



COVID-19 (Coronavirus Disease)

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Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes

Updated Dec. 10, 2020

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This document provides a summary of considerations for use of SARS-CoV-2 (the virus that causes COVID-19) antigen testing in nursing homes and is intended for nursing home providers and state and local public health departments.

Antigen tests are available as point-of-care (POC) diagnostics for SARS-CoV-2. They have a rapid turnaround time, which is critical to the identification of SARS-CoV-2 infection and rapid implementation of infection prevention and control strategies. These tests can augment other testing efforts, especially in settings where RT-PCR testing capacity is limited or testing results are delayed (e.g., >48 hours). In general, these POC antigen tests have a lower sensitivity, but similar specificity, for detecting SARS-CoV-2 compared to reverse-transcriptase polymerase chain reaction (RT-PCR) tests.

This document pertains to antigen tests that have been granted a US Food and Drug Administration's Emergency Use Authorization (FDA EUA) to detect SARS-CoV-2. The first two SARS-CoV-2 antigen tests to receive FDA EUA are authorized for testing symptomatic persons within 5 days of symptom onset and there are limited data on antigen test performance in asymptomatic persons. However, given the transmission of SARS-CoV-2 from asymptomatic and presymptomatic nursing home residents and healthcare personnel (HCP) with SARS-CoV-2 infection, CDC is providing considerations for the use of antigen tests in asymptomatic persons during this public health emergency. Facilities should be aware of the [FDA EUA](#) [for antigen tests](#) and potential implications for the [Clinical Laboratory Improvement Amendments \(CLIA\)](#) certificate of waiver when using antigen tests in asymptomatic individuals and in persons >5 days from symptom onset.

Helpful Links

[Testing Overview](#)

[Using Antigen Tests](#)

[Testing for Nursing Homes](#)

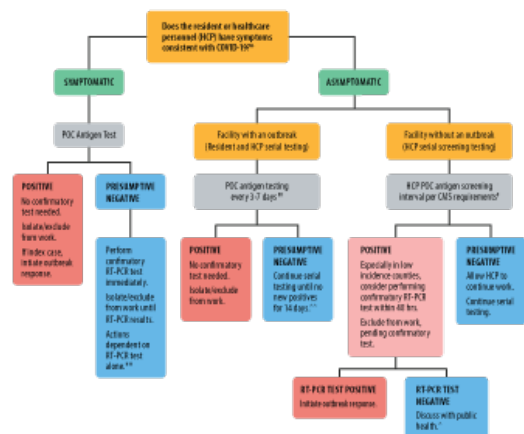
[Testing Healthcare Personnel](#)

[Interpreting Test Results](#)

[Point-of-Care Testing](#)

When a confirmatory molecular test should be considered

Considerations for Interpreting Antigen Test Results in Nursing Homes



[PDF - 135 KB]

As the sensitivity of antigen tests is generally lower than RT-PCR, [FDA EUA](#) recommends that negative POC antigen tests be considered presumptive. Clinical staff in nursing homes should consider when confirmatory RT-PCR testing [might be needed](#) prior to making clinical decisions, cohorting residents, or excluding HCP from work. When interpreting the results of antigen tests, test characteristics and probability of infection should be considered.

- Test sensitivity might vary between antigen testing platforms. Facilities should be aware of which platform is being used and the sensitivity of the test for the patient population to be tested. For example, the first two antigen tests that have received [FDA EUAs](#) range in sensitivity from 84% to 97% when used within 5 days of symptom onset.
- Factors that increase the probability of infection include the presence of symptoms in the person being tested, recent exposure to someone diagnosed with COVID-19, and whether testing is being conducted in a nursing home with an outbreak or within a high-prevalence community. These factors inform the decision of whether confirmatory testing by RT-PCR is indicated following an antigen test.

If a confirmatory RT-PCR test is performed within 48 hours, individuals should be assumed infectious until the confirmatory test results are completed. For instance, if a symptomatic resident tests presumptive negative on antigen test and a RT-PCR is performed, the resident should remain in [Transmission-Based Precautions](#) until the RT-PCR test results. If an asymptomatic HCP working in a nursing home without an outbreak and in a county with low community prevalence tests antigen positive, they should be excluded from work until a negative RT-PCR test is available.

Reporting requirements for SARS-CoV-2 tests

Every COVID-19 testing site is [required to report](#) to the appropriate state or local public health department every diagnostic and screening test performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19. POC testing may be performed with a [Clinical Laboratory Improvement Amendments \(CLIA\)](#) [☑](#) certificate of waiver, but reporting of test results to state or local public health departments are mandated by the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

CMS-certified long-term care facilities are [required by the Department of Health and Human Services](#) [🇺🇸](#) [🔗](#) (HHS) to use the [National Healthcare Safety Network](#) (NHSN) to report SARS-CoV-2 point-of-care antigen test data, and other on-site COVID-19 laboratory testing data, to appropriate federal and state health authorities.

