STAY SAFE MN

Using Antigen-based Point of Care Testing for COVID-19 in Long-term Care Facilities

Antigen tests for the virus that causes COVID-19, SARS-CoV-2, directly detect the presence or absence of viral protein. Antigen tests detect different viral components than do real-time reverse transcription polymerase chain reaction (RT-PCR), which is used to detect viral RNA. The antigen tests currently available for diagnosing COVID-19 are faster than RT-PCR and can be conducted on-site in a facility (i.e., at the point of care). However, they can have more limitations, which are outlined in this document. It is important to keep in mind the following qualities of SARS-CoV-2 antigen tests.

- Antigen tests detect the presence or absence of SARS-CoV-2 protein.
- In general, antigen tests have very good specificity.
- However, antigen tests have a relatively low sensitivity when compared with RT-PCR. This means that individuals who test negative might, in fact, have the disease. Antigen test manufacturers indicate that negative tests should be considered presumptive and be confirmed by using RT-PCR testing. Because of this known limitation, antigen tests are best used to test symptomatic people in situations of high disease prevalence.
- Because each point-of-care antigen test can take up to 15 minutes to complete (excluding time spent preparing and swabbing), completing a large number of tests might be prohibitively time-consuming. For example, running 200 tests would take more than 50 hours. With only one machine, facility-wide testing could take multiple days. In contrast, diagnostic laboratories are able to conduct RT-PCR testing on more specimens in less time.
- A provider order is needed for all antigen testing conducted on-site at a long-term care (LTC) facility.
- Careful specimen handling is essential to ensure reliable test results.

Considerations for use of SARS-CoV-2 antigen testing in long-term care

When is it appropriate to use a SARS-CoV-2 antigen test?

Antigen tests can be considered for symptomatic individuals (within the first five days of symptom onset) in settings 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 (IPC) actions. Below are potential situations in which this testing could be used, with confirmation of negative results by RT-PCR.

- In long-term care facilities experiencing a COVID-19 outbreak (i.e., more than one case has been confirmed in residents or in staff who worked while infectious).
- When the individual will benefit clinically from a rapid result.
- Symptomatic individuals in remote populations with known high incidence and limited alternative access to testing.

Use of antigen tests for screening of asymptomatic individuals could be warranted in certain situations where RT-PCR testing is not available (i.e., there is no testing alternative to antigen tests). If antigen tests are used in these settings, negative results should be considered presumptive, and individuals should continue to practice preventive measures (e.g., social distancing, wearing a mask, frequent hand hygiene).

Antigen tests may be considered for serial screening of asymptomatic individuals in a closed LTC setting, when negative individuals will receive recurrent testing and timely RT-PCR testing is not available. When used for screening in congregate care settings, test results should be considered presumptive and may need confirmation.

When is it inappropriate to use a SARS-CoV-2 antigen test?

Antigen tests should not be routinely considered for non-serial testing of asymptomatic individuals, in settings where there is a low probability that an individual will test positive, or in situations where a positive result will not lead to changes in clinical management.

Confirmation of antigen test results

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.

Testing symptomatic individuals

- **No known cases:** In situations where there are no known COVID-19 cases, confirm positive antigen tests with RT-PCR. Once a positive case(s) is confirmed by RT-PCR, stop using antigen testing and use RT-PCR for testing of high-risk contacts and for point-prevalence survey (PPS) testing as you define the scope of the outbreak.
- **Outbreak response:** In situations where there are already confirmed COVID-19 cases in residents or staff, RT-PCR confirmation of positive antigen tests is not needed.
- Confirm all negative tests from symptomatic individuals with RT-PCR. Symptomatic residents should be placed in appropriate Transmission-based Precautions, and symptomatic staff should be excluded from work while awaiting confirmatory testing.

