HealthCap
RISK MANAGEMENT SERVICES

SARS-CoV-2 Antigen Testing in Long-Term Care Facilities - CDC

Antigen tests are available as point-of-care (POC) diagnostics for SARS-CoV-2. Most have a rapid turnaround time, which is critical to the rapid identification of SARS-CoV-2 infection and implementation of infection prevention and control strategies. These tests can augment other testing efforts, especially in settings where testing capacity for nucleic acid amplification tests (NAAT), such as reverse transcriptase polymerase chain reaction (RT-PCR), is limited or testing results are delayed (i.e., >2 days). In general, these POC antigen tests ***have a lower sensitivity*** but similar specificity for detecting SARS-CoV-2 compared to RT-PCR tests. However, ***false positives have been identified***, particularly when users do not follow the instructions for use of the antigen tests or perform testing in low-prevalence populations (i.e., screening asymptomatic healthcare personnel (HCP) in non-outbreak settings).

This document pertains to antigen tests that have been granted a U.S. Food and Drug Administration's emergency Use Authorization (FDA EUA) to detect SARS-CoV-2. Antigen tests perform best when the person is tested within the first days of symptom onset when viral load is generally highest. There are limited data on antigen test performance in asymptomatic persons. Preliminary reports suggest that antigen tests have lower percent positive agreement with RT-PCR when performed in asymptomatic individuals compared to symptomatic individuals. However, given the transmission of SARS-CoV-2 from asymptomatic and pre-symptomatic LTCF residents and HCP with SARS-CoV-2 infection and the need for more timely testing results, 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 CMS's enforcement discretion regarding the Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver when using antigen tests in asymptomatic individuals.

When a confirmatory molecular test should be considered

As the sensitivity of antigen tests is generally lower than RT-PCR the FDA EUA recommends that negative POC antigen tests be considered presumptive. Clinical staff in LTCFs should consider when confirmatory NAAT, such as 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 must be considered.

- Test sensitivity varies 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 EUA range in reported 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 when testing is being conducted in a LTCF with an outbreak or within a high-prevalence community. These factors should inform the decision of whether confirmatory testing by NAAT is indicated following an antigen test.
- To understand the sensitivity of the confirmatory test, CDC recommends using a NAAT that has been evaluated against the FDA reference panel for analytical sensitivity.

If a confirmatory NAAT is performed within 2 days, people should be assumed to be infectious until the confirmatory test results are completed. For instance, in general, if a symptomatic resident tests presumptive negative by antigen test and a NAAT is performed, the resident should remain in Transmission-Based Precautions until the NAAT result is available. Similarly, if an asymptomatic HCP working in a LTCF without an outbreak tests antigen positive, they should be excluded from work until a negative NAAT 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 waive 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 may submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC's National healthcare Safety Network (NHSN). This CDC and CMS-preferred pathway to submit data to CDC's NHSN applies only to CMS-certified long-term care facilities. Test data submitted to NHSN will be reported to appropriate state and local health departments using standard electronic laboratory messages. Other types of LTC facilities may also report testing data in NHSN for self-tracking or to fulfill state or local reporting requirements, if any. While NHSN is the CDC and CMS-0preferred pathway, Medicare and Medicaid-certified LTC facilities may submit data through the other mechanisms described in the Current Methods of Submission section of HHS Laboratory Reporting Guidance to meet the reporting requirements.

Uses of antigen testing in long-term care facilities

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 or testing of asymptomatic residents or HCP who are known close contacts of persons with COVID-19 and
- Testing of asymptomatic HCP in facilities without a COVID-19 outbreak as part of expanded screening testing.

Testing in other circumstances are likely to occur, such as testing asymptomatic residents and HCP who were exposed to persons with COVID-19 outside the LTCF (i.e., 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 NAAT.

Considerations for interpreting antigen test results in long-term care facilities

Testing of symptomatic residents or HCP

If an antigen test is positive, no confirmatory test is necessary

- Resident 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.
- Confirmatory testing may be considered in some situations, including if there are other unexpected positive results from testing performed on specimens collected from other persons that were run on the same day or if the person has a low likelihood of SARS-CoV-2 infection (i.e., non-respiratory systemic symptoms soon after SARS-CoV-2 vaccine administration in HCP or LTF resident with no known exposures in a non-outbreak facility).

