Technical Bulletin

Date: December 18, 2020
Topic: ***Update: COVID-19 Point of Care Antigen Testing***
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To: Healthcare Providers and Long-Term Care Facilities

Background

Point of care (POC) COVID-19 antigen tests can be used in a variety of testing strategies to respond to the COVID-19 pandemic. Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection. Antigen tests are currently authorized to be performed on nasopharyngeal or nasal swab specimens. The U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for antigen tests that can identify COVID-19. See FDA's list of In Vitro Diagnostics EUAs.

Interpretation of Antigen Tests

Proper interpretation of both antigen test results and confirmatory Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) testing, when indicated, is important for accurate clinical management of patients with suspected COVID-19, or for identification of infected persons when used for screening asymptomatic individuals especially in communities with low prevalence of COVID-19 infections.

The clinical performance of antigen diagnostic tests largely depends on the circumstances in which they are used. Both antigen and molecular tests perform best when the person is tested when viral load is generally highest. They also may be informative in diagnostic testing situations in which the person has a known exposure to a person with COVID-19.

Evaluating the results of an antigen test for COVID-19 should take into account the performance characteristics and the instructions for use of the FDA-authorized assay, the prevalence of COVID-19 in that particular community (positivity rate over the previous 7–10 days or the rate of cases in the community), and the clinical and epidemiological context of the person who has been tested.[1]

The evaluation of an antigen test result should consider whether a person is experiencing symptoms, and if so the length of time the symptoms have been present. While it can be used on asymptomatic individuals, antigen tests should be performed within 7 days of symptom onset.

It may be appropriate to confirm antigen test results with another test. Based on performance data of various antigen tests collected federally, within Nevada and from other states, the Nevada Department of Health and Human Services (DHHS) recommends the following:

1. BinaxNOW:

   Performance studies of the BinaxNOW have been performed in San Francisco, California and in the state of Massachusetts. Both study methodologies included collecting specimens for RT-PCR testing concurrent with the BinaxNOW antigen test among both symptomatic and asymptomatic individuals. Both studies concluded that the BinaxNOW antigen tests has a very high specificity (99-100%), which means the test is extremely accurate for detecting individuals with COVID-19. The studies found the sensitivity to also be

[1] https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

relatively high (93-98.6%), which means the test performs relatively well for detecting when someone does not have COVID-19. [2] [3]

Based on these quantitative finding which validate the efficacy of the BinaxNOW in both symptomatic and asymptomatic individuals, DHHS recommends confirmatory RT-PCR testing under specific circumstances. A confirmatory RT-PCR should be performed when:

- A symptomatic person tests negative using the BinaxNOW
- An asymptomatic person that has no known exposure to COVID-19 tests positive

This approach will also help to reduce the burden on laboratories as the RT-PCR testing demands across Nevada continue to increase.

2. All other COVID-19 antigen tests:

   Limited data exists to evaluate the performance of many of the FDA EUA approved antigen tests. DHHS in collaboration with the Nevada State Public Health Laboratory (NSPHL) was able to analyze findings from the BD Veritor and the Quidel Sofia antigen tests and published the finding in a Technical Bulletin. These finding showed an overall 60% false positivity rate for the BD Veritor and the Quidel Sofia. These tests are authorized under the FDA EUA to be used on both symptomatic and asymptomatic individuals. However, based upon a combination of limited data for some of the antigen tests and the findings published in the aforementioned Technical Bulletin, DHHS recommends these antigen tests only utilized on symptomatic individuals and that both positive and negative results have a confirmatory RT-PCR sample collected for testing within 48 hours.[4]

Clearance from Quarantine Utilizing Antigen Tests

CDC updated their quarantine guidance on December 2, 2020. The updated guidance allows for shortened quarantine options, which includes the ability to be removed from quarantine after seven (7) days **IF** the exposed person is asymptomatic and has a negative test result on or after day five (5) of their last exposure.[5] DHHS recommends utilizing one of the following tests for removal from quarantine, based upon efficacy findings:

1. RT-PCR
2. Abbott IDNOW
3. Abbott BinaxNOW

DHHS does not recommend utilization of other antigen tests for the purpose of removal from quarantine.

Nevada Administrative Code (NAC) 441A

According to NAC 441A.230 it is the duty of the health care provider to report a case or a suspected case to the public health authority. The report must include:

- The communicable disease or suspected communicable disease.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7654907/

[3] https://search.mass.gov/?q=binax

[4] Note that the development of additional antigen tests is an active and ongoing process. As new tests enter the market, data on their performance will determine their utility on a case-by-case basis. This means that future additional guidance may be required.

[5] https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html

- The name, address and, if available, telephone number of the case or suspected case.
- The name, address and telephone number of the health care provider making the report.
- The occupation, employer, age, sex, race and date of birth of the case or suspected case, if available.
- The date of diagnosis of the communicable disease.
- The date of onset of the communicable disease, if available.
- Any other information requested by the health authority, if available. (For example, an if an email address is available, it is helpful include in the report.)

Reporting:

Report laboratory results through the electronic laboratory reporting (ELR) system. The Nevada Division of Public and Behavioral Health (DPBH), Office of Public Health Investigation and Epidemiology (OPHIE) team will assist in onboarding laboratories into the ELR system and can be contacted at dpbhelronboarding@health.nv.gov. During the onboarding process OPHIE will provide instructions on the best interim alternative mechanism to report until the completion of ELR onboarding.

Questions:

For updated guidance, please review the DPBH Technical Bulletin website and Nevada's health response website regularly. You may email dpbhepi@health.nv.gov with questions.

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