STAY SAFE MN

Using Antigen-based Point-of-Care (POC) 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), used to detect viral RNA and is the best available test for SARS-CoV-2 detection. The antigen tests currently available for diagnosing COVID-19 are faster than RT-PCR and potentially conducted on-site in a long-term care (LTC) facility, at the point of care. However, they can have more limitations, 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.
- The FDA emergency authorized use of these tests is specific to testing of individuals with acute respiratory symptoms within five to seven days of symptom onset. Consider the off-label use of these tests for screening of asymptomatic individuals, when timely availability of RT-PCR testing is inadequate.
- 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 negative tests presumptive and confirmed by using RT-PCR testing. Because of this known limitation, use antigen tests 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 LTC facility needs to be aware of whether a provider order is needed for the antigen test being used.
- 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?

Consider antigen tests for symptomatic individuals, within the first five to seven days of symptom onset, in the situations/settings described below.

- In settings where there is a high probability that the individual or population to be tested is positive.
- For situations in which a positive result would lead to changes in clinical management or in infection prevention and control (IPC) actions.

Consider antigen tests for symptomatic individuals, with confirmation of negative results by RT-PCR, in the situations/settings described below.

- In LTC facilities experiencing a COVID-19 outbreak, where more than one case 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.

Consider antigen tests for screening of asymptomatic individuals in certain situations where RT-PCR testing is not available, where there is no testing alternative to antigen tests. If using antigen tests in these settings, consider negative results presumptive. Individuals should continue to practice preventive measures, such as social distancing, wearing a mask, and frequent hand hygiene.

Consider antigen tests 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, consider test results presumptive and request confirmation (see additional information below).

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

Do not routinely consider antigen tests 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, consider the RT-PCR test a separate test, not a confirmatory test. See the Figure for a flow chart describing MDH recommendations for antigen-test confirmation.

LTC Facilities with COVID-19 Case(s) in the Last 14 Days

- **Symptomatic individuals:** In situations where there are already confirmed COVID-19 cases in residents or staff, RT-PCR confirmation of positive antigen tests from symptomatic individuals is not needed.
- **Asymptomatic individuals:** Confirmatory RT-PCR testing following a positive antigen test is not necessary when there is an outbreak in the facility or test positivity in the county is high, 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 test again in three to seven days.
  - See COVID-19 Testing Recommendations for Long-term Care Facilities (PDF). Long-term Care Testing: COVID-19 (www.health.state.mn.us/diseases/coronavirus/hcp/ltctesting.html).

LTC Facilities without COVID-19 Case(s) in the Last 14 Days

- **Symptomatic individuals:** In situations where there are no known COVID-19 cases, confirm both positive and negative antigen tests with RT-PCR within 48 hours.
  - Positive antigen tests: If the confirmatory RT-PCR test is positive, this is a confirmed case. If the confirmatory RT-PCR test is negative, the antigen test result might be a false positive. Obtain a second RT-PCR at least 24 hours after the first RT-PCR. If the second RT-PCR test is also negative, this is not a case. Report discrepant the result to MDH through the online case report form (see reporting information below). If the second RT-PCR test is positive, this is a confirmed case.
  - Negative antigen tests: Confirm all negative tests from symptomatic individuals with RT-PCR. Place symptomatic residents in appropriate Transmission-based Precautions. Exclude symptomatic staff from work while awaiting confirmatory testing.
- **Asymptomatic individuals:** If screening asymptomatic individuals when the probability of a positive test is low (no known cases in the facility and low positivity rate in the county), confirm positive tests by RT-PCR within 48 hours.
  - Positive antigen tests: If the confirmatory RT-PCR test is positive, this is a confirmed case. If the confirmatory RT-PCR test is negative, the antigen test result might be a false positive. Obtain a second RT-PCR at least 24 hours after the first RT-PCR. If the second RT-PCR test is also negative, this is not a case. Report discrepant the result to MDH through the online case report form (see reporting information below). If the second RT-PCR test is positive, this is a confirmed case.
  - 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.

