

Health Advisory: Health Advisory: Antigen-based Tests for Detection of SARS-CoV-2

Minnesota Department of Health, Wed, Oct 14 11:00 CDT 2020

Action Steps

Local and tribal health department: Please forward to hospitals, clinics, urgent care centers, emergency departments, and convenience clinics in your jurisdiction.

Hospitals, clinics and other facilities: Please forward to infection preventionists, infectious disease physicians, emergency department staff, hospitalists, primary care clinicians, and all other health care providers who might see patients with COVID-19.

Health care providers:

- Use SARS-CoV-2 antigen tests only for individuals with signs and/or symptoms of acute respiratory infection, within five to seven days of symptom onset.
- Recognize the limitations of SARS-CoV-2 antigen tests.
- Treat negative test results from symptomatic individuals as presumptive, and confirm negative tests with RT-PCR when possible.
- [Report COVID-19/SARS-CoV-2 Infections](https://www.health.state.mn.us/diseases/coronavirus/hcp/report.html) (<https://www.health.state.mn.us/diseases/coronavirus/hcp/report.html>) within one working day by phone to 651-201-5414 or 877-676-5414 or using the [COVID-19 Case Report Form](https://www.health.state.mn.us/diseases/coronavirus/hcp/covidreportform.pdf) (<https://www.health.state.mn.us/diseases/coronavirus/hcp/covidreportform.pdf>).

Background

Antigen tests directly detect the presence of proteins from SARS-CoV-2, unlike real-time reverse transcription polymerase chain reaction (RT-PCR), which detects viral RNA. While RT-PCR is the best available test to detect SARS-CoV-2 infection, the antigen tests currently available are faster and can be conducted on-site in a facility that has a CLIA waiver (i.e., at the point of care). However, they have more limitations than RT-PCR. When using antigen tests, it is important to keep the following in mind:

- Antigen tests currently available to diagnose SARS-CoV-2 infection are intended for use in individuals with acute respiratory symptoms within five to seven days of symptom onset.
- Antigen tests have lower sensitivity when compared with RT-PCR, meaning that they do not always correctly identify infected people as positive. Therefore, false negative results can occur, regardless of the prevalence of SARS-CoV-2 at the time of testing.
- Antigen test manufacturers indicate that negative tests from symptomatic people should be considered presumptive and be confirmed by RT-PCR testing.
- Careful specimen handling and following all package insert instructions is essential to ensure reliable test results.

SARS-CoV-2 Antigen Tests are not Intended for Use on Asymptomatic Individuals

Over the last month, nationally and in Minnesota, there have been multiple reports of false-positive results from SARS-CoV-2 antigen tests, particularly when used for screening of asymptomatic residents and staff in long-term care facilities. Antigen tests that have been authorized by the FDA under an Emergency Use Authorization (EUA) have only been approved for use in symptomatic individuals, shortly after symptom onset. In addition, these tests have only recently entered the market for SARS-CoV-2 testing and their use in other populations is still being studied. As a result, there is insufficient information available regarding test performance when the pre-test probability of SARS-CoV-2 is low, such as when individuals are asymptomatic or when the prevalence of SARS-CoV-2 is low. Use of these tests on asymptomatic individuals remains an area of uncertainty and should be avoided.

Appropriate Use of SARS-CoV-2 Antigen Tests

Antigen tests should be considered for use on symptomatic individuals within the first five to seven days of symptom onset or in situations where there is a high probability that the individual or population to be tested is positive. These tests should also be considered for situations in which a positive result would lead to changes in clinical management or in infection prevention and control actions.

Recommendations for the use of antigen testing specific to long-term care facilities is available from MDH in [Using Antigen-based Point-of-Care \(POC\) Testing for COVID-19 in Long-term Care Facilities](https://www.health.state.mn.us/diseases/coronavirus/hcp/ltcantigentest.pdf) (<https://www.health.state.mn.us/diseases/coronavirus/hcp/ltcantigentest.pdf>).

Confirmatory Testing

When confirming an antigen test result with an RT-PCR test, the time interval between the two specimen collections must be less than 48 hours, with no opportunities for new exposures between the two tests. If this is not the case, the RT-PCR test should be considered a separate test, not a confirmatory test.

Confirm negative tests from symptomatic individuals with RT-PCR. Antigen test manufacturers indicate that negative tests conducted on symptomatic people should be considered presumptive and be confirmed by using RT-PCR testing.

A person who has a positive test result on an antigen-based test should be considered infectious and positive for SARS-CoV-2 infection. Positive results from antigen tests will be included in the state case count and will receive the same public health follow-up including recommended isolation of the case and quarantine of contacts, even if a subsequent antigen test or RT-PCR test is negative.

Disease Reporting

All COVID-19 test results, positive and negative, performed on a point-of-care testing platform must be reported by the facility within 24 hours of resulting. For information or assistance in setting up electronic reporting or submitting results in a flat file, contact MDH.

For More Information

- [MDH Coronavirus Disease \(COVID-19\) webpage \(https://www.health.state.mn.us/diseases/coronavirus/index.html\)](https://www.health.state.mn.us/diseases/coronavirus/index.html)
- [CDC's Coronavirus Disease 2019 webpage \(https://www.cdc.gov/coronavirus/2019-ncov/index.html\)](https://www.cdc.gov/coronavirus/2019-ncov/index.html)
- Call MDH at 651-201-5414 or 877-676-5414.

A copy of this HAN is available at: [MDH Health Alert Network \(http://www.health.state.mn.us/han\)](http://www.health.state.mn.us/han)

The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties..