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BD Expands Fully Automated High-Throughput Molecular Diagnostic Platform for Core Labs

BD COR™ MX for Infectious Disease Testing Receives CE Mark and is Final Instrument Introduced on BD COR™ System

FRANKLIN LAKES, N.J., Dec. 17, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced it has expanded the BD COR™ System to include a new MX instrument for high-throughput molecular testing for infectious diseases. The new instrument and its first test for sexually transmitted infections have been CE marked to the IVD directive 98/79/EC.

The new MX instrument is the final piece of the BD COR™ System, which also includes a PX instrument that can prepare diagnostic samples by automating appropriate pre-analytical processing steps and a GX instrument that can leverage the BD Onclarity™ HPV Assay with extended genotyping to screen for HPV infections.

The MX instrument is built off the proven BD MAX™ System molecular PCR (polymerase chain reaction) technology platform, a medium-throughput system typically found in hospital labs, and BD intends to leverage the BD MAX™ System menu of infectious disease tests to create assays that can be performed in high-throughput central reference labs on the BD COR™ System.

The first test available on the MX instrument is the BD CTGCTV2 for BD COR™ System, which is designed to use a single test to detect the three most prevalent non-viral sexually transmitted infections — Chlamydia trachomatis (CT), Neisseria gonorrhoeae (GC) and Trichomonas vaginalis (TV).

In addition to CE mark, the BD CTGCTV2 for BD COR™ System assay was also included on the Australian Register for Therapeutic Goods (ARTG) following review by Australia's Medical Devices Regulator, the Therapeutic Goods Administration (TGA).

"The BD COR™ PX/GX system is already used at laboratories across Europe and in Israel, helping to improve diagnostics and positively impact patient care," said Nikos Pavlidis, vice president of Molecular Diagnostics at BD. "The availability of the MX instrument expands the

use of the platform and automates testing for an expanding list of high-demand, essential assays for women's health and STI testing using multiplex PCR assay design, starting with BD's CTGCTV2 test."

The BD COR™ MX/PX System allows 1,700 specimens to be loaded, with onboard capacity for reagents and samples that provide more than six hours of unimpeded system processing and up to 1,000 sample results in 24 hours, eliminating multiple technologist interactions currently required per shift.

The BD COR™ System integrates and automates the complete molecular laboratory workflow from sample processing to diagnostic test result. The BD COR™ PX instrument integrates and automates the sample workflow for diagnostic specimens and assays, preparing the samples by performing the appropriate pre-analytical processing steps and automatically delivering the samples to the MX or GX instruments for molecular analysis. The MX instrument will perform the analytical steps of the BD CTGCTV2 molecular assay, including extraction, amplification and detection. Additional assays for the MX module are in development. The GX module is exclusively used for HPV testing. The BD COR™ PX/GX System has been in use in Europe since 2019.

The system is modular and scalable, and designed to address multiple needs within laboratories for expanding molecular testing and increasing test volumes. The system is particularly well-suited to laboratories requiring high throughput for sample results and high capacity, minimizing staff interactions. The system enables the processing of samples directly from liquid-based cytology vials and other BD sample collection devices, and the creation of molecular aliquot tubes and assay testing — automating labor-intensive and error-prone manual processes.

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.

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