Upon confirmation of a positive case(s) 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.

Use of Testing to Guide IPC Actions

- Act on positive antigen tests for both residents and staff.
  - Antigen-positive residents for whom confirmatory testing is not indicated should be placed into Transmission-based Precautions in the COVID-19 unit.
  - Antigen-positive staff for whom a confirmatory test is not indicated should be excluded from work, regardless of symptoms.
  - Residents who test positive but for whom a confirmatory RT-PCR test is indicated, 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. Do not place residents into the COVID-19 unit unless confirmatory RT-PCR testing is positive.
  - Staff who test positive but for whom a confirmatory RT-PCR test is indicated should be excluded from work, regardless of symptoms. Staff can return to work if they have two negative RT-PCR tests at least 24 hours apart.
- Place symptomatic residents with a negative test into Transmission-based Precautions while awaiting confirmatory testing by RT-PCR. Do not place residents into the COVID-19 unit unless confirmatory RT-PCR testing is positive.
- Place residents who are high-risk contacts of a known COVID-19-positive individual 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, prioritize antigen testing to individuals who are at high risk of infection or spreading the virus to others.
- Examples of high-risk residents include those 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 mask.
- Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, including gown, gloves, and eye protection. Staff should wear masks 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 below for the three antigen-test systems distributed to eligible U.S. LTC facilities by HHS, 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. LTC facilities should be aware of the platform used and the sensitivity of the test for the population to be tested.

Quidel Sofia SARS Antigen FIA

- Approved use: respiratory specimens collected from individuals who are suspected of COVID-19 within the first five days of the onset of symptoms
- 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 SARS Antigen FIA Intended Use (www.fda.gov/media/137885/download)
- FDA: Quidel Sofia SARS Antigen FIA Fact Sheet For Healthcare Providers (www.fda.gov/media/137884/download)

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

- Approved use: nasal swab specimens collected from individuals who are suspected of COVID-19 within the first five days of the onset of symptoms
- 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)

Abbott BinaxNOW COVID-19 Ag Card

- Approved use: nasal swab specimens collected from individuals who are suspected of COVID-19 within the first seven days of the onset of symptoms
- Specimen types: nasal swabs, directly only
- Time to results: 15 minutes
- Test performance for symptomatic individuals: sensitivity, 97.1%; specificity, 98.5%
- FDA: BinaxNOWTM COVID-19 Ag CARD Intended Use (www.fda.gov/media/141570/download)
- FDA: BinaxNOW COVID-19 Ag Card Fact Sheet For Healthcare Providers (www.fda.gov/media/141568/download)

Reporting Positive and Negative Point of Care Antigen Test Results

Interpret rapid antigen tests 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.

Laboratory Reporting for Point of Care Antigen Testing

The following specifics on reporting are not relevant to COVID-19 testing completed by an external laboratory. If you send specimens to a reference laboratory for testing, the laboratory will do the reporting. If you conduct the testing inside your facility, you are acting as a laboratory and must report results to MDH. This information is relevant for facilities using point of care antigen tests provided by HHS.

All COVID-19 test results, positive and negative, performed on a laboratory testing platform inside your facility must be reported within 24 hours of results using the *MDH COVID-19 Lab Results Reporting File Template* Microsoft Excel spreadsheet.

- MDH has an automated procedure for processing files. For this reason, we ask that you use the Excel reporting template exactly.

  - *MDH COVID-19 Lab Results Reporting File Template* and the *Antigen MDH COVID-19 Lab Results Reporting File Key,* with instructions on how to complete the template, can obtained by emailing Health.ELRmeaningfuluse@state.mn.us.
  - Take note of the "Test_result_coded" field in the Excel sheet, where you record the test results. The "presumptive positive" code (720735008) should be used if you have submitted, or will be submitting, a confirmatory RT-PCR test. Specimens for confirmatory RT-PCR must be collected within 48 hours of antigen-test specimen collection. In addition, please submit with the comment field to specify that a specimen has been/will for RT-PCR testing.
- You might be able to export data from your electronic health records, or from your testing device, to paste into the Excel template. You can also type into the Excel template.
- Submit reporting data within 24 hours of test resulting, by using the MN COVID-19 Provider Portal. If you are testing onsite every day, you will submit reporting data daily.
- The provider portal is a secure web survey that allows you to submit files without needing a username and password. You will need to contact MDH to request access. When you are ready to start submitting, please email Health.ELRmeaningfuluse@state.mn.us.

