BD Launches Fully Automated High-Throughput Molecular Diagnostic Platform for U.S. Laboratories

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BD COR™ PX/GX System integrates robotics and sample management software algorithms to automate the complete molecular laboratory workflow from sample processing to diagnostic test result

FRANKLIN LAKES, N.J., Aug. 25, 2021 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that it has launched a new, fully automated high-throughput diagnostic system using robotics and sample management software algorithms to set a new standard in automation for infectious disease molecular testing in core laboratories and other centralized laboratories in the United States.

The launch will make the BD Onclarity™ HPV Assay with extended genotyping for the BD COR™ System available to the high-throughput labs that process the majority of cervical cancer screening specimens in the U.S. Persistent infection with human papillomavirus (HPV) is one of the primary causes of cervical cancer[i].

The BD COR™ System integrates and automates the complete molecular laboratory workflow from sample processing to diagnostic test result. The system is modular and scalable, and designed to address multiple needs within laboratories for expanding molecular testing and increasing test volumes. It has onboard capacity for reagents and samples that provide six to eight hours of unimpeded system processing, eliminating multiple technologist interactions currently required per shift.

"Testing labs may report results for hundreds of thousands of women each year, and automation can help labs enhance and standardize the quality of the results," said Brooke Story, president of Integrated Diagnostic Solutions for BD. "We watched how specimens make their way through labs and saw how much handling was needed both before and after the test, and we knew our expertise in robotics could help. We also heard firsthand from customers that laboratory instruments have begun to manage them and their time instead of helping them improve efficiency of the lab. The fully automated BD COR™ System addresses these needs and gives control back to medical laboratory scientists."

The BD COR™ PX/GX System has been in use in Europe since 2019 through a CE-mark in compliance with the European *in vitro* diagnostic Medical Devices Directive 98/79/EC and is now approved within the United States with the U.S. Food and Drug Administration (FDA). The new system is well suited to address centralized labs needs for high-volume processing and increases in efficiency.

"The U.S. launch of the BD COR™ System is an important milestone on our molecular diagnostics roadmap, allowing us to offer sample processing automation and high-throughput molecular testing to our largest laboratory customers," said Dave Hickey, president of Life Sciences for BD. "Along with our BD MAX™ System, BD can now offer our U.S. customers a full spectrum of molecular testing and informatics solutions, from acute hospital settings to centralized laboratories."

The BD COR™ System will be initially available with the BD Onclarity™ HPV Assay with extended genotyping, a qualitative *in vitro* test for the detection of HPV in cervical specimens collected by a clinician and placed in a BD SurePath™ vial. The BD Onclarity™ HPV Assay offers extended genotyping capabilities by detecting 14 high-risk (HR) HPV types in a single analysis. The BD Onclarity™ HPV Assay is the only FDA-approved HPV test that can identify and report genotypes beyond 16, 18 and 45, to include individual results for 31, 51, 52 and grouped results for 33/58, 35/39/68, and 56/59/66. The BD Onclarity™ HPV Assay can be used as a component of routine cervical cancer screening programs, with indications for HPV primary screening, triage for ASC-US cytology and co-testing with cytology.

The system enables the processing of samples directly from liquid-based cytology vials, the creation of molecular aliquot tubes and assay testing — automating labor-intensive and error-prone manual processes.

With this approval, the BD COR™ System offers two instruments. The BD COR™ PX instrument integrates and automates the sample workflow for diagnostic specimens and assays and the BD COR™ GX instrument automates the BD Onclarity™ HPV Assay with extended genotyping, specifically. The PX instrument will prepare the samples by performing the appropriate pre-analytical processing steps and automatically deliver the samples to the GX instrument for analysis. The GX instrument will perform the analytical steps of the BD Onclarity™ HPV Assay, including extraction, amplification and detection.

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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[i] Walboomers J, Jacobs M, Manos M et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. *J Pathol*. 1999;189(1):12-19.

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