New Chlamydia and Gonorrhea Assays on the BD Viper(TM) LT System Receive FDA 510k Clearance

Assays bring an innovative solution to microbiology and molecular labs

PR Newswire

BALTIMORE, July 28, 2014 /PRNewswire/ -- BD Diagnostics, a segment of BD (Becton, Dickinson and Company), (NYSE: BDX) announced today it has received 510(k) clearance from the U.S. Food and Drug Administration for the BD ProbeTec(TM) *Chlamydia trachomatis* (CT) Q(x) Amplified DNA Assay and the BD ProbeTec(TM) *Neisseria gonorrhoeae* (GC) Q(x) Amplified DNA Assay on the BD Viper(TM) LT System.

The BD Viper LT System is a bench-top molecular platform that automates sample liquid handling, nucleic acid extraction, amplification, detection and result reporting without any user intervention. The BD Viper LT System is designed to manage primary sample tubes with pierceable caps and ready to use reagents. This "load and go" reagent and sample capability along with the easy to use design of the BD Viper LT System delivers true walkaway time to the laboratorian and maximizes productivity.

The combination of the BD Viper LT System and the BD ProbeTec *Chlamydia trachomatis* (CT) Q(x) and the BD ProbeTec *Neisseria gonorrhoeae* (GC) Q(x) Amplified DNA Assays brings an innovative solution to microbiology and molecular labs that increases flexibility and improves laboratory efficiency. Improved efficiency provides more timely diagnostic information to clinicians for more effective patient management of two of the most common sexually transmitted bacterial infections - Chlamydia and gonorrhea. If left untreated, these infections can lead to pelvic inflammatory disease, infertility, ectopic pregnancy and chronic pelvic pain.(1)

"The BD Viper LT System and BD ProbeTec Q(x) Amplified DNA Assays are designed to meet the needs of today's clinical laboratories, providing automated, accurate, and reliable detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, for all genital sample types," said Doug White, Vice President, General Manager, Molecular Diagnostics & Women's Health, BD Diagnostics - Diagnostic Systems.

The World Health Organization estimates that 105.7 million new cases of Chlamydia and 106.1 million new cases of gonorrhea are diagnosed each year.(2) Chlamydia is the most frequently reported sexually transmitted bacterial infection in the United States. Based on CDC estimates, nearly 2.86 million people in the United States are infected with Chlamydia.(3)The Centers for Disease Control and Prevention estimates that more than 820,000 persons contract new gonorrheal infections each year in the United States.(3)

The new BD Viper LT System is designed to provide low and mid-volume laboratories with highly reliable detection(4) of Chlamydia and gonorrhea from all genital sample types on an automated and easy to use platform. When tested with the BD Viper LT System, the BD ProbeTec Q(x) Assays use BD proprietary ferric oxide, FOX(TM) Extraction, and Strand Displacement Amplification technologies for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA. The tests are performed on clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens (in a clinical setting), male and female urine specimens (neat and UPT) and gynecological specimens collected in BD SurePath(TM) Preservative Fluid or PreservCyt(TM) Solution. These assays are indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial and gonococcal urogenital disease.

About BD

BD is a leading medical technology company that partners with customers and stakeholders to address many of the world's most pressing and evolving health needs. Our innovative solutions are focused on improving drug delivery, enhancing the diagnosis of infectious diseases and cancers, supporting the management of diabetes and advancing cellular research. We are nearly 30,000 associates in 50 countries who strive to fulfill our purpose of "Helping all people live healthy lives" by advancing the quality, accessibility, safety and affordability of healthcare around the world. For more information, please visit www.bd.com.

[1] U.S. Preventive Services Task Force. (2001). Screening for chlamydial infection: recommendations and rationale. *American Journal of Preventive Medicine 20*(Suppl. 3), 90-94.

[2] World Health Organization. (2012). Global prevalence and incidence of selected curable sexually transmitted infections overview and estimates. Retrieved May 22, 2014 from http://apps.who.int/iris/bitstream/10665/75181/1/9789241503839_eng.pdf?ua=1

[3] Centers for Disease Control and Prevention (2013). CDC Fact Sheet: Incidence, Prevalence, and Cost of Sexually Transmitted Infections in the United States. Retrieved May 22, 2014 from http://www.cdc.gov/std/stats/STI-Estimates-Fact-Sheet-Feb-2013.pdf.

[4] Package Inserts: ProbeTec(TM) Chlamydia trachomatis (CT) Q(x) Amplified DNA Assay, ProbeTec(TM) Neisseria gonorrhoeae (GC) Q(x) Amplified DNA Assay. Retrieved June 04, 2014 from http://moleculardiagnostics.bd.com/product/viperlt/

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