BD Receives FDA 510(k) Clearance for First-of-Its-Kind High-Throughput Diagnostic Test for Infectious Vaginitis

BD Vaginal Panel on BD COR™ System Tests for Multiple Common Types of Vaginitis Using Only One Swab, One Test

FRANKLIN LAKES, N.J., March 16, 2023 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the BD Vaginal Panel on the BD COR™ System, a comprehensive diagnostic test that directly detects the three most common infectious causes of vaginitis using BD's high-throughput molecular diagnostic platform for large laboratories.

Originally granted marketing authorization for the BD MAX™ System in 2016, the BD Vaginal Panel is the first microbiome-based polymerase chain reaction (PCR) assay that uses a single swab and test to simultaneously detect organisms associated with *bacterial vaginosis* (BV), *vulvovaginal candidiasis* (VVC) and *Trichomonas vaginalis* (TV), and reports a clear positive or negative result for each condition separately. This 510(k) clearance for the BD Vaginal Panel on the BD COR™ System is the first high-throughput version of the test. Accurate diagnosis of BV, VVC and TV is critical to ensuring appropriate treatment regimens and decreasing the risk of associated complications and resistance to treatment. Using a single test can also help reduce the need for repeat testing unnecessary use of treatments and lower the risk of contracting STIs.

"Most women have a vaginal infection during their lifetime and millions of them receive inadequate treatment," said Nikos Pavlidis, vice president of Diagnostics for BD. "A recent study showed that four out of 10 women didn't receive the appropriate diagnosis and treatment for their vaginitis symptoms after an initial physician visit, which led to four out of 10 women having to schedule a new appointment because of persistent symptoms. The BD Vaginal Panel can help end the cycle of repeat visits, misdiagnosis and ineffective treatment for the millions of women suffering from vaginitis."

If a test is positive for VVC (commonly referred to as a "yeast infection"), the BD Vaginal Panel is the only FDA-cleared Nucleic Acid Amplification Test (NAAT) that provides separate results for *C. glabrata* and *C. krusei* — two Candida species that are known to carry resistance to traditional antimicrobials — to ensure proper treatments are prescribed.

The availability of the BD Vaginal Panel on the automated BD COR™ System in the U.S. reflects BD's commitment to expand the menu of available assays for women's health and other infectious diseases.

The BD Vaginal Panel is the third assay available for use on the BD COR™ System in the U.S. The first being the BD Onclarity™ HPV assay (the only FDA-approved HPV test with extended genotyping that can individually identify and report HPV genotypes including HPV 16, 18 and 31, which have the highest contribution to cervical precancer and cancer). The second was the BD CTGCTV2 molecular assay, a single test that detects from one sample the three most prevalent non-viral sexually transmitted infections (STIs) — *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC) and *Trichomonas vaginalis* (TV). These STIs can also have overlapping symptoms making one test to identify all three important for patient care. With the clearance of BD Vaginal Panel on the BD COR™ System, labs can now offer physicians both BD Vaginal Panel and BD CTGCTV2 testing from one swab and one patient collection.

The BD COR™ System is the only high-throughput, fully integrated preanalytical and analytical system on the market, providing access to critical women's health and STI testing by enhancing both laboratory operations and patient management with advanced molecular diagnostic capabilities. The BD COR™ System allows 1,700 specimens to be loaded at a time, with onboard capacity for reagents and samples that provide more than eight hours of unimpeded system processing. The system is capable of delivering nearly 2,000 sample results in 24 hours, eliminating multiple manual interactions per shift that were traditionally required.

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.

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