Preparing for Widespread Testing in Long Term Care

Testing residents and staff in long term care is vital to control the spread of COVID-19. This document contains guidance for providers on testing staff and residents. Navigate to a specific section by selecting it below:

- Who Should be Tested
- Types of Testing
- Limits of Testing and Caution on Assumptions from Results
- How to Access Testing
- Point-of-Care Antigen Test Devices
- Specimen Collection
- What to do When Residents Test Positive
- What to do When Staff Test Positive
- Reimbursement for Testing
- Legal Issues

Who Should be Tested

Providers should follow guidance from their state health departments regarding testing strategies for both residents and staff (who should be tested, at what frequency, resulting actions, etc.) It’s extremely important that providers document the guidance from state health departments and their efforts to obtain testing and meet that guidance.

In absence of state guidance, providers should consider CDC guidance on testing for COVID-19 in nursing homes. CDC has published the following guidance for testing in nursing homes, which is also applicable to other long-term care settings, such as assisted living.

- **CDC Testing Guidance for Nursing Home Residents**: This guidance addresses the appropriate use of testing among nursing home residents. It also and aligns with CMS’ reopening guidance for state and local officials.
- **CDC Guidance on Testing Healthcare Personnel**: This guidance addresses the appropriate use of testing among healthcare personnel.
- **CDC Guidance on Performing Facility-wide Testing in Nursing Homes**: This guidance is meant for both state health departments and nursing homes and addresses considerations for performing facility-wide testing among both nursing home residents and staff.
- **CDC Interim Guidance for Rapid Antigen Testing**: This guidance covers the use of rapid antigen test devices across settings, which includes long term care.
- **CDC FAQ on Testing in Nursing Homes**: CDC has also published frequently asked questions related to testing in nursing homes.
## Types of Testing

There are three types of tests currently available: molecular, antigen and serology.

<table>
<thead>
<tr>
<th></th>
<th>Molecular</th>
<th>Antigen</th>
<th>Serology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Also known as</strong></td>
<td>Polymerise chain reaction (PCR)</td>
<td>Yes</td>
<td>Antibody, IgM/IgG</td>
</tr>
<tr>
<td><strong>Does it diagnose active infection?</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>What does it do?</strong></td>
<td>Detect the RNA genetic material in the COVID-19 virus.</td>
<td>Identifies the presence of COVID-19 specific protein particles.</td>
<td>Detects antibodies made by the body to help recognize the virus.</td>
</tr>
<tr>
<td><strong>How is the sample collected?</strong></td>
<td>Principally nasal or throat swab or saliva collection but can be done on other body fluids.</td>
<td>Principally nasal or throat swab but can be done on other body fluids.</td>
<td>Principally blood test but can be done (rarely) in some labs on saliva.</td>
</tr>
<tr>
<td><strong>Where is the test conducted?</strong></td>
<td>Most currently available COVID-19 molecular tests are performed in a lab, with the exception of a few point-of-care tests on the market.</td>
<td>Most are done as point-of-care, meaning that it can be performed at any patient care setting with a CLIA waiver (such as a nursing home) but some are also done in commercial labs.</td>
<td>Either in a lab or point-of-care, depending on the methodology of the test.</td>
</tr>
<tr>
<td><strong>How long does it take to get results?</strong></td>
<td>If being tested in a lab, it generally takes 24-48 hours for results to return. However, many labs are backed up right now, causing delays in turnaround times.</td>
<td>Point-of-care antigen tests generate results immediately in as little as 15 minutes.</td>
<td>Point-of-care serology tests generate immediate results while lab tests generally take 24-48 hours.</td>
</tr>
<tr>
<td><strong>Is it accurate?</strong></td>
<td>Most molecular tests are highly accurate, which is why they are considered the “gold standard” for COVID-19 diagnostic tests but sample collection and process handling can drop the accuracy. Molecular tests can keep detecting RNA fragments after the person has recovered.</td>
<td>Antigen tests tend to be less accurate than molecular tests.</td>
<td>The accuracy of a serology test depends on the quality of the test. Check to make sure the test is FDA approved and has a very high specificity and sensitivity (e.g. 95% and above) before using.</td>
</tr>
<tr>
<td><strong>Is it possible to get a false positive (i.e. poor specificity)?</strong></td>
<td>Molecular tests tend to have a very high specificity, which means that a false positive is rare. However, equipment and user errors can cause false positives.</td>
<td>Antigen tests also tend to have a very high specificity, which means that a false positive is rare. However, equipment and user errors can cause false positives.</td>
<td>False positives may occur if the body has made antibodies to some other virus or protein in the past and if those antibodies are very similar to the COVID-19 antibodies. The likelihood of getting a false positive also relates to the prevalence of the disease in a population.</td>
</tr>
<tr>
<td><strong>Is it possible to get a false negative (i.e. poor sensitivity)?</strong></td>
<td>False negatives can occur when there is too little virus in the sample to be detected. This can happen when a good sample is not collected, or the person is too early in the incubation period to detect COVID-19.</td>
<td>False negatives are much more likely to occur with antigen tests, which is why there are limits on their use (see below). Proper device usage and sample collection is important to improving the sensitivity of a POC antigen test.</td>
<td>It takes time to make antibodies, so you may get negative tests if you test too early in the course of the virus.</td>
</tr>
</tbody>
</table>