If an antigen test is presumptive negative, perform NAAT immediately (i.e., within 2 days)

- Symptomatic residents should be kept on transmission-based precautions and symptomatic HCP should be excluded from work until NAAT results return.
- Clinical discretion should be utilized to determine if people who test negative on such platforms should be retested with NAAT. Some antigen platforms have higher sensitivity when testing people within 5 days of symptom onset. In some instances, confirmatory testing may not be necessary if the individual has a low likelihood of SARS-CoV-2 infection (i.e., non-respiratory systemic symptoms soon after SARS-CoV-2 vaccine administration in a HCP or LTCF resident with no known exposures in a non-outbreak facility).
- Facilities should test for both influenza and SARS-CoV-2 if influenza and SARS-CoV-2 are circulating in the community.
- If antigen and confirmatory tests are negative and the individual resides or works in an outbreak facility, the confirmatory negative test does not affect implementation of appropriate precautions for facilities with an outbreak. Additionally, both residents and HCP should be serially tested every 3-7 days until no new cases are identified for 14 days.
- If antigen and confirmatory tests are negative and the person is a known contact, residents should remain in quarantine for 14 days from exposure and HCP should follow risk assessment guidance. Alternatives to the 14day quarantine period are described in the Options to Reduce Quarantine for Contacts of Persons with SARS-CoV-2 infection Using Symptom Monitoring and Diagnostic Testing. Healthcare facilities could consider these alternatives as a measure to mitigate staffing shortages, space limitations or PPE supply shortages. However, these alternatives are not a preferred option because of the special nature of healthcare settings (i.e., patients at risk for severe illness, critical nature of healthcare personnel, challenges with social distancing). See above guidance on use of antigen testing for this purpose and when a negative antigen test can be used to determine that a person is not infected with SARS-CoV-2.
- Symptomatic HCP who test negative for SARS-CoV-2 should continue work exclusion and return to work per institutional policy.

- NOTE If a reason 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 LTCF as part of an outbreak response* or those who are known close contacts of persons with COVID-19

If an antigen test is positive, perform confirmatory NAAT.

- Residents should be placed in transmission-based precautions in a single room or if single rooms are not available, remain in their current room pending results of confirmatory testing. They should NOT be transferred to a COVID-19 unit or placed in another shared room with new roommates. HCP should be excluded from work.
- In situations where the pre-test probability is high (i.e., facility with large outbreak, such as prevalence >20%, and the person resided with another infected person), the antigen positive test might not require confirmation and the individual should be treated as infectious.
- If confirmatory NAAT is positive, then resident should transfer to COVID-19 unit. HCP should remain excluded from work until they meet return to work criteria.

If an antigen test is presumptive negative OR if the antigen test is positive but the confirmatory NAAT (performed within 2 days) is negative:

- In facilities experiencing an outbreak, residents should be placed on appropriate transmission-based precautions. HCP should be allowed to continue to work with continued symptom monitoring. The facility should continue serial viral testing (antigen or NAAT) every 37 days until no new cases are identified in 14 days.
- If a person is a known close contact of a person with confirmed COVID-19, residents should remain in quarantine for 14 days from exposure and HCP should follow risk assessment guidance. Alternatives to the 14-day quarantine period are described in the Options to Reduce quarantine for Contacts of Persons with SARS-CoV-2 Infection Using Symptom Monitoring and Diagnostic Testing. Healthcare facilities could consider reducing the quarantine period as a measure to mitigate staffing shortages, space limitations, or PPE supply shortages; however, these alternatives are not a preferred option because of the special nature of healthcare settings (i.e., patients at risk for severe illness, critical nature of healthcare personnel, challenges with social distancing). See above guidance on use of antigen testing for this purpose and when a negative antigen test can be used to determine that a person is not infected with SARS-CoV-2.
- Note: Asymptomatic people who have recovered from SARS-CoV-2 infection in the past 3 months and live or work in a LTCF performing facility-wide testing should not be tested for SARS-CoV-2.

Testing of asymptomatic HCP in LTCF without an outbreak as part of expanded screening testing to reduce asymptomatic disease spread

CMS recommends serial testing of nursing home HCP at an interval based on local incident of COVID-19. Testing asymptomatic HCP in other LTCFs can be considered if resources are available; general guidance is available in the CDC Guidance for Expanded Screening Testing to Reduce Silent Spread of SARS-CoV-2.

- If an antigen test is positive, perform confirmatory NAAT within 2 days of the antigen test. Asymptomatic HCP who are antigen test positive but in an LTCF without an outbreak should be excluded from work but outbreak response, including facility-wide testing, can be delayed until confirmatory test results are completed.
    - If the confirmatory test is positive, then continue to 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, the antigen test should be considered a false positive and the HCP should return to work.
- If an antigen test is negative, allow HCP to continue to work. The HCP should continue recommended infection prevention measures (i.e., universal masking), monitor for symptoms and serial testing should continue per expanded screening testing strategy or 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:

**In general, a COVID-19 outbreak response in a LTCF is triggered when a resident or HCP tests positive for SARS-CoV-2. Among residents, this should include SARS-CoV-2 infections that originated in the LTCF 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 14 days after admission.*

https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html
January 7, 2021
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf
January 15, 2021
https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/expanded-screening-testing.html
December 3, 2020
https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-options-to-reduce-quarantine.html
December 2, 2020
https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html
December 14, 2020
https://www.cdc.gov/flu/professionals/diagnosis/testing-management-considerations-nursinghomes.htm
November 23, 2020
https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html
January 5, 2021