Healthcare Providers Can Diagnose Group A Strep in Minutes with New Test

BD Veritor(TM) System for Rapid Detection of Group A Strep Receives 510(k) Clearance and CLIA Waiver

PR Newswire

FRANKLIN LAKES, N.J., Feb. 25, 2014 /PRNewswire/ -- BD Diagnostics, a segment of BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, announced today that it received 510(k) clearance and Clinical Laboratory Improvement Amendments (CLIA) Waiver from the U.S. Food and Drug Administration (FDA) for the BD Veritor(TM) System for Rapid Detection of Group A Strep. This is the first commercially available rapid Group A Strep test system that incorporates a digital result to receive CLIA Waiver. The new assay is cleared for use in hospitals, outpatient clinics and other patient-care settings.

Group A Strep is the most common bacterial cause of pharyngitis. More accurately determining the etiology of pharyngitis can help providers make more appropriate antibiotic treatment decisions.

"The BD Veritor System for Rapid Detection of Group A Strep has demonstrated proven performance as compared to bacterial culture methods, while delivering an objective test result in about eight minutes from specimen processing to results," said Alberto Mas, President, BD Diagnostics - Diagnostic Systems. "Rapid detection enables clinicians to initiate treatment immediately in cases of Group A Strep."

When used in conjunction with the BD Veritor System Reader, the Group A Strep test utilizes Advanced Nano-particle and Adaptive Read technologies to obtain an accurate result while providing objective results on a hand held reader with an easy-to-read digital display. This digital immunoassay (DIA) for Rapid Detection of Group A Strep offers healthcare professionals a new option for Group A Strep testing versus current visual read CLIA-waived assays.

The BD Veritor System for Rapid Detection of Group A Strep joins the previously FDA-cleared and CLIA-waived BD Veritor(TM) System for Rapid Detection of Flu A+B and FDA-cleared BD Veritor(TM) System for Rapid Detection of Respiratory Syncytial Virus. These assays work in conjunction with the BD Veritor System Reader. BD plans to continue to launch additional assays on this new platform.

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* .

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