



Act Now to Meet FDA Flu Testing Reclassification

The FDA has announced the reclassification of rapid influenza antigen detection tests (RIDTs). Devices that do not meet these new standards will not be available after January 12, 2018. Now is the perfect time to explore testing options that meet the new performance requirements.

For more details about this reclassification, talk to your Account Executive or visit the Federal Register at <http://bit.ly/2pAmkVx>.

Readers or Molecular

These testing options meet the new FDA requirements. What best meets your needs?

Readers	Molecular
<ul style="list-style-type: none"> • Minimizes visual subjectivity • Similar cost as visually-read rapids • Increases accuracy of results 	<ul style="list-style-type: none"> • Amplification technology increases specimen sample quality • Produces extremely accurate and, in some cases, definitive test results

BD Veritor™ Plus

- CLIA-waived: flu, strep, RSV
- Results in 10 minutes
- The ability to run 3,500 tests vs. 3,000 previously
- Upgradeable for traceability and connectivity



Alere™ i

- CLIA-waived: flu, strep and RSV
- Results provided quickly
- Transport media included



Quidel Sofia®

- CLIA-waived: flu, strep, RSV
- Batches multiple samples per hour
- “Virena” provides real-time data to public health for actionable community response
- Talk to your LPOC about the new Sofia 2 option



Roche cobas® Liat® System

- PCR molecular technology
- CLIA-waived: flu, strep and RSV
- No negative confirmation required on Strep A
- Minimal steps required
- Runs flu and RSV simultaneously



Quidel Solana™

- Moderately complex: flu, strep, strep complete, trichomonas, HSV
- No negative confirmation required on Strep A
- Minimal steps required



“The AAP finds the FDA proposal to reclassify influenza virus antigen detection test systems from class I devices to class II devices to be much needed and appropriately written ... RIDTs have proven to be inaccurate ... Pediatricians are concerned that these devices are giving false positives or negatives on the children on whom these tests are used... without treatment the infection could worsen and subsequent negative consequences could occur. It is crucial for the treatment and health of children that these tests are safe, accurate and effective.”



- The American Academy of Pediatrics



Contact Your Account Executive for more information or to schedule a product demonstration.

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