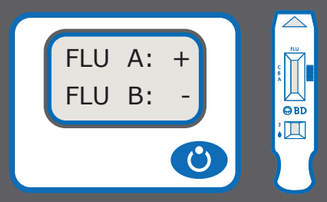
What You Need to Know About Rapid Influenza Antigen Detection Tests (RIDTs) and the New FDA Reclassification

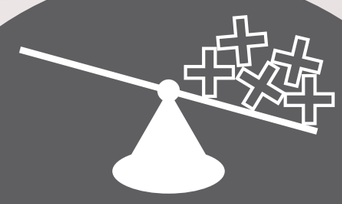


What are RIDTs?
Diagnostic tests intended to provide valuable information to HCPs to aid in the diagnosis of patients with influenza A or B viruses at the point of care.

Why is the Reclassification Necessary?
The 2009 flu pandemic emphasized inadequate performance of some existing RIDTs and raised concerns about their ability to detect influenza strains.[ii]

Which Tests Meet the New Requirements?
The BD Veritor™ System, a digital immunoassay, meets the new FDA requirements to assure safety and effectiveness for RIDTs.

What is the New FDA Reclassification?
Current RIDTs are being moved from Class I to Class II devices, requiring them to meet increased sensitivity, specificity and annual strain testing regulatory controls.[i]



Anticipated Impact of Reclassification?
Improvements in RIDTs allow more appropriate treatment of patients and meet the needs of HCPs and the public health.[ii]

Learn more about the FDA reclassification and make sure the test being used meets the new FDA requirements.
Visit **www.bd.com/ds/veritorsystem** for more information.

[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. Accessed January 18, 2017.

[ii]Executive Summary Proposed Reclassification of the Rapid Influenza Detection Tests CDRH Microbiology Devices Advisory Committee Meeting June 13, 2013, Gaithersburg, Maryland

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