Testing asymptomatic individuals

- **No known cases:** If screening asymptomatic individuals when the probability of a positive test is low (no known cases in the facility and low incidence in the county), confirm positive tests by RT-PCR within 48 hours. If the confirmatory test is negative, discuss interpretation of the discordant results with the Minnesota Department of Health (MDH) or an infectious disease specialist.
  - In a low-incidence screening situation, confirmatory RT-PCR for negative antigen tests may not be necessary if the person is asymptomatic or has no known exposures, or is part of a group that will receive rapid antigen tests on a recurring basis.
- **Outbreak response:** Confirmatory RT-PCR testing following a positive antigen test is not necessary when the probability of a positive test is high (outbreak in the facility, high incidence in the county), especially if the person is symptomatic or has a known exposure.
  - Confirmatory testing of negative tests is not necessary, but staff and residents who test negative should be tested again in three to seven days (see COVID-19 Testing Recommendations for Long-term Care Facilities on the MDH webpage, Long-term Care Testing: COVID-19 (www.health.state.mn.us/diseases/coronavirus/hcp/ltctesting.html).

Using testing to guide infection protection and control (IPC) actions

- Positive antigen tests should be acted upon for both residents and staff.
  - Residents who test positive should be placed into Transmission-based Precautions in an observation unit or single room with private bathroom, when possible, while awaiting confirmatory testing by RT-PCR. Residents should not be placed into the COVID-19 unit unless confirmatory RT-PCR testing is positive.
  - Positive staff should be excluded from work, regardless of symptoms.
- Symptomatic residents with a negative test should be placed into Transmission-based Precautions while awaiting confirmatory testing by RT-PCR. Residents should not be placed into the COVID-19 unit unless confirmatory RT-PCR testing is positive.
- Residents who are high-risk contacts of a known COVID-19-positive individual should be placed into Transmission-based Precautions while awaiting confirmatory testing by RT-PCR, even if asymptomatic.
- CDC does not recommend routinely using a test-based approach, including with antigen tests, to make decisions about discontinuing isolation.

Test prioritization

- When financial or testing resources are limited, antigen testing can be prioritized to individuals who are at high risk of infection or spreading the virus to others.
- Examples of high-risk residents include those who have been admitted from a hospital or other facility, roommates of known positive or symptomatic residents, and residents who leave the facility regularly for dialysis or other essential medical services.

- High-risk staff might include those who work at other health care facilities and those who had close contact with a co-worker, resident, household member, or social contact with confirmed COVID-19.

IPC during specimen collection and handling

- The personal protective equipment that should be worn during specimen collection includes gloves, gowns, face shield (or other front and side eye protection), and N95 respirator (if available) or face mask.
- Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, including gown, gloves, and eye protection. Face masks should be used by staff at all times in health care facilities.

Currently available SARS-CoV-2 antigen tests

There are currently four SARS-CoV-2 antigen-based diagnostic tests with U.S. Food and Drug Administration (FDA) emergency use authorization.

- U.S. Food and Drug Administration: In Vitro Diagnostics EUAs (www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas)

Details are provided below for the two antigen-test systems that will be distributed to eligible U.S. nursing homes by CMS, summarized from information available from manufacturers (i.e., intended-use documents), FDA, and Association of Public Health Laboratories.

- U.S. Department of Health and Human Services: Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/ Nursing Homes (www.cms.gov/files/document/covid-faqs-snf-testing.pdf)
- Association of Public Health Laboratories (APHL): Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing (www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf)

Test sensitivity varies among antigen testing platforms. Facilities should be aware of which platform is being used and the sensitivity of the test for the population to be tested.

Quidel Sofia 2 SARS Antigen FIA

- Specimen types: NP or nasal swabs directly or after transport in viral transport media.
- Time to results: 15-30 minutes.
- Test performance for symptomatic individuals: sensitivity, 97%; specificity, 100%.
- FDA: Quidel Sofia 2 SARS Antigen FIA Intended Use (www.fda.gov/media/137885/download)
- FDA: Quidel Sofia 2 SARS Antigen FIA Fact Sheet For Healthcare Providers (www.fda.gov/media/137884/download)

BD Veritor System for Rapid Detection of SARS-CoV-2

- Specimen types: nasal swabs (supplied with kit), directly only.
- Time to results: 15 minutes.
- Test performance for symptomatic individuals: sensitivity, 84%; specificity, 100%.
- FDA: BD Veritor System for Rapid Detection of SARS-CoV-2 Intended Use (www.fda.gov/media/139755/download)
- FDA: BD Veritor System for Rapid Detection of SARS-CoV-2 Fact Sheet For Healthcare Providers (www.fda.gov/media/139753/download)

Reporting of positive and negative antigen test results

Rapid antigen tests should be interpreted in the context of the prevalence of infection or disease, the device's performance characteristics and instructions for use, and the patient's clinical signs, symptoms, and history. Follow the manufacturer's recommendation for interpreting and reporting test results to tested individuals.