If you are using a large healthcare system's laboratory information system, MDH may be able to connect you with automated electronic laboratory reporting instead of using the Excel sheet. If you have questions about this, please email Health.ELRmeaningfuluse@state.mn.us.

The *MDH COVID-19 Lab Results Reporting File Template* incorporates the United States Health and Human Services' reporting guidance. You will not need to report laboratory results separately to HHS. MDH will report these results on your behalf.

- 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)

Case Reporting for Point of Care Antigen Testing

Report additional information on positive cases as soon as possible via a secure web form (preferred) or by faxing the MDH COVID-19 case report form. This information is required for all cases, whether tested with a point of care antigen test or with RT-PCR by a reference laboratory.

The secure web-based case report form and case report form for faxing are on the MDH website.

- Submitting Clinical Information on Long Term Care COVID-19 Cases and Reporting Discrepant Laboratory Results (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=H8MT9TTNCD)
- COVID-19 Case Report Form (www.health.state.mn.us/diseases/coronavirus/hcp/covidreportform.pdf).

If you conduct RT-PCR testing to confirm a positive antigen test, and the RT-PCR test is negative, tell us about the discrepant result by filling in the case report form and selecting "Discordant results in a staff or resident (positive antigen test followed by a negative PCR collected less than 48 hours later)" under "What are you reporting?".

- Submitting Clinical Information on Long Term Care COVID-19 Cases and Reporting Discrepant Laboratory Results (https://redcap-c19.web.health.state.mn.us/redcap/surveys/?s=H8MT9TTNCD)

Other Required Reporting

LTC 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 (PDF) (www.cms.gov/files/document/qso-20-29-nh.pdf)

Reporting Details for Specific Antigen Test Systems

Reporting details for users of Quidel Sofia SARS Antigen FIA

Testing sites using the Quidel Sofia SARS Antigen FIA 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 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

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	455371000124106	Invalid
SARS coronavirus+SARS coronavirus 2 Ag [Presence] in Respiratory specimen by Rapid immunoassay	95209-3	720735008	Presumptive positive

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 Quidel Sofia Results

Specimen_type_description	Specimen_type_code
Nasopharyngeal swab	258500001
Nasal swab	445297001

Reporting details for users of BD Veritor System for Rapid Detection of SARS-CoV-2

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 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

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	260415000	Not detected
SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay	94558-4	455371000124106	Invalid
SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay	94558-4	720735008	Presumptive positive

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 BD Veritor Results

Specimen_type_description	Specimen_type_code
Nasal swab	445297001

Reporting details for users of Abbott BinaxNOW COVID-19 Ag Card

Testing sites using the Abbott BinaxNOW COVID-19 Ag Card must use the test and result codes shown in Table 5. These data fields align with the required fields provided in the MDH reporting template.

Table 5: Test and Result Codes Required for Reporting Abbott BinaxNOW Results

Test Performed Description	Test_performed_code	Test_result_coded	Test_result_description
SARS-CoV-2 nucleocapsid protein antigen	94558-4	10828004	Positive
SARS-CoV-2 nucleocapsid protein antigen	94558-4	260385009	Negative
SARS-CoV-2 nucleocapsid protein antigen	94558-4	455371000124106	Invalid
SARS-CoV-2 nucleocapsid protein antigen	94558-4	720735008	Presumptive positive

Users of the Abbott BinaxNOW must use the specimen sources and codes shown in Table 6.

