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LETTER TO THE EDITOR

False positive Influenza rapid tests using newly EUA cleared multiplex assay in a low prevalence setting

To the Editor,

We report a cluster of false positive Influenza A and B rapid antigen tests from a point of care testing laboratories within a large healthcare system in central Texas.

In the backdrop of current coronavirus disease 2019 pandemic and due to heightened epidemiological interventions by governments and public health authorities there has been a significant reduction in the cases of respiratory viruses including Influenza viruses.

Given the very low prevalence of respiratory viruses and in the context of emerging infectious diseases diagnostic kits being approved under Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration, it is becoming incumbent upon the local CLIA certified laboratories to establish assay performance characteristics.

Between November 15, 2020 and mid-December 2020, six BSW Healthcare clinics in central Texas reported 22 (11.1%) positive rapid antigen test results of the 197 total tests performed. The rapid antigen test is a newly EUA cleared test that detects Influenza A, Influenza B and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Of the 22 Influenza-positive tests, 2 (9%) were Influenza A and 20 (90.9%) were Influenza B. Considering the very low prevalence of Influenza in the region, we decided to confirm all 22 rapid antigen positive tests by a molecular reference method. All 22-specimens tested negative on Influenza molecular test indicating 100% of the Influenza results were false positive on the new EUA cleared rapid antigen test.

To assess the performance characteristics of the rapid antigen test, specifically the SARS-CoV-2 target, all negative SARS-CoV-2 specimens were reflexed to an EUA molecular test for confirmation. Of the 139 SARS-CoV-2 antigen negative specimens, 14 (10%) were confirmed to be positive by molecular test indicating 10% of the antigen tests were false negative.

Influenza activity in the United States between September 2020 and mid-December 2020 was relatively low with laboratory-confirmed influenza test positivity rate at 0.2%.[1] It is very well-known in the clinical laboratory community that rapid antigen tests lack sensitivity. Studies have shown that the sensitivity of these tests can be less than 60% in a normal Influenza season. It can be speculated that due to very low prevalence of Influenza viruses, rapid antigen tests might be experiencing some assay interference, producing false positive results. 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.[2–4] The false-positive influenza results reported here may have resulted in increased health care costs and potential inappropriate use of antiviral medications.

While a negative rapid test may not be useful for categorically ruling out SARS-CoV-2, it may be useful in certain clinical context.

A technical inquiry with the manufacturer has yielded no response citing further investigation is warranted at their end.

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