All sites conducting testing under CLIA certification or CLIA Certificate of Waiver must report both positive and negative results within 24 hours to MDH. For each individual tested, all COVID-19 test results (positive and negative) performed by your facility must be reported to MDH, as required by state law and U.S. Health and Human Services (HHS) guidance.

- U.S. Department of Health and Human Services: COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 (www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf)
- U.S. Department of Health and Human Services: Frequently Asked Questions: Laboratory Data Reporting for COVID-19 Testing (www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf)
- U.S. Department of Health and Human Services: QSO-20-37-CLIA, NH (www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-updating-requirements-reporting-sars-cov-2-test-results-clia)

Reporting should occur electronically, by electronic laboratory reporting (ELR) when possible. Please contact MDH at Health.ELRmeaningfuluse@state.mn.us with questions about reporting or to receive an MDH Excel reporting template.

Additional information on positive cases must be reported as soon as possible via a secure web form or by faxing the MDH COVID-19 case report form.

- The secure web-based case report form can be found at MDH: Web COVID-19 Patient Reporting Form (redcap-c19.web.health.state.mn.us/redcap/surveys/?s=9XMX7WKRTM).

- The case report form for faxing can be found at MDH: COVID-19 Case Report Form (www.health.state.mn.us/diseases/coronavirus/hcp/covidreportform.pdf).

This document will be updated if new reporting requirements are put in place by HHS or MDH. In addition to reporting these test results in accordance with CLIA requirements, facilities must continue to report other COVID-19 information to the CDC's National Healthcare Safety Network (NHSN).

- U.S. Department of Health and Human Services: QSO-20-29-NH (www.cms.gov/files/document/qso-20-29-nh.pdf)
- Reporting details for users of Quidel Sofia

Testing sites using the Quidel Sofia must use the test and result codes shown in Table 1. These data fields align with the required fields provided in the MDH reporting template.

Table 1: Test and result codes required for reporting of Quidel Sofia results

Test Performed Description	Test_performed_code	Test_result_coded	Test_result_description
SARS coronavirus+SARS coronavirus 2 Ag [Presence] in Respiratory specimen by Rapid immunoassay	95209-3	260373001	Positive
SARS coronavirus+SARS coronavirus 2 Ag [Presence] in Respiratory specimen by Rapid immunoassay	95209-3	260415000	Not detected
SARS coronavirus+SARS coronavirus 2 Ag [Presence] in Respiratory specimen by Rapid immunoassay	95209-3	455371000124106	Invalid

Users of the Quidel Sofia must use the specimen sources and codes shown in Table 2.

Table 2: Specimen sources and codes required for reporting of Quidel Sofia results

Specimen_type_description	Specimen_type_code
Nasopharyngeal swab	258500001
Nasal swab	445297001

Reporting details for users of BD Veritor

Testing sites using the BD Veritor must use the test and result codes shown in Table 3.

Table 3: Test and result codes required for reporting of BD Veritor results

Test Performed Description	Test_performed_code	Test_result_coded	Test_result_description
SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay	94558-4	260373001	Positive
SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay	94558-4	260415000	Not detected
SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay	94558-4	455371000124106	Invalid

Users of the BD Veritor must use the specimen sources and codes shown in Table 4.

Table 4: Specimen sources and codes required for reporting of BD Veritor results

Specimen_type_description	Specimen_type_code
Nasal swab	445297001

Resources

- CDC: Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes (www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html)
- CDC: Interim Guidance for Rapid Antigen Testing for SARS-CoV-2 (www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html)
- Association of Public Health Laboratories (APHL): Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing (www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf)
- Centers for Medicaid and Medicare Services (CMS): Nursing Home Data - Point of Care Device Allocation (data.cms.gov/Special-Programs-Initiatives-COVID-19-Nursing-Home/Nursing-Home-Data-Point-of-Care-Device-Allocation/jbvf-tb74)
- MDH: COVID-19 Testing Recommendations for Long-term Care Facilities (www.health.state.mn.us/diseases/coronavirus/hcp/ltctestrec.pdf)
- HHS: Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency (www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf)

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Contact health.communications@state.mn.us to request an alternate format.

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