

New RSV Test Provides Healthcare Providers Objective Results in Minutes

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

PR Newswire

FRANKLIN LAKES, N.J., March 19, 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 nasopharyngeal swab specimens on the [BD Veritor\(TM\) System for Rapid Detection of Respiratory Syncytial Virus \(RSV\)](#). This is the first commercially available rapid CLIA-waived RSV test system that incorporates a digital result. The new assay is cleared for use in physician offices, hospitals, and other patient-care settings.

According to the U.S. Centers for Disease Control and Prevention, RSV is the most common cause of pneumonia and bronchiolitis in the United States in children under one year of age, leading to approximately 75,000 to 125,000 hospitalizations annually. Most children hospitalized for RSV infection are under six months of age.⁽ⁱ⁾ Almost all children have been infected with the virus by the time they are two years old.

"Early and reliable detection of RSV is critical among high-risk populations to treat and prevent the spread of this contagious virus and hospitalizations," said Alberto Mas, President, BD Diagnostics - Diagnostic Systems. "The CLIA-waived BD Veritor System for Rapid Detection of RSV has demonstrated good performance when compared to PCR, the highest reference lab based standard, while providing an objective test result in only 10 minutes."

When used in conjunction with the BD Veritor System Reader, the RSV 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. The Advanced Particle Technology along with improved chemistries helps improve the sensitivity of the test while the Adaptive Read Technology helps reduce false-positive results by examining and compensating for many of the effects of non-specific binding which improves specificity. This digital immunoassay (DIA) for Rapid Detection of RSV offers healthcare professionals a new option for RSV testing versus current visual read CLIA-waived assays.

The CLIA-waived BD Veritor System for Rapid Detection of RSV joins the previously FDA-cleared and CLIA-waived BD Veritor System for Rapid Detection of Flu A+B and Group A Strep. The BD Veritor System for Rapid Detection of RSV is the third CLIA-waived offering and BD plans to launch additional FDA-cleared assays on this 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.

(i) <http://www.cdc.gov/rsv>

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