---

1 Currently, the BD Veritor and Sofia2 are only two antigen tests with an EUA from the FDA. These devices are authorized only for nasal and nasopharyngeal collection.
Important: Per CDC guidance, providers should not use antibody tests in place of PCR or antigen tests. In their Testing Guidance for Nursing Homes, the CDC states “At the current time, antibody test results should not be used to diagnose someone with an active SARS-CoV-2 infection and should not be used to inform IPC action.” The role of antibody tests will evolve and will likely complement either PCR or antigen tests but at this time they are generally being used by public health officials and researchers to understand the extent of viral spread and the role of immunity following recovery.

Limits of Testing and Caution on Assumptions from Results

Test results capture the presence or absence of the virus at the time the specimen was collected. The person’s condition may change with subsequent exposure, and per CDC guidance, testing must be implemented in addition to recommended IPC measures.

Considering test results are not 100% accurate, nor do test results always identify when a person is actually infected due to the incubation period, AHCA recommends considering every interaction as a risk of potential transmission. This is why source control masks are recommended by CDC for all residents and staff during the pandemic.

Increased testing may result in an increase in confirmed cases. This increase may be due to the implementation of the new testing which provides new information about existing conditions. It does not necessarily indicate that the facility is experiencing an increase in the number of new cases of the virus.

How to Access Testing

First, contact your local or state health department to seek availability of tests. States with state-wide orders to test may have preferred vendors or specific guidance on testing protocols. Document your communications and the steps you take as a result.

In the absence of direction from the local or state health department, facilities can refer to AHCA/NCAL’s list of vendors who provide testing in nursing home settings using FDA approved tests. This list is continually updated as new vendors and testing opportunities are available, so please check back frequently.

HHS is undergoing an initiative to ship antigen point-of-care testing devices to all nursing homes across the country. See section on these test devices below.

Point-of-Care Antigen Test Devices

On July 14, Centers for Medicare and Medicaid (CMS) announced an initiative to distribute of point-of-care antigen COVID-19 testing devices to nursing homes across the country. Nursing facilities will receive one of two testing devices:

- Quidel Sofia 2 SARS Antigen FIA
- BD Veritor System for Rapid Detection of SARS-CoV-2
There are a few key cautions that nursing homes should understand before using these antigen tests, including:

- Nursing homes must have a Clinical Laboratory Improvement Amendments (CLIA) waiver to receive these test devices
- Due to the lower sensitivity and specificity of these test devices, not all state public health departments allow for their use, and many have certain requirements in place for using these tests appropriately. The CDC has published interim guidance for rapid antigen testing, which AHCA has summarized here.
- The CARES Act requires all laboratories with a CLIA certificate to report the results of every COVID-19 tests that they conduct (positives and negatives) to the appropriate state or local public health department. This is in addition to the reporting completed through the CDC NHSN website and other state reporting requirements. Nursing homes should contact their state/local health departments to identify options to align existing reporting to those agencies.

More information on what SNFs need to know before utilizing these devices can be found here.

**Specimen Collection**

The CDC Guidance on Performing Facility-wide Testing in Nursing Homes contains important consideration for specimen collection, including location/environmental considerations, PPE and cleaning. Providers should review this guidance before conducting facility-wide testing.

Providers should check with state regulations including scope of practice on who can collect these samples in nursing homes and also who can perform the tests if they are being done on site. CMS also indicates in their guidance that home health nurses are able to collect the specimen. Providers should also be sure to carefully follow the test instructions because specimen collection can impact the accuracy of the results.

**What to do When Residents Test Positive**

Residents who test positive for COVID-19 must be isolated and wear a source control mask until placed in isolation. Providers should explore cohorting with other positive residents, if possible.

Caution needs to be applied to actions after a new confirmed test in a resident, so it does not trigger unnecessary moving of the resident out of their existing room where exposure has already occurred. Providers should refer to AHCA/NCAL’s algorithm for testing and cohorting nursing home residents for more information.

AHCA/NCAL has also updated this guidance on what to do when COVID-19 gets in as COVID-19 is increasingly impacting nursing homes and assisted living communities. Due to the rapid progression of this virus, centers should assume it is already in their surrounding community and may be in their facility. This resource outlines four action steps facilities and communities
can take.

**What to do When Staff Test Positive**

Per CDC [Return to Work Criteria guidance](https://www.cdc.gov/coronavirus/2019-ncov/worksafety/covid-19-return-to-work.html), health care facilities must be prepared for potential staffing shortages and have plans and processes in place to mitigate them, including considerations for permitting health care providers (HCP) to return to work without meeting all return to work criteria outlined.

