BD MAX™ Vaginal Panel Receives FDA Market Authorization to Detect Most Common Causes of Vaginal Infections

Expands Reproductive and Sexually Transmitted Infections Portfolio with First Test Using Microbiome-based Algorithm for Bacterial Vaginosis Detection

FRANKLIN LAKES, N.J., Oct. 31, 2016 - BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced U.S. Food and Drug Administration (FDA) market authorization for a first-of-its-kind molecular test to detect the most common causes for vaginitis.

Laboratories and clinicians will now have the ability to use a single test to detect microorganisms responsible for Bacterial Vaginosis (BV), Trichomoniasis (TV) and Vulvovaginal Candidiasis (VVC), also known as a yeast infection, which are the most common infectious causes of vaginitis.[1,2,3] The new in vitro diagnostic (IVD) assay is the first multiplex, real-time polymerase chain reaction (PCR) assay authorized by FDA for the diagnosis of both vaginitis and vaginosis in women that exhibit symptoms of vaginal infections. BV diagnosis is challenging, as it is caused by bacterial imbalances in the vagina. To address this challenge, the BD MAX Vaginal Panel has a unique algorithm that determines the ratio of healthy versus unhealthy bacteria, improving BV diagnosis."

Vaginitis is highly prevalent, with large gaps in clinical management that improved diagnostics could help address," said Dr. Mark Martens, MD, FACOG, Chair, Dept. of Obstetrics and Gynecology Jersey Shore University Medical Center, part of the Hackensack Meridian Health. "Traditional methods used to detect vaginitis can be challenging due to the presence of many interfering substances in specimens, the large number of mixed infections, and the subjectivity of these methods. A multiplex microbiome-based real-time PCR assay has the potential to help clinicians improve patient management and help laboratories increase workflow efficiency."

Vaginal infections result in more than 10 million office visits each year in the US, with up to 75 percent of women experiencing at least one case of Vaginitis (VVC, TV) or Vaginosis (BV) in their lifetime.[1,2,7] As many as half the women who suffer from vaginal infections incorrectly assume it is a simple case of a yeast infection and attempt to self-treat with over-the-counter options before consulting a clinician.5 Additionally, inaccurate and inconsistent diagnosis of these conditions can leave up to 30 percent of women seeking treatment with the wrong diagnosis. This can lead to continued symptoms, repeat visits, inappropriate or missed treatment and unnecessary associated health care system costs.[2] In addition to irritating symptoms that disrupt quality of life, these infections can have serious risks, including pre-term or low birth-weight babies, late term miscarriage, and increased risk of STI transmission or acquisition such as HIV and Pelvic Inflammatory Disease (PID).[3,4,6,7]

"With the FDA market authorization of the BD MAX Vaginal and CT/GC/TV Panels, BD is now able to offer clinical laboratories automated PCR tests to aid in the detection and diagnosis of important reproductive and sexually transmitted infections, " said Doug White, vice president and general manager of Molecular Diagnostics and Women's Health for BD. "The US launch of the BD Max Vaginal Panel signifies BD's continued commitment to elevating the standard of care for women's health and sexually transmitted infections."

FDA market authorization was granted under a *de novo* petition, which is a regulatory pathway for novel products that are first-of-a-kind. This represents the second addition to the BD Reproductive and Sexually Transmitted Infections portfolio within the last quarter. In September, BD obtained FDA clearance for the BD MAX CT/GC/TV assay, which provides laboratories the ability to detect Chlamydia, Gonorrhea and Trichomoniasis from a single specimen with one test.

The BD MAX System offers an efficient path to results by combining and automating real-time PCR extraction, amplification and detection into a single platform capable of running both FDA-cleared and open-system assays. For more information on BD Molecular Diagnostics, please visit: http://moleculardiagnostics.bd.com

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 healthcare by developing innovative technology, services and solutions that help advance both

clinical therapy for patients and clinical process for healthcare 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 healthcare. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com

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Troy Kirkpatrick

858 617 2361
Email Troy

Monique N. Dolecki

201 847 5378
Email

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