

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Technical Bulletin

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Topic: Update: COVID-19 Point of Care Antigen Testing in Community Settings

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To: Public Health Professionals, Health Care Providers, Health Care Facilities, Schools, Employers and

Businesses

Background:

Point of care (POC) COVID-19 antigen tests are one testing option available 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.¹

Interpretation of Antigen Tests:

Proper interpretation of both antigen test results and confirmatory molecular tests such as the 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 generally perform best when the person tested has a high viral load. They also may be informative in diagnostic testing situations in which the person has a known exposure to a person with COVID-19.

The health care provider should consider several things when evaluating the results of an antigen test for COVID-19, including 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 transmission within the community); and the clinical and epidemiological context of the person who has been tested.²

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 upon the clinical and epidemiological context of the person who has been tested.

¹ https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

² https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Testing a Symptomatic Person in a Community Setting:

In a community setting, when testing a person who has symptoms consistent with COVID-19, the health care provider generally can interpret a positive antigen test to indicate if the person is infected with SARS-CoV-2; this person should follow CDC's updated guidance for isolation: https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html A negative antigen test result for a symptomatic person should be confirmed with a laboratory-based Nucleic Acid Amplification Test (NAATS can use many different methods to amplify nucleic acids and detect the virus such as such as the RT-PCR. A negative antigen result for a symptomatic person may not need confirmatory testing if the person has a low likelihood of SARS-CoV-2 infection. Testing for other respiratory viruses, such as influenza and respiratory syncytial virus may also be warranted. Information on these viruses and testing can be found in the Division of Public and Behavioral Health's previously published Technical Bulletin: (RSV))

A symptomatic person who has received a negative antigen test result and then a positive confirmatory NAAT should follow CDC's updated guidance for isolation: https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html A symptomatic person who has received a negative antigen test result and then a negative confirmatory NAAT should follow CDC's updated guidance for quarantine: https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html if they have had close contact or suspected exposure to a person with COVID-19 within the last 14 days. If that same person has not had any known exposure to COVID-19, then they do not need to quarantine.

Testing an Asymptomatic Person in a Community Setting:

When testing an asymptomatic person in a community setting for COVID-19, the health care provider generally can interpret a positive antigen test to indicate that the person is infected with SARS-CoV-2; this person should follow CDC's updated guidance for isolation https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html A positive antigen test result from an asymptomatic person may need confirmatory testing if the person has a low likelihood of SARS-CoV-2 infection. For example, a low likelihood of SARS-CoV-2 infection would be a person who has had no known exposure to a person with COVID-19 within the last 14 days and lives in a community with low transmission, is fully vaccinated and/or has had a SARS-CoV-2 infection in the last 3 months.

When testing an asymptomatic person for COVID-19, the health care provider generally can interpret a negative antigen result to indicate that a SARS-CoV-2 infection is not present. However, a negative antigen test result may need confirmatory testing utilizing a laboratory-based NAAT if that asymptomatic person has a high likelihood of SARS-CoV-2 infection, such as a person who has had close contact or suspected exposure to COVID-19 within the last 14 days.

An asymptomatic person who has received a negative antigen test result should follow CDC's updated guidance for quarantine https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html if they have had close contact or suspected exposure to a person with COVID-19 within the last 14 days.

Utilizing Antigen Tests in Combination with Quarantine:

Quarantine requirements are dependent upon COVID-19 vaccination and booster status. Diagnostic testing should be utilized in combination with these measures.

• Quarantine of unvaccinated close contacts: For people who are unvaccinated or are more than 6 months out from their second mRNA dose (or more than 2 months after J&J) and not yet boosted, CDC now recommends a quarantine period of 5 days followed by strict mask use for an additional 5 days.

³ https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html

Alternatively, if a 5-day quarantine is not feasible, it is imperative that an exposed person wear a mask for 10 days after exposure.

- Quarantine of fully vaccinated close contacts: Persons who have completed the primary series of Pfizer or Moderna vaccine within the past 6 months or completed the J&J within the past 2 months, or those who have received their booster shot do not need to quarantine following an exposure to COVID-19.
 However, the following must still occur:
 - Wear a mask around others for 10 days after known exposure.
 - Be tested for COVID-19 on day 5, if possible.
 - If symptoms develop, immediately self-isolate and get tested for COVID-19.

Nevada Administrative Code 441A:

According to Nevada Administrative Code (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.
- 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:

The Nevada Division of Public and Behavioral Health (DPBH), Office of Public Health Investigation and Epidemiology (OPHIE) team will assist in onboarding laboratories and testing entities. Before testing begins, OPHIE should be contacted at dpbhelronboarding@health.nv.gov to start the process. Labs with HL7 capability should plan to report laboratory results through the electronic laboratory reporting (ELR) system. OPHIE will provide instructions on the best alternative mechanism to report for entities without HL7 capability.

Questions:

For updated guidance, please review the DPBH Technical Bulletin <u>website</u> and Nevada's health response <u>website</u> regularly. Email <u>dpbhepi@health.nv.gov</u> with questions.

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