Table 6: Specimen Sources and Codes Required for Reporting Abbott BinaxNOW 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)
- 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)

Management of Point-of-Care (POC) Antigen-Test Results in Long-Term Care Settings

CASE(S) IN LTC FACILITY IN PAST 14 DAYS

Symptomatic[1]

- Positive POC Antigen Test
  - No confirmatory RT-PCR testing needed. This is a case.
- Negative POC Antigen Test[2]
  - Confirm RT-PCR.[5, 6]
    - Positive RT-PCR. This is a case.
    - Negative RT-PCR. This is not a case.

Asymptomatic

- Positive POC Antigen Test
  - Confirmatory testing not needed if probability of a positive test is high, especially if individual had a known exposure. This is a case.
- Negative POC Antigen Test[2]
  - Repeat testing for (presumptive) negative individuals according to recommendations.[3, 4]

NO CASE(S) IN LTC FACILITY IN PAST 14 DAYS

Symptomatic[1]

- Positive POC Antigen Test
  - Confirm by RT-PCR.[2, 5, 6]
    - Positive RT-PCR. This is a case.
    - Negative RT-PCR. Obtain a 2nd RT-PCR greater than 24 hours later.
      - Positive RT-PCR. This is a case.
      - Negative RT-PCR. RULE OUT Report discrepant results to MDH.[7]
- Negative POC Antigen Test
  - Confirm by RT-PCR.[2, 5]
    - Positive RT-PCR. This is a case.
    - Negative RT-PCR. This is not a case.

Asymptomatic

- Positive POC Antigen Test
  - Confirm RT-PCR.[5, 6]
    - Positive RT-PCR. This is a case.
    - Negative RT-PCR. Obtain a 2nd RT-PCR greater than 24 hours later.
      - Positive RT-PCR. This is a case.
      - Negative RT-PCR. RULE OUT Report discrepant results to MDH.[7]
- Negative POC Antigen Test
  - Presumptive negative result; no confirmatory test needed unless individual had high-risk exposure and is not part of serial testing.[4]

Footnotes

1. Symptomatic staff should be excluded from work; symptomatic residents should be placed in Transmission-based Precautions.
2. Symptomatic residents who test negative and/or who are high-risk contacts of known COVID-19-positive individual should be placed in Transmission-based Precautions (e.g., single room, private bathroom) while awaiting confirmatory RT-PCR. Residents should not be placed into COVID-19 unit unless confirmatory RT-PCR testing is positive. Symptomatic staff who test negative should be excluded from work, with return to work determined based on results of RT-PCR testing and alternative diagnoses, if any. See COVID-19 Recommendations for Health Care Workers (www.health.state.mn.us/diseases/coronavirus/hcp/hcwrecs.pdf).
3. As part of outbreak response, negative staff and residents should be retested every three to seven days, in accordance with recommendations. See Long-term Care Testing: COVID-19 (www.health.state.mn.us/diseases/coronavirus/hcp/ltctesting.html).
4. Negative staff in federally certified nursing facilities should be tested routinely in accordance with CMS: QSO-20-38-NH (www.cms.gov/files/document/qso-20-38-nh.pdf).
5. Confirmatory RT-PCR must happen with 48 hours. Place antigen-positive residents in Transmission-based Precautions and exclude antigen-positive staff from work while awaiting confirmatory testing, even if asymptomatic.
6. When confirming results with RT-PCR, indicate that the antigen-test result is "presumptive positive" in your laboratory reporting file sent to MDH. Information about reporting antigen-test results can be found in Reporting Results of COVID-19 Tests Conducted in Your Long-term Care Facility (www.health.state.mn.us/diseases/coronavirus/hcp/ltcantigenreport.pdf). Facilities should still follow appropriate infection prevention and control and work exclusion guidance triggered by the positive antigen test
7. Once RT-PCR testing is completed, discrepant results can be reported to MDH at Submitting Clinical Information on Long Term Care COVID-19 Cases and Reporting Discrepant Laboratory Results (redcap-c19.web.health.state.mn.us/redcap/surveys/?s=H8MT9TTNCD).

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