COVID-19 Testing Requirements in Nursing Homes

Frequently Asked Questions and Quick Links

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Type of Tests and Turnaround Times

Q. When does the rule go into effect?
A. This rule went into effect on September 2, 2020. CMS published this regulation as part of an interim final rule, which means that facilities need to begin complying with the regulation as soon as it is published. There is a 60-day comment period where the public is allowed to submit comments. CMS will then use those comments to publish a final rule. Facilities should anticipate having to perform ongoing COVID-19 testing for the foreseeable future.

Q. What type of testing can be used to meet this requirement?
A. Providers can use either PCR/molecular or antigen test to meet this requirement.

Q. Can I use an antibody test to meet this requirement?
A. No, an antibody is not a diagnostic test and thus, does not meet this requirement.

Q. Is the 48-hour turnaround from the time of specimen collection or the time of lab receiving results?
A. The CDC Testing Guidelines for Nursing Homes recommends that "*testing practices should aim for rapid turnaround times (e.g. less than 24 hours).*" From this guidance, it is our interpretation that the 48-hours is from the time the specimen is collected (or as close as possible). However, we recognize that many labs are interpreting this as 48 hours from the time they receive the specimen. This is something AHCA is working to verify with CMS and we also recommend that members reach out to their state survey offices with this question.

Routine Testing Requirements

Q. How do I find my testing frequency?
A. Facilities should test all staff based on the county positivity rate in the prior week. County rates of positivity are available on the [CMS COVID-19 Nursing Home Data website](#). Testing frequency based on county positivity rate is as follows:

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency[1]
Low	<5% (less than 5%)	Once a month
Medium	5%-10%	Once a week
High	>10% (more than 10%	Twice a week

Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above.

- If the county positivity rate decreases, the facility should continue testing at the higher frequency level for at least two weeks.
- If a county positivity increases, the facility should immediately adjust to that testing frequency.

Q. How often do I need to check my county rate?
A. CMS has recommended checking it every other week.

Q. Who am I supposed to test as part of routine staff screening?
A. In the [QSO memo 20-38](#), CMS defines staff as "includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff." Employees who do not work or enter the building (e.g. billing personnel) do not need to be tested.

Legally, we believe this requirement does not apply to delivery personnel, van drivers, attending physicians, family, visitors, who are not an employee, consultant or contractor. So many vendor personnel, other health care providers (e.g. hospice, pharmacy, therapy, housekeeping, dietary) are there as a result of a contract. The medical director would have a contract but attending physicians and specialists may not but could reasonably be assumed to fall under consultant role. Regardless of the legal arrangements, the purpose and intent of this rule is to prevent the entry and spread of the virus to staff or residents. So, if a person is entering the building (regardless of their job title or contractual relationship) and is going to interact with staff in the building on a regular basis, we recommend they be included in testing protocol. The testing of these nonemployees does not need to be conducted by the facility, but proof of testing should be provided.

The rule also is clear that it is the minimum requirement and facilities should assess their unique situation to establish their own testing policies. This might include testing individuals such as visitors, or considering using the adjoining county COVID-19 rates in their decision making if employees are living in the adjoining county.

Q. Can you provide examples of contractors, consultants, volunteers I am supposed to be testing?
A. Facilities are responsible for testing anyone entering the building who interact with either any staff in the building or residents, prioritizing those that are in the building regularly. This could include hospice workers, therapists, agency staff or medical directors. CMS has specifically identified that this this testing can be performed by the company that employ the individuals (e.g., the hospice provider), but the facility is responsible for ensuring this happens in the appropriate timeframe and documenting these results. The virus does not distinguish who it infects nor how it spreads based on the contractual relationship a person has with the facility. So people who are entering the facility and interacting with either staff or residents should be included.