CDC refers to the [Strategies to Mitigate Healthcare Personnel Staffing Shortages](https://www.cdc.gov/coronavirus/2019-ncov/healthcare-workforce-strategies.html) for information which provides both contingency and crisis strategies. Contingency strategies apply when staffing shortages are anticipated and crisis strategies apply when staffing shortages are happening.

Facilities can activate these strategies based on their staffing situation and should document when they are activating these strategies with the reason why they were activated. Also, notify the local or state health departments of these actions. AHCA/NCAL summarized this guidance in more detail in a recent [member update](https://www.ahca.org/coronavirus/return-to-work/).

The CMS [Nursing Home Toolkit](https://www.cms.gov/medicare-coverage-database/details/nca-coverage-detail.aspx?N=0351175F0&Profile=NursingHome) also outlines state specific resources and strategies on a number of topics including Workforce and Staffing. Check with your state to see what additional resources may be available.

**Reimbursement for Testing**

**Medicare Coverage of Testing**

Medicare fee for service and Medicare Advantage plans will cover the cost of COVID-19 diagnostic (PCR) tests as long as the tests are used for diagnostic purposes. The excerpt from the [July 30 CMS MLN Matters](https://www.cms.gov/medicare-coverage-database/details/nca-coverage-detail.aspx?N=0351175F0&Profile=NursingHome) is as follows:

Starting on July 6, 2020, and for the duration of the public health emergency, consistent with sections listed in the CDC guidelines titled, “Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel,” original Medicare and Medicare Advantage plans cover diagnostic COVID-19 lab tests:

**Diagnostic Testing**

- Testing residents with signs or symptoms of COVID-19
- Testing asymptomatic residents with known or suspected exposure to an individual infected with SARS-CoV-2, including close and expanded contacts (e.g., there is an outbreak in the facility)
- Initial (baseline) testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2 is part of the recommended reopening process
- Testing to determine resolution of infection
Original Medicare and Medicare Advantage Plans don’t cover non-diagnostic tests.

Tests range in cost depending on which test you are using (point-of-care antigen vs. molecular) and which lab you are using. Medicare Part B will only reimburse approximately $100 for the PCR and $35 for other tests. Labs have promoted and physicians may order respiratory panel tests that include testing for COVID 19 and other respiratory illnesses. These tests range in cost from $375-$500. If a resident is under a Medicare Part A stay the facility will be responsible for the cost of the tests. It’s important to be aware of what tests are being ordered in your facility.

Not all labs will bill Medicare directly. AHCA recommends that, wherever possible, providers use labs that will bill Medicare. If a lab does not have the ability to bill Medicare, the facility will need to pay for the tests upfront and get reimbursed through Medicare Part B for the cost of the test. Guidance on billing and CPTs is located here. CMS has confirmed that health care providers and laboratories may bill Medicare and other health insurers for COVID-19 tests performed on or after February 4.

Whether all antibody tests will be covered is questionable. Due to the number of antibody tests with low reliability, Medicare and Medicare Advantage plans are being more cautious about reimbursement for these tests. It is likely that more guidance will be required on this issue.

Medicaid Coverage of Testing
Generally, state Medicaid plans should cover the cost of testing. However, since Medicaid is state by state, providers should contact their state about reimbursement and if they are supplying the tests.

CARES Act Grant Funds
The CARES Act Grant Funds can be used to cover costs for testing for resident tests that are not otherwise reimbursable. This does not include testing for residents under a Part A stay where it is included in consolidated billing. It is not clear if it can be used to cover the costs associated with testing staff, we are seeking additional clarification.

Health Plan Coverage
The CARES act requires health plans to cover the cost of COVID-19 diagnostic testing for beneficiaries at no cost to the beneficiary. However, group and individual health insurance plans are NOT required to cover testing when it’s related to return to work policies or public health surveillance.

CMS is requiring Medicare Advantage Plans to cover the costs of testing for MA plan beneficiaries when it is diagnostic in nature. Limitations on coverage for public health surveillance do exist. This includes waiving any applicable deductible.
Legal Issues

Resident Refusals
Residents that refuse to be tested for COVID-19 cannot be discharged involuntarily, unless the facility is otherwise incapable of caring for residents with a confirmed diagnosis of COVID-19. If residents refuse to be tested and follow infection prevention practices (e.g. stay in their room, use source control masks, etc.) then you may be able to discharge the person as a risk to others, but you should confer with the Ombudsman and state survey agency prior to taking such action. See the April 24 CMS QSO memo FAQs question #10 about discharging a resident against medical advice (AMA).

If a resident cannot be tested voluntarily (e.g., a resident with dementia who would have to be forcibly held by staff in order to be tested), forcible administration (e.g. use of restraints) of COVID-19 testing would violate regulations. We are seeking further guidance from CMS.

Employee Refusals
Finally, employers can require COVID-19 testing as a condition of employment. This includes terminating or not hiring a person who refuses a COVID-19 test. However, employers must make this a condition of employment and follow state requirements for making such a policy, which may include modifying employment contracts where applicable.