

FAQ for Lab Briefings webinar: FDA's New Reclassification of Rapid Influenza Diagnostic Tests: Are you Prepared?

Below are the questions from *FDA's New Reclassification of Rapid Influenza Diagnostic Tests: Are you Prepared?* presented on September 27, 2017.

Please note that the information in the related presentation and the answers below are provided for educational purposes only and is not legal advice. It is intended to highlight changes in laws that you are likely to encounter, but is not a comprehensive review. Please consult with a licensed attorney in the event you have questions or concerns.

Q: Will the presentation slides be available to print and when will this webinar be available online?

A: Yes, at www.whitehatcom.com/cardinalhealth

Q: Do these waived tests still require culture confirmation for negative results?

A: You should always refer to the Instructions For Use (IFU) for your test kit. Some rapid test kit manufacturers advise that a negative test result does not exclude infection with influenza A or B. Therefore, the results obtained should be used in conjunction with clinical findings to make an accurate diagnosis.

Q: With molecular flu tests being cost prohibitive, what safeguards are required by CAP/CLIA (not recommended) to be in place when using rapid influenza testing systems?

A: The safeguard is the FDA reclassification of rapid diagnostic flu tests to Class II. The new higher sensitivity and specificity for Influenza A and Influenza B, respectively, will ensure better test accuracy with proper use.

CLIA Waived tests used in the CLIA Waived arena are only for certain specimen types so read your package insert carefully.

Q: Should negative flu be reflexed to molecular testing if the direct antigen tests are re-classified?

A: Refer to the IFU of your test kit for requirements.

Q: This doesn't affect PCR testing, does it?

A: No, this reclassification does not affect PCR tests because "molecular" flu tests, regardless of the methodology, already were cleared as Class II devices so they meet the FDA Class II requirements.

Q: Is there an age restriction on the collection of using nasopharyngeal swabs? We do nasal aspirates on infants, these cannot be used for waived testing?

A: You should refer to the IFU of your test kit.

Q: If it is waived, why would you implement Individualized Quality Control Plan (IQCP) if you follow manufacturers requirements?

A: Waived tests do not require IQCP.

Q: I thought that a reader was required - how is the visual dipstick and such meeting the new guidelines?

A: A reader is not required to meet the new FDA Class II requirements. The test platforms that do meet the FDA reclassification requirements as of September 2017 include options which are

1. Molecular
2. Reader based
3. Visually read

Q: What are good sources of actual performance data for the different traditional RIDT's? How does one find reliable performance results for multiple practice types?

A: Refer to the IFU and the Manufacturer's Technical Support line; As of July 2017, manufacturers are required to test and report their results on a panel of flu viruses on an annual basis

The following is taken from The Final Rule published by the FDA, reference the resources below:

The appropriate strains to be tested will be identified by FDA in consultation with CDC and sourced from CDC or a CDC-designated source. If the annual strains are not available from CDC, FDA will identify an alternative source for obtaining the requisite strains. The testing must be conducted according to a standardized protocol considered and determined by FDA to be acceptable and appropriate. By July 31 of each calendar year, the results of the last 3 years of annual analytical reactivity testing must be included as part of the device's labeling. If a device has not been on the market long enough for 3 years of annual reactivity testing since the device was given marketing authorization, then the results of every designated annual reactivity testing since the device was given marketing authorization by FDA, including the results of annual analytical reactivity testing performed on the viral strains provided that calendar year, must be included. The results must be presented as part of the device's labeling in a tabular format, which includes the detailed information for each virus tested as described in the certificate of authentication, either by: A) Placing the results directly in the device's § 809.10(b) (21 CFR 809.10(b)) compliant labeling in a section of the labeling devoted to annual analytical reactivity testing; or B) Providing a hyperlink in a section of the device's labeling to the manufacturer's public Web site where the annual analytical reactivity testing data can be found. If this option is chosen, the manufacturer's home page must publicly provide a hyperlink, which can easily be found and executed, to the annual analytical reactivity testing results and the Web page containing those annual analytical reactivity testing results must allow unrestricted viewing access. This includes being easy to locate the results from the primary part of the manufacturer's Web site that discusses the device.

If an emergency, or a potential emergency, is declared by the Secretary of Health and Human Services (HHS) for an influenza viral strain: Within 30 days from the date that FDA notifies manufacturers that characterized viral samples are available for test evaluation, the manufacturer must have testing performed on the device with that viral strain in accordance with a standardized protocol considered and determined by FDA to be acceptable and appropriate. The procedure and location of testing may depend on the nature of the emerging virus.

Q: For the RIDTs molecular influenza kits categorized as moderate complexity, do you think they will require IQCP?

A: If you run daily QC, then IQCP is not required. If you do not run daily QC, then you will need to follow IQCP guidelines.

Only Waived tests are exempt from requiring IQCP.

Q: Are the kits that re-classified going to be marked as such?

A: Product labeling is determined by each manufacturer and cleared through the FDA.

Manufacturers are required to test their product against influenza viral panels the CDC will provide. Strains to be tested will be identified by the FDA in consultation with the CDC and they are anticipated to be largely based on the strains selected by the WHO for the annual vaccine. Manufacturers are required to include their test results in a separate section of their product insert or post on their website with a clear link for customers/potential customers to review and must keep three (3) years of data on their site.

Q: How do the new minimum requirements compare to previous minimum limits for sensitivity and specificity?

A: Please follow the following link where you can find the new, higher sensitivity and specificity requirements that the Rapid Influenza Detection Flu Kits are now required to meet: <https://www.federalregister.gov/documents/2017/01/12/2017-00199/microbiology-devices-reclassification-of-influenza-virus-antigen-detection-test-systems-intended-for>

(See under “Supplementary Information, Section II. Public Comments in Response to the Proposed Order → Part C: Clinical Performance Standards and Comparator Methods → (21 CFR 866.3328)

Q: Is the BD Veritor also going on the not comply list on January 12, 2018?

A: The BD Veritor meets the FDA Class II guidelines for Rapid Flu tests so it will remain in the market today and as of January 12, 2018 forward.

Resources:

Microbiology Devices; Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly With Clinical Specimens, A Rule by the Food and Drug Administration on 01/12/2017 - <https://www.federalregister.gov/documents/2017/01/12/2017-00199/microbiology-devices-reclassification-of-influenza-virus-antigen-detection-test-systems-intended-for>

Microbiology Devices; Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly with Clinical Specimens - <https://www.regulations.gov/docket?D=FDA-2014-N-0440>

Update Regarding the Reclassification of Influenza Diagnostics, Alere, April 2017 - <http://www.alere.com/en/home/support/reclassification-of-influenza-diagnostics.html>

Rapid Influenza Diagnostic Tests - https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_ridt.htm