

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

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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) tests, which detect viral RNA. RT-PCR 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 can be conducted on-site in a long-term care (LTC) facility. However, they can have more limitations, as 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 Use Authorization 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.
- Antigen tests have a lower 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 are presumptive and should be confirmed by using RT-PCR testing.
- There have also been reports of SARS-CoV-2 antigen tests providing false positive results, so confirmatory RT-PCR testing is also recommended after some positive tests, such as when it is an asymptomatic person and/or a low prevalence setting.
- 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. 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 SARS-CoV-2 point of care antigen test being used in LTC.
- 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.
- In LTC facilities experiencing a COVID-19 outbreak, where more than one case has been confirmed in residents or in staff who worked while infectious.
- For symptomatic individuals in populations with known high incidence and limited alternative access to testing.

Consider antigen tests for screening of asymptomatic individuals in certain situations where timely RT-PCR testing is not available and there is no testing alternative to antigen tests. If using antigen tests in these settings, consider negative results presumptive. Negative 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 staff is not

USING ANTIGEN-BASED POINT-OF-CARE TESTING FOR COVID-19 IN LONG-TERM CARE FACILITIES

needed. Conduct confirmatory testing on antigen-positive residents if positive residents are to be placed into a COVID-19 unit. Confirm negative tests by RT-PCR.

- **Asymptomatic individuals:** Confirmatory RT-PCR testing within 48 hours following a positive antigen test is recommended for asymptomatic individuals, especially when the test positivity rate in the county is low and the individual has had no known exposures. 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 [Long-term Care Testing: COVID-19 \(www.health.state.mn.us/diseases/coronavirus/hcp/lctesting.html\)](http://www.health.state.mn.us/diseases/coronavirus/hcp/lctesting.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.
- **Asymptomatic individuals:** When screening asymptomatic individuals and the probability of a positive test is low (no known cases in the facility), 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.
 - Negative antigen tests: 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, if able, 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 residents and staff.
- Antigen-positive staff for whom a confirmatory test is not indicated should be excluded from work, regardless of symptoms.

USING ANTIGEN-BASED POINT-OF-CARE TESTING FOR COVID-19 IN LONG-TERM CARE FACILITIES

- 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 or meet symptom- and time-based criteria to return.
- Residents who test positive by antigen test 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.
 - Ideally, all antigen-positive results should be confirmed by RT-PCR before moving a resident into the COVID-19 unit.
 - If there are space constraints in a facility with RT-PCR confirmed COVID-19 cases, consider putting symptomatic antigen-positive residents into the COVID-19 unit, in private rooms if possible, before RT-PCR confirmation.
 - Asymptomatic antigen-positive residents should be confirmed with RT-PCR before moving into the COVID-19 unit.
- 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 have had high-risk exposure to 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.
- 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.
 - [COVID-19 Recommendations for Health Care Workers \(www.health.state.mn.us/diseases/coronavirus/hcp/hcwrecs.pdf\)](https://www.health.state.mn.us/diseases/coronavirus/hcp/hcwrecs.pdf)

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 medical-grade facemask.

- Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, including gown, gloves, and eye protection. Staff should wear medical-grade facemasks at all times in health care facilities.

Testing of individuals who previously tested positive

Because individuals can test positive, persistently or intermittently, following COVID-19 infection, CDC recommends that asymptomatic individuals be excluded from routine screening (e.g., weekly staff testing, PPS testing) for 3 months after initially testing positive by RT-PCR. However, given the potential for false-positive antigen test results, individuals who tested positive by antigen test without confirmatory RT-PCR testing and were asymptomatic during the initial infection should continue to be included in routine screening. Any asymptomatic individual that tests positive on a screening antigen test should have confirmatory RT-PCR conducted. After testing RT-PCR positive, individuals should be excluded from routine testing for three months.

Exclude individual from routine screening for three months following initial positive test if:

- Individual was positive by RT-PCR testing, regardless of symptoms during the initial infection.
- Individual was positive by antigen test (with or without RT-PCR confirmation) AND was symptomatic at time of testing or developed symptoms during the initial infection.

Continue to include individual in routine screening after initial positive test if:

- Individual was positive by antigen test (without confirmatory test) AND individual had no symptoms during the initial infection.*
- Individual was positive by antigen test but determined to be a false positive after obtaining a negative confirmatory RT-PCR test (within 48 hours of antigen specimen collection) and a second negative RT-PCR test at least 24 hours after the first.