Uses of antigen testing in nursing homes

This document guides the interpretation of results when antigen tests are used in the following circumstances:

- Testing of symptomatic residents and HCP,
- Testing of asymptomatic residents and HCP in facilities as part of an COVID-19 outbreak response, and
- Testing of asymptomatic HCP in facilities without a COVID-19 outbreak as required by CMS recommendations.

Testing in other circumstances are likely to occur, such as testing asymptomatic residents and HCP who were exposed to persons with COVID-19 outside of the nursing home (e.g., recent hospitalization or outpatient services) or through other screening activities. The principles described here can be used to guide the interpretation of antigen test results in those situations.

Antigen tests should not be utilized to determine the [duration of Transmission-Based Precautions](#) nor [when HCP can return to work](#). Test-based strategies are not generally recommended to determine duration of transmission-based precautions, nor to determine when HCP may return to work. If used, test-based strategies should rely only on RT-PCR.

Considerations for interpreting antigen test results in nursing homes

Testing of symptomatic residents or HCP


- If an antigen test is positive, no confirmatory test is necessary.
 - Residents should be placed in [Transmission-Based Precautions](#) or [HCP should be excluded from work](#).
 - If the resident or HCP is the first positive test for SARS-CoV-2 within the facility (i.e., an index case), an [outbreak response](#) should be initiated immediately.*
- If an antigen test is presumptive negative, perform RT-PCR immediately (e.g., within 48 hours).


- Symptomatic residents and HCP should be kept in transmission-based precautions or excluded from work until RT-PCR results return.
- Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if individuals who test negative on such platforms should be retested with RT-PCR.
- Note: if an individual has recovered from SARS-CoV-2 infection in the past 3 months and develops new symptoms suggestive of COVID-19, alternative diagnoses should be considered [prior to retesting for SARS-CoV-2](#).

Testing of asymptomatic residents or HCP in nursing homes as part of an outbreak response*

- If an antigen test is positive, no confirmatory test is necessary.
 - Residents should be placed in transmission-based precautions, and HCP should be excluded from work.
- If an antigen test is presumptive negative, residents should be placed in [appropriate precautions for facilities with an outbreak](#). HCP should be allowed to continue to work with [continued symptom monitoring](#). The facility should continue serial viral testing (antigen or RT-PCR) every 3-7 days until no new cases are identified for a 14-day period.
- Note: asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a nursing home performing facility-wide testing [should not be tested](#) for SARS-CoV-2.

Testing of asymptomatic HCP in nursing homes without an outbreak per CMS recommendations

[CMS recommends](#)  initial testing of all HCP as part of the nursing home reopening process and serial testing of HCP at an interval based on local incidence of COVID-19.

- If an antigen test is positive, perform confirmatory RT-PCR test within 48 hours of the antigen test, especially in counties with low prevalence. If confirmatory test is performed, HCP should be excluded from work until confirmatory test results are completed.
 - If the confirmatory test is positive, then [exclude the HCP from work](#) and [initiate an outbreak response](#) including facility-wide testing of all residents and HCP.
 - If the confirmatory test is negative, discuss results with the local public health department to determine how to interpret the discordant results and next steps. The incidence of SARS-CoV-2 infection in the local community can help interpret the likelihood of a false positive antigen test. The time between antigen test and RT-PCR test should also be considered. If RT-PCR is performed >48 hours after an antigen test, it is possible that the viral dynamics have changed during the time between antigen and RT-PCR and testing. Therefore, the antigen test may indicate a true infection even if the RT-PCR is negative.
- If an antigen test is presumptive negative, allow HCP to continue to work. The HCP should continue to monitor for symptoms, and serial testing should continue per [CMS recommendations](#) .

- Note: HCP who have recovered from SARS-CoV-2 infection in the past 3 months and are asymptomatic should [not be tested for SARS-CoV-2](#).

Notes:

*A COVID-19 outbreak response in a nursing home is triggered when a resident or HCP tests positive for SARS-CoV-2. An index infection in a resident should include SARS-CoV-2 infections that originated in the nursing home and should not include:

- Residents who were known to have COVID-19 on admission to the facility and were placed into [Transmission-Based Precautions](#).
- Residents who were placed into Transmission-Based Precautions on admission and developed SARS-CoV-2 infection within the 14-day period after admission.

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Content source: [National Center for Immunization and Respiratory Diseases \(NCIRD\), Division of Viral Diseases](#)