

Rapid Influenza Testing: False Positives (Influenza B)

Target audience: Clinical laboratories

Friday, November 16, 2012

This message is being shared on behalf of the Association of Public Health Laboratories.

CDC (Centers for Disease Control and Prevention) is aware of five laboratories in three different states that have experienced false influenza B positive results with the Quidel Sofia Influenza A&B test. Quidel is aware of the problem and is working to identify and solve the issue.

If you believe you may be experiencing a problem, consider obtaining a second specimen from patients with positive Influenza B results for confirmation via PCR testing. In addition, since influenza activity is currently at sporadic levels in Michigan, confirmatory testing on rapid test-positive influenza specimens is strongly encouraged. PCR testing is available at the Michigan Department of Community Health Bureau of Laboratories; call (517) 335-8099 for more information.

If you identify and confirm false positive results with this test or with any other test, please contact the company with the lot number(s) and expiration dates of the product.

If you choose, you may report test malfunctions to FDA by completing [FDA Form 3500](#). This form is used for reports submitted by persons who are not required to report events by the MDR regulation. If the reporting falls under mandatory reporting by a user facility (events in which there is a reasonable suggestion that a medical device has or may have caused or contributed to a death or serious injury) you should use FDA Form 3500A. The FDA Form 3500A, instructions for completing specific items on the form, and the coding manual can be found [here](#).

Steps for laboratories to take now:

- Since influenza activity is currently at sporadic levels in Michigan, confirmatory testing on rapid test-positive influenza specimens is strongly encouraged.
- Consider obtaining a second specimen from patients with positive Influenza B results for confirmation via PCR testing.

Questions and Additional Information:

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