New Assay for Neisseria gonorrhoeae (GC) Testing Incorporates Real-Time PCR Technology

BD MAX™ GC rt PCR Assay Receives CE Mark

BALTIMORE, MD, April 09, 2014 – BD Diagnostics, a segment of BD (Becton, Dickinson and Company), a leading global medical technology company, announced today the CE mark and launch of the BD MAX™ GC rt PCR assay in Europe. The BD MAX GC rt PCR assay is an ***in vitro*** diagnostic test intended for testing ***Neisseria gonorrhoeae*** (GC) positive results from the BD ProbeTec™ GC Qx Amplified DNA Assay performed on the BD Viper™ System with XTR™ Technology. The assay may be used for detection of GC DNA in residual male or female urine specimens, or residual endocervical, vaginal or male urethral swab specimens that have tested positive for GC using the BD ProbeTec GC Qx Amplified DNA Assay.

“This new assay marks another pivotal step toward increasing diagnostic accuracy and fulfilling our efforts to prevent the spread of infectious disease,” said Alberto Mas, President, BD Diagnostics – Diagnostic Systems. “This new assay is a great addition to our existing solutions and provides an important tool to laboratorians and clinicians to improve the management of sexually transmitted infections.”

Neisseria gonorrhoeae is one of the most prevalent sexually transmitted bacterial infections. Worldwide, more than 106 million cases are estimated to occur annually.[i] In Europe, following chlamydial infections, gonorrhoeaeis the second most common sexually transmitted infection. In 2011, 39,179 gonorrhoeaecases were reported from the majority of EU Member States and the rate was estimated to be 12.6 per 100,000 populations.[ii] Men were reported to be infected three times more often than women, with an overall rate for men of 21.2 per 100,000 and 7.6 per 100,000 in women. Forty-two percent of cases were among young adults. Despite the increase of reported numbers, the incidence in several countries is underestimated because of suboptimal diagnostics, case reporting and surveillance.

Compared to culture, nucleic acid amplification test (NAAT) assays are more sensitive, allowing testing of a wide range of specimen types and can support extended transportation and storage conditions.[iii] NAATs have exhibited high sensitivity in both symptomatic and asymptomatic patient populationsand equivalent sensitivity demonstrated between male urine and urethral swab specimens, and between clinician-obtained and patient-collected vaginal swabs.[iii] The BD MAX GC rt PCR assay is designed for use with specimens that have tested positive for GC on the BD Viper System. Automated DNA extraction, amplification and detection maximize laboratory efficiency and quality of results. High specificity helps to improve the positive predictive value in low prevalence populations as well as meeting regional guidelines.

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

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[i] http://apps.who.int/iris/bitstream/10665/85376/1/9789241505895_eng.pdf

[ii] European Centre for Disease Prevention and Control. Sexually transmitted infections in Europe 2011. Stockholm: ECDC; 2013.

[iii] IUSTI / WHO. (2012). 2012 European Guideline on the Diagnosis and Treatment of Gonorrhoeaein Adults

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