Q. How often do I test when a staff person, contractor or consultant come in at frequency that is less than the testing requirement (e.g. a staff person who works monthly in a facility testing weekly)?
A. This is a question that we plan on clarifying with CMS. In the meantime, we would recommend members develop a policy around this and share it with their state survey office to ask if they agree with your approach. It is our recommendation based on the intent of the regulation that you should test individuals who come in at a lower frequency than the required testing every time they come into the building using the POC testing devices or that they have proof of recent test results. However, the approach you develop should be shared with the state survey office to make sure they agree.

Q. If an employee is on vacation for several weeks, do they need to continue to be tested within the weekly or twice weekly time frame?
A. Similar to the above, this is another question that still needs clarification from CMS. In the meantime, we would recommend members develop a policy that seem reasonable and meets the intent of the rule and then share it with their state survey office to verify your planned approach. It is our recommendation based on the intent of the regulation not to test staff who are on vacation or out of the building for an extended period of time, but ensure that you begin testing them as soon as they return. However, this approach should be verified with the state survey office.

Q. Can I use pool testing to meet the routine testing requirements?
A. CMS has not addressed this question directly. However, in reading the CMS QSO 20-38 memo, it is AHCA's understanding is that pooled testing will not meet this requirement for the following reasons:

1) The requirement for turnaround time for results is 48-hours: if you have a positive in your sample, you will have to retest within 48 hours of the original sample collection

2) If there are any positives in the pooled sample, all staff in that sample will have to be excluded from work until the samples are re-run individually
3) Pooled samples will make the documentation requirements complicated

Q. Do I have to perform weekly testing on staff who work from home?
A. No, as long as they do not come into the building, they do not need to be tested.

Q. Do I have to perform weekly testing on a consultant (e.g. a bookkeeper) who works in an office and has no contact with residents?
A. Yes. Even though that individual doesn't have contact with the residents, they do have contact with other staff and can spread the virus to residents through other staff members. Also, keep in mind that outbreak testing protects the health and safety of both residents and staff.

Q. do I have to test construction or lawn maintenance personnel who do not come into the building or do not interact with the staff or residents?
A. No, as long as they do not come into the building nor interact with residents or other staff if they do, they do not need to be tested.

Outbreak Testing Requirements

Q. If I am doing routine testing and a staff person tests positive, do I have to test everyone in the building or just the unit?
A. Yes, the CMS QSO 20-38 memo explains that outbreak testing requires testing all staff and residents in response to an outbreak (any single new infection). Continue to test all staff and residents that tested negative every 3-7 days until 14 days since the most recent positive result has passed. This testing is to be done facility wide.

Q. What is the time frame that triggers outbreak testing?
A. Per CDC guidance, the incubation period for COVID-19 is 14 days. This means any individual who has been in the facility within 14 days of developing symptoms and/or receiving a positive COVID-19 test (whichever comes first) would trigger an outbreak investigation.

Examples of situations that would trigger an outbreak investigation are below:
- A staff person or contractor/consultant who developed symptoms of COVID-19 while at work and then tests positive
- A staff person or contractor who worked on the 1st of the month, developed symptoms on the 10th of the month and then tested positive on the 15th
- A resident who has contracted COVID-19 while living at the facility
- A resident who was admitted from the hospital and had a test obtained in the facility three days after admission and it tests positive.

Examples of situations that would NOT trigger an outbreak investigation are below:
- A staff person is away on vacation for 16 days or longer and gets tested upon return before working and tests positive.

- A new admission who has a test performed in the hospital, but results come back after admission to the SNF. This would not be considered a new case.
- A contractor who comes to the building once a month (e.g. the consultant pharmacists) who has not been in the facility for three weeks but reports testing positive 4 days ago.

A resident admitted with known COVID-19 infection would not trigger an outbreak investigation.

If you are unsure whether a situation would warrant an outbreak investigation, we would recommend you contact your local state or local public health agency for guidance.

Q. If I cannot meet the 48-hour turnaround for tests, do I still have to initiate outbreak testing?
A. Yes, facilities must initiate outbreak testing even if they cannot meet the 48-hour turnaround requirement. They must document their efforts to obtain testing within 48-hours and need to contact their local/state public health department.

