We report a cluster of false-positive influenza B rapid test results associated with the use of red-top tube Vacuette plastic tube Z serum clot activator (item no. 454204).

Influenza activity in New York City (NYC), New York, between October 2011 and mid-February 2012 was relatively low, with laboratory-confirmed influenza test positivity rates between 1 and 3% citywide. Between 15 December 2011 and 19 February 2012, hospital A reported 48 positive rapid antigen test (RAT) results for influenza B for a mean positivity rate of 25% (weekly range of 13% to 42% for positive specimens) or 69% of positive influenza B results during this period. No common risk factors, including staff responsible for specimen collection and testing, were identified. Thirty-eight (79%) of these patients were treated with oseltamivir, presumably based on the positive influenza finding. Five primary specimens that had tested positive for influenza B by RAT were negative using PCR at another laboratory.

Suspecting a problem with the RAT assay, hospital A’s microbiology laboratory supervisor substituted assays from different lot numbers several times, with no change in results. The RAT manufacturer reviewed batch records for the relevant kit lots and test devices. All quality control release testing was valid and performed within specifications.

The kits used by hospital A were tested by the manufacturer using in-house controls. All tests were valid and performed as expected with no problems observed. However, the false influenza B results were replicated by the manufacturer when patient samples from hospital A were tested.

All false-positive influenza B results emanated from nasal aspirate specimens collected in the Emergency Department (ED). ED staff transferred nasal aspirates to red-top tubes coated with microscopic silica beads to promote blood clotting. The RAT manufacturer repeated testing on samples using the same brand of red-top tubes obtained independently and replicated the results reported by hospital A.

True influenza-positive results result from an immunological sandwich assay. It is speculated that the false-positive result was due to a filtration phenomenon. The largest silica particles did not pass into the nitrocellulose, whereas a subset of the smaller ones were trapped in the pores that were tighter due to immobilized antibody. Once the subset of silica particles further restricted flow, the visualizing gold particles could not pass through, and a non-immunological false-positive result was seen. Hospital A’s use of butterfly needles to inject the specimen into the septum of the red top worsened the interaction, as it decreased the amount of clinical sample, increasing the overall concentration of silica particles.

Studies on the sensitivity of influenza rapid tests (2) have demonstrated sensitivity rates of 60% or less compared to viral culture or PCR. Rapid tests were more sensitive at detecting influenza A than influenza B. A negative rapid test is not useful for categorically ruling out influenza, while a positive result can be useful clinically because the specificity of the rapid test is generally high. However, when the prevalence of the disease is low, the positive predictive value of the test is low, and false-positive test results are more likely (1, 3) The false-positive influenza results reported here may have resulted in increased health care costs and potential adverse reactions from the use of oseltamivir.

REFERENCES


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Published ahead of print 20 June 2012
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doi:10.1128/JCM.01452-12