BD Newsroom

BD Veritor(TM) System Meets FDA's New Performance Requirements for Rapid Influenza Antigen Detection Tests

Health care providers and laboratories may be better equipped to test and treat patients during the flu season

PR Newswire

FRANKLIN LAKES, N.J., Feb. 22, 2017 /PRNewswire/ -- Effective Feb. 13, 2017, the Food and Drug Administration (FDA) has reclassified antigen based rapid influenza virus antigen detection systems (RIDTs) intended to detect influenza virus directly from clinical specimens from Class I devices into Class II devices subject to special controls.

BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that its BD Veritor(TM) System Flu A+B, a digital immunoassay for the rapid detection of influenza, meets the new FDA performance requirements.(i)

Prompting these changes was the inadequate performance of some point-of-care flu tests available during the 2009 flu pandemic, which raised concerns regarding the accuracy of detecting influenza in patients. With the new FDA requirements,(i)rapid flu tests, which are used by health care providers and laboratory personnel, must now attain a higher level of performance.

"The change to the new performance standards may help improve the overall quality of testing for influenza," said Dr. Charles Cooper, vice president of medical affairs at BD. "This agency's decision has the potential to improve patient outcomes -- ensuring that the tools health care providers use for diagnosing influenza meet new, higher standards for accuracy. As we know, an accurate diagnosis helps to determine appropriate use of antiviral medications, while at the same time reducing inappropriate over-prescription of antibiotics, which can only help in the fight against antimicrobial resistance."

As part of the new reclassification of rapid flu tests from Class I to Class II, the FDA is raising the tests to higher performance standards. This change will help to ensure that health care providers and allied health professionals who use rapid flu tests to detect influenza viruses will have quick access to more accurate information.

In recognizing the need to improve diagnostics, BD developed and launched the BD Veritor System for Rapid Detection of Flu A+B. This was the first Clinical Laboratory Improvement Amendments (CLIA)-waived flu test that provides objective results on an easy-to-read digital display. The now Class II BD Veritor System Flu A+B test became available in 2011, and is the same test used on the new BD Veritor Plus System, a next generation wireless rapid diagnostic system for detection of influenza A and B, respiratory syncytial virus (RSV) and group A strep.

More information about the FDA reclassification and the BD Veritor Plus System are available at http://www.bd.com/ds/VeritorSystem or through BD Technical Service at 800.638.8663.

About BD
BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. BD leads in patient and health care worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance medical research and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, and support the management of diabetes. The company partners with organizations around the world to address some of the most challenging global health issues. BD has more than 40,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety and expand access to health. For more information on BD, please visit bd.com.

(i)Microbiology Devices; Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly With Clinical Specimens, 82 Fed. Reg. 3609 (January 12, 2017)
https://www.federalregister.gov/documents/2017/01/12/2017-00199/microbiology-devices-reclassification-of-

influenza-virus-antigen-detection-test-systems-intended-for.

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