Q. If a non-direct staff member with no resident contact (e.g. a food service professional) tests positive for COVID-19, do we still need to initiative outbreak testing?
A. Yes. Even though that staff person doesn't have contact with the residents, they do have contact with other staff and can spread the virus to residents through other staff members. Also, keep in mind that outbreak testing protects the health and safety of both residents and staff.

Q. I have an outbreak on a specific wing or floor of my building. Do I need to test my entire building?
A. Yes. Outbreak testing is required for the entire building regardless of the physical structure.

Finding a Vendor for Testing

Q. Where can I find a list of labs that may be able to provide test results within 48-hours?
A. AHCA has a list of vetted lab vendors here. These vendors all use PCR tests and can provide results with a minimum 72-hour response time (some will be able to meet the 48-hours). AHCA is continually updating this list with new labs and as we receive feedback from members. If you have any feedback on working with any of these lab companies, or want to suggest a company for this list, please contact us at covid19@ahca.org.

Q. What are some considerations I should have in mind when choosing a lab vendor?
A. Providers should consider the following when selecting a vendor:
- Type of testing being used (must be antigen or molecular/PCR):
- Ability to provide results within 48-hours (CMS requirement)
- Supply availability (test kits for POC antigen devices or specimen collection kits)
- Ability to bill Medicare or Medicaid directly

Rapid Antigen Point-of-Care (POC) Tests

Q. Where is the list of facilities who will receive a rapid antigen POC test device?
A. The list of facilities who will receive a rapid Point-of-Care Antigen Test Device is located on the NHSN website: https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/

Q: What training is available for use with the rapid antigen POC devices sent by HHS?
A: The two rapid antigen point of care devices sent by HHS, the Quidel Sofia2 and BD Veritor System, have established training programs specific to long term care providers:

> ### Quidel Sofia 2
> https://togetheragain.quidel.com/
> This website is the source for all information regarding the Sofia 2 SARS Antigen FIA test. You can access:
> - Training – both online and live virtual training resources
> - Kit reordering instructions
> - Technical support
> - FAQ's
>
> This site was developed to ensure the success of the implementation of the Quidel Sofia 2 testing in your facility.
>
> ### BD Veritor ™ System
> https://www.bdveritor.com/
> This website provides access to all training and information long term care providers need to get started with the BD Veritor. Providers must log into the BD website to access training resources. If you need to establish an account, please complete the registration form by clicking on "Register yourself!"

Q. My facility is not on the list to receive a rapid POC antigen test device, who do I contact?
A. Please first contact your state CLIA office to ensure you have a CLIA waiver. If you have a waiver in place, you can then email CMS at LabExcellence@cms.hhs.gov to be added to the list. If you don't have a waiver you need to contact your state CLIA office to apply.

Q. Do I have to use my rapid POC antigen test device to meet CMS' testing requirements?
A. There is no requirement to use the rapid POC antigen test to meet the CMS testing requirements. If a facility can obtain PCR test results within 48-hours, it is fine for them to continue PCR testing.

Q. Am I allowed to use the rapid POC antigen test in routine testing of asymptomatic patients?
A. Yes. The key issue here is that the rapid POC antigen tests have received authorization for use on symptomatic patients. Using them on asymptomatic patients is considered "off-label"

use. However, in an effort to ensure access to rapid and reliable testing for nursing homes, the federal government is strongly encouraging these test devices for screening purposes. The CDC, FDA and HHS have all issued guidance to ensure providers can use the antigen POC test devices to meet all their testing requirements. Most recently, HHS issued guidance to allow the use of antigen tests for off-label person (e.g. use with asymptomatic individuals), to override any state restrictions and extended the PREP act for liability to providers who use these devices.

Q. Do I have to confirm all negatives with the rapid POC antigen test?
A. The short answer is only in certain situations. The CDC has published an algorithm/decision tree that clearly explains how to interpret Antigen test results in nursing homes. Additional links to CDC guidance on antigen testing are included in the links section below.

