BD Expands Portfolio of Reproductive and Sexually Transmitted Infections Solutions

BD Obtains FDA Clearance for the BD MAX CT/GC/TV Assay on the BD MAX™ System

FRANKLIN LAKES, N.J., Sept. 13, 2016 – BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that it obtained U.S. Food and Drug Administration (FDA) clearance for the BD MAX™ CT/GC/TV assay, which is also CE marked in Europe, Canada and Australia and launched there in spring of 2015.

The BD MAX CT/GC/TV assay provides health care providers the ability to detect for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC) and *Trichomonas vaginalis* (TV) from a single specimen in just one test.

CT, GC and TV are among the most prevalent sexually transmitted infections (STIs). Reports from the U.S. Centers for Disease Control and Prevention (CDC) estimate 2.86 million new chlamydial infections and 820,000 gonorrheal infections each year.[1,2] Trichomoniasis, a much neglected STI until recently, ranks third among all common STIs after HPV and Chlamydia, with nearly an estimated 1.1 million new infections each year in the U.S.[3] Although most of these infections are asymptomatic, they can have serious consequences if left unaddressed, such as pelvic inflammatory disease, ectopic pregnancies, infertility, pre-term or low birth-weight babies and increased risk of STI transmission or infection (including HIV) in males and females. Trichomonas can be difficult to diagnose with manual methods, and despite its high prevalence in many populations, awareness remains low. The CDC 2015 guidance recommends the use of highly sensitive and specific tests, such as nucleic acid amplification test (NAAT) technology, as the recommended test for Trichomonas detection.

The BD MAX CT/GC/TV assay allows health care providers to detect these common and addressable STIs from a single specimen in just one test. Specimen collection options are flexible, allowing for male or female urines, self-collected vaginal swabs and clinician collected endocervical swabs. Once samples are loaded onto the BD MAX System, results will be ready in less than three hours, and all reagents are ready-to-use and can be stored at room temperature.

"The FDA clearance and launch of the BD MAX CT/GC/TV assay in the U.S. brings a “one-test” approach to detect for three sexually transmitted infections,” said Doug White, vice president and general manager of Molecular Diagnostics and Women’s Health for BD. “This represents just one of several expansions to the BD MAX portfolio in 2016, as BD continues to expand the capabilities of the platform with a focus on comprehensive syndromic solutions with an emphasis on improving clinical outcomes and laboratory efficiency.”

The BD MAX System offers an efficient path to accurate, reproducible, clinically actionable results — often in less time than conventional methods — through automated nucleic acid extraction, real-time PCR amplification and detection. System flexibility and standardization allow health care providers to address a wide breadth of testing needs. The BD MAX System is part of the Diagnostic Systems portfolio of molecular solutions from BD. 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

For more information on BD, please visit bd.com.

Troy Kirkpatrick

858 617 2361
Email Troy

Monique N. Dolecki

201 847 5378
Email

---

https://news.bd.com/2016-09-13-BD-Expands-Portfolio-of-Reproductive-and-Sexually-Transmitted-Infections-Solutions