*Although these individuals will not be excluded from testing after their infection, they should be treated as positive. Staff should be isolated, including exclusion from work for a minimum of 10 days, including at least 24 hours fever-free and with improving symptoms. Residents should be placed into transmission-based precautions.

Required reporting

Laboratory reporting for POC testing

If you send specimens to a reference laboratory for testing, the laboratory will do the reporting. If you conduct the testing inside your facility, as with POC antigen tests, you are acting as a laboratory and must report results to CDC or MDH. Reporting is mandatory, and this information is relevant for facilities using point of care antigen tests provided by HHS and for facilities who obtained testing platforms on their own.

- [Reporting Results of COVID-19 Tests Performed Inside Your Long-term Care Facility](http://www.health.state.mn.us/diseases/coronavirus/hcp/ltcantigenreport.pdf)
(www.health.state.mn.us/diseases/coronavirus/hcp/ltcantigenreport.pdf)

Case reporting

Report additional information on positive cases as soon as possible via the secure web form. This information is required for all cases, whether tested with a POC antigen test or with RT-PCR by a reference laboratory.

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

The same form can be used if you conduct RT-PCR testing to confirm a positive antigen test, and two subsequent RT-PCR tests are negative. Tell us about the discrepant results 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 the section, “What are you reporting?”.

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](http://www.cms.gov/files/document/qso-20-29-nh.pdf)
(www.cms.gov/files/document/qso-20-29-nh.pdf)

Currently available SARS-CoV-2 antigen tests

There are currently seven 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](http://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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](http://www.cms.gov/files/document/covid-faqs-snf-testing.pdf)
(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 per manufacturer (not field conditions): sensitivity, 97%; specificity, 100%
- [FDA: Quidel Sofia SARS Antigen FIA Intended Use \(www.fda.gov/media/137885/download\)](https://www.fda.gov/media/137885/download)
- [FDA: Quidel Sofia SARS Antigen FIA Fact Sheet For Healthcare Providers \(www.fda.gov/media/137884/download\)](https://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 per manufacturer (not field conditions): sensitivity, 84%; specificity, 100%
- [FDA: BD Veritor System for Rapid Detection of SARS-CoV-2 Intended Use \(www.fda.gov/media/139755/download\)](https://www.fda.gov/media/139755/download)
- [FDA: BD Veritor System for Rapid Detection of SARS-CoV-2 Fact Sheet For Healthcare Providers \(www.fda.gov/media/139753/download\)](https://www.fda.gov/media/139753/download)

