRANKLIN LAKES, N.J., March 10, 2020 /PRNewswire/ -- CerTest Biotec, along with BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit adapted for the BD MAX™ System has been CE marked to the IVD Directive (98/79/CE). The molecular test for detection of COVID-19 is available to clinical laboratories in countries recognizing the CE mark.*

"The CerTest-developed kit will bring rapid COVID-19 diagnostic capabilities to many laboratories acrossEurope which desperately need the ability to quickly identify COVID-19 patients so that proper protocols for infection prevention can be instituted," said Nelson Fernandes, managing director of CerTest BioTec.

The test is a real-time reverse transcriptase polymerase chain reaction (PCR) assay for use on the fully automated BD MAX™ System. It detects SARS-CoV-2 in clinical samples by amplification of a fragment of the *S* gene of the virus. RNA is extracted, amplified using RT-PCR and detected using fluorescent reporter dye probes specific to SARS-CoV-2. This VIASURE kit contains in each well all the components necessary for real-time PCR assay in a stabilized format, as well as an internal control to monitor PCR inhibition.

As with all CerTest tests, the VIASURE *SARS-CoV-2* Real Time PCR Detection Kit for the BD MAX™ System is offered in a lyophilized format. Accordingly, the test comes in a tube that snaps into the test-specific position on the BD MAX™ ExK™ TNA extraction strip, which is supplied by BD.

"Together with CerTest, we can offer our customers inEurope a complete solution for COVID-19 diagnostics. Leveraging the significant install-base of the BD MAX System in Europe and other countries, we hope this kit will greatly enhance capacity for COVID-19 testing, thereby helping clinicians rapidly diagnose patients and ultimately prevent the spread of COVID-19," said Nikos Pavlidis, vice president of molecular diagnostics and women's health and cancer for BD.

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.

VIASURE *SARS-CoV-2* Real Time PCR Detection Kit for the BD MAX™ System is sold through BD's network and it is not available for sale in the United States. To locate an authorized BD representative or request information, visit:www.bd.com or www.certest.es

*VIASURE *SARS-CoV-2* Real Time PCR Detection Kit is not available for sale in the U.S. Product availability may differ in different countries, please contact your local BD representative.

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.

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 65,000 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.

*BD and BD MAX trademarks are property of BD (Becton, Dickinson and Company).
*__VIASURE__ is a registered trademark of __CerTest Biotec, S.L.__

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