

Technical Bulletin



Date: October 1, 2021

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

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To: Public Health Professionals, Healthcare 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 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 healthcare 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.

Testing a Symptomatic Person in a Community Setting

In a community setting, when testing a person who has symptoms consistent with COVID-19, the healthcare 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 guidance for <u>isolation</u>.³

¹ <u>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</u>

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

³ https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/isolation.html

A positive antigen test result for a symptomatic 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, is fully vaccinated, and/or had a SARS-CoV-2 infection in the last 3 months.

A negative antigen test result for a symptomatic person should be confirmed with a laboratory-based Nucleic Acid Amplification Test (NAAT).⁴ 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, as determined by the examples above. Testing for other respiratory viruses, such as influenza and respiratory syncytial virus (RSV) 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: COVID-19, Influenza and RSV.

A symptomatic person who has received a negative antigen test result and then a positive confirmatory NAAT should follow CDC's guidance for <u>isolation</u>. A symptomatic person who has received a negative antigen test result and then a negative confirmatory NAAT should follow CDC's guidance for <u>quarantine</u> if they have had close contact or suspected exposure to a person with COVID-19 within the last 14 days.⁵ If that same person has not had any known exposure to COVID-19, then they do not need to quarantine.⁶

Testing an Asymptomatic Person in a Community Setting

Asymptomatic people who are fully vaccinated should follow CDC's Interim Public Health Recommendations for Fully Vaccinated People. When testing an asymptomatic person in a community setting for COVID-19, the healthcare 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 guidance for isolation. 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 healthcare 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. For example, a high likelihood of SARS-CoV-2 infection would be a person who has had close contact or suspected exposure to COVID-19 within the last 14 days, they are not fully vaccinated, **and** they have not had a SARS-CoV-2 infection in the last 3 months.

An asymptomatic person who has received a negative antigen test result should follow CDC's guidance for <u>quarantine</u> if they have had close contact or suspected exposure to a person with COVID-19 within the last 14 days; <u>fully vaccinated people</u> and those who have had a SARS-CoV-2 infection in the last 3 months do not need to quarantine.

Clearance from Quarantine Utilizing Antigen Tests

Quarantine requirements are dependent upon COVID-19 vaccination status and previous infection. Diagnostic testing options exist which may reduce the period of time a person must remain in quarantine. The diagnostic testing options include both NAATs and antigen tests that have FDA approval or FDA EUA.

⁴ https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html

⁵ https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html

⁶ https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

⁷ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

- Quarantine of unvaccinated close contacts: Those that meet CDC's close contact definition must quarantine consistent with CDC guidelines. Those identified as close contacts must quarantine and can resume normal activities after day 10 with no symptoms, or after day 7 if they are asymptomatic and tested negative on or after day 5 of the quarantine. Note, quarantine ends after day 7 with a negative test on or after day 5, or after day 10 with no testing performed. This means exposed individuals would be able to return to normal activities on day 8 or day 11, depending on if they were tested or not. The individual should continue to self-monitor for symptoms for the full 14 days following exposure. In the case symptoms develop during these 14 days, the person should get (re)tested and quarantine until their test results come back. If their result is positive, they should immediately self-isolate.
- Quarantine of persons who tested positive for COVID-19 in the past 3 months: Persons that
 tested positive for COVID-19 in the past 3 months, with no COVID-like symptoms do not need to
 quarantine, be restricted from work, or tested following an exposure to someone with suspected
 or confirmed COVID-19, as their risk of infection is low. However, they should still monitor for
 symptoms of COVID-19 for 14 days following last exposure. If symptoms develop, they should be
 clinically evaluated and self-isolate.
- Quarantine of vaccinated close contacts: Fully vaccinated people who have been in close contact
 with someone with suspected or confirmed COVID-19 should get tested 3-5 days after the
 exposure, even if they don't have symptoms. They should also wear a mask indoors in public for
 14 days following an exposure or until their test result is negative. If symptoms develop, they
 should be clinically evaluated and tested for COVID-19 if indicated.

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.
- 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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