BD Supports the FDA's Proposal to Reclassify Rapid Influenza Tests

PR Newswire

BD, a leading global medical technology company, supports the U.S. Food and Drug Administration's (FDA's) proposed reclassification of rapid influenza detection tests. A hearing, held on June 13th by FDA's CDRH Microbiology Devices Advisory Committee Meeting, examined the FDA's proposal to reclassify rapid influenza detection tests (RIDTs) currently regulated as Class I devices, into Class II devices.

The recent 2009 flu pandemic has emphasized the poor performance of point-of-care flu tests available at the time. The new performance standards will provide healthcare providers with criteria for evaluating the tests that they use. The proposal would increase performance requirements for RIDTs to attain at least a sensitivity of 90 percent for influenza A and 80 percent for influenza B versus viral culture and/or 80 percent versus polymerase chain reaction (PCR) methods. If these minimum clinical performance criteria are not met, marketed devices will need to be withdrawn from the market one year after the rule is finalized. This proposal culminates years of publications showing that many of the visual read RIDTs had poor sensitivity when compared to viral culture and to reverse transcription PCR methods.

"This proposal is a step in the right direction as physicians and hospitals routinely rely on rapid diagnostic influenza tests to help manage patients that are suspected of having influenza," said Tom Polen, President, BD Diagnostics – Diagnostic Systems. "Raising the standards of rapid influenza tests will provide healthcare providers the right information to guide patient diagnosis and treatment without requiring repeat testing."

BD pioneered the development of a higher performing test platform two years ago with the launch of the BD Veritor™ System Flu A+B test. BD recognized the need for an improved test early and developed and launched the first CLIA-waived flu test referenced to PCR that provides objective results on an easy-to-read digital display. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other management decisions.

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