Q. Are there licensing requirements for the person who can perform the test on the antigen device?
A. CLIA regulations require proper training and proficiency in performing the test. Training information is listed above. However, your state may have additional scope of practice requirements, so please check with your state licensing offices for more information.

Specimen Collection

Q. Who can collect the specimen for COVID-19 testing?
A. CMS has largely been silent on this issue. We recommend providers follow scope of practice laws within their state to determine what license is necessary to collect specimens for COVID-19 testing.

Q. What requirements do I need to follow for specimen collection?
A. Facilities should refer to CDC's guidance on collecting, handling and testing clinical specimens. During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens. Please note workers handling collecting/handling specimens from potentially infected individuals are considered very high exposure risk per OSHA's Occupational Risk categorization.

How to Report Results

Q. How do I report results from my rapid antigen POC test device?
A. Providers must contact their state/local health department for guidance on how to report these test results. CARES Act requires all laboratories or provider settings who are performing COVID-19 tests with a CLIA certificate to report the results to the appropriate state or local public health department. Providers can also review the HHS laboratory reporting guidance and related FAQ's for more information, including what specific information must be submitted. The CDC laboratory reporting website also provides information.

Q. Do I have to report results if an external lab is processing our tests?
A. No, you only have to report results if you are performing the tests in your facility using a rapid antigen POC device.

Q. I am already reporting results to NHSN. Do I need to add any additional reporting in response to this regulation?
A. Only if you are using an antigen POC test device. If so, you will need to report the outcome of those tests (positive and negative) to your state/local health department. Providers must contact their state/local health department for guidance on how to report these test results.

Q. What should I do if my state health department doesn't have a method of receiving data from me for the required elements under the CARES Act?
A. We recognize that many states are building reporting systems from scratch and in a very short time frame. We think CMS will recognize that as well. We recommend that facilities maintain internal records of the 18 required elements and prepare to report them once your state develops a reporting mechanism. The 18 required elements can be found on the [CDC laboratory reporting website.](#)

How to Document Results

Q. How do I document results for staff and contractors?
A. CMS doesn't specifically indicate how those results should be documented. We recommend keeping a log of staff and contractors testing with all the required fields from the [QSO memo 20-38](#).

Staff Refusals

Q. What should I do with a staff person who refuses routine testing?
A. CMS advises that for staff persons who refuse routine testing, the facility should "follow its occupational health and local jurisdiction policies." We advise facilities to develop a policy that takes into account the safety of your residents and staff and propose it to your state survey office and local OSHA office to see if they agree that it will comply with this regulation.

Reimbursement for Testing

Q. What will Medicare ffs and Medicare Advantage cover related to COVID-19 testing?
A. Per CMS [guidance](#) from 8/26/20, Medicare ffs and Medicare Advantage will cover diagnostic testing for COVID 19. Diagnostic testing is defined as:

1. Testing residents with signs or symptoms of COVID 19.
2. 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)
3. 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
4. Testing to determine resolution of infection

Q. For providers using the rapid antigen POC devices, can they get reimbursed for test kits (after the initial supply provided by HHS runs out)?
The provider will have to pay up front for the new tests (those not supplied by CMS). However, they can bill Medicare for tests on residents under Part B stays. Under Part A the cost of the test is included in consolidated billing.

Q. Can I bill private insurance for staff testing?
A. If a facility is testing an employee the insurance company will likely assess for medical necessity. Being symptomatic or being exposed to someone with COVID-19 may meet medical necessity criteria. If the testing is being done as a requirement of work (i.e. routine screening), the insurance company to deny it.
Insurance companies have also been told they have to allow out of network provider use during the PHE to enhance access to COVID care and prevention. So, if the nursing facility/lab is out of network that should not be a reason for denial. We recommend that members bill private insurance but understand they may get a denial based on medical necessity or testing related to work.

Clinical Considerations

Q. How do I determine when an infection has been resolved?
We refer providers to CDC's guidance for resolution of infection. CDC guidance recommends a symptom-based strategy rather than a test-based strategy to define recovery. This is because there is long term