Abbott BinaxNOW COVID-19 Ag Card

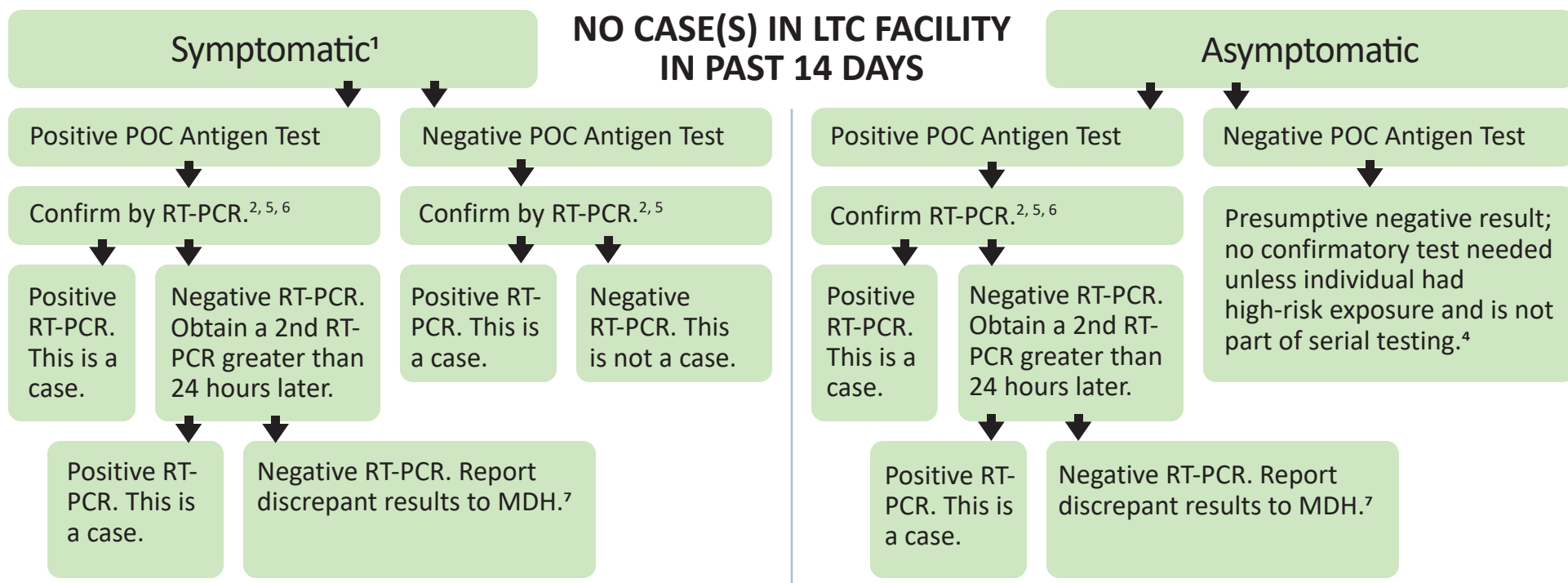
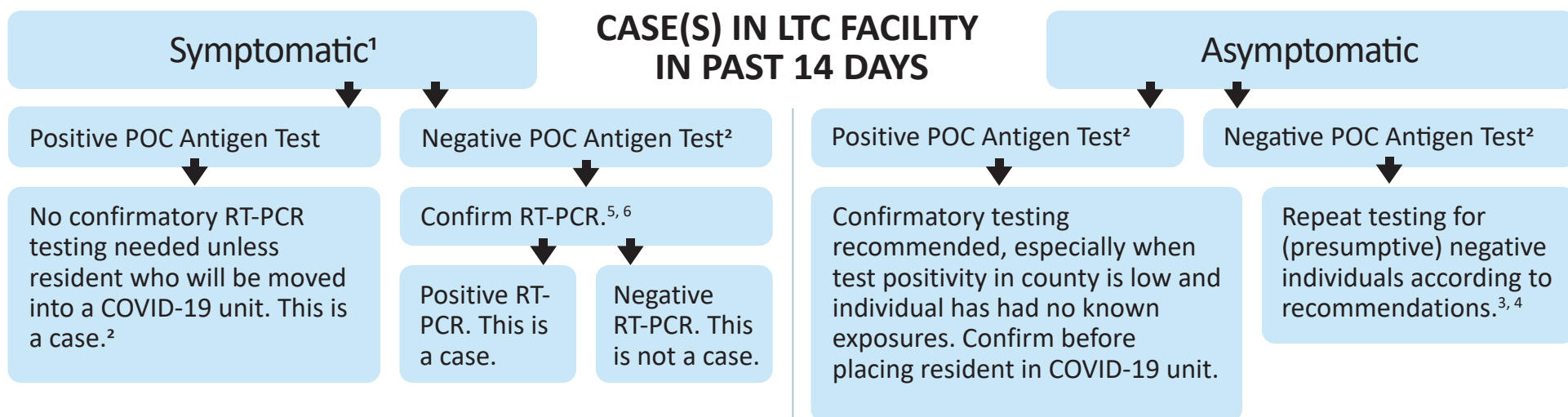
- Approved use: nasal swab specimens collected from individuals who are suspected of COVID-19 within the first seven days of the onset of symptoms
- Specimen types: nasal swabs, directly only
- Time to results: 15 minutes
- Test performance for symptomatic individuals per manufacturer (not field conditions): sensitivity, 97.1%; specificity, 98.5%

- [FDA: BinaxNOW™ COVID-19 Ag CARD Intended Use \(www.fda.gov/media/141570/download\)](https://www.fda.gov/media/141570/download)
- [FDA: BinaxNOW COVID-19 Ag Card Fact Sheet For Healthcare Providers \(www.fda.gov/media/141568/download\)](https://www.fda.gov/media/141568/download)

Resources

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



Flowchart footnotes

1. Symptomatic staff should be excluded from work; symptomatic residents should be placed in Transmission-based Precautions.
2. Symptomatic residents and those who are high-risk contacts of a known COVID-19-positive individual should be placed in Transmission-based Precautions (e.g., single room, private bathroom), when possible, while awaiting confirmatory RT-PCR. Residents who test positive by antigen test 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. Ideally, all antigen-positive results should be confirmed by RT-PCR before moving into the COVID-19 unit. If there are space constraints in a facility with RT-PCR confirmed COVID-19 cases, consider putting symptomatic antigen-positive residents into the COVID-19 unit, in private rooms if possible, before RT-PCR confirmation. Asymptomatic antigen-positive residents should be confirmed with RT-PCR before moving into the COVID-19 unit.

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/lctesting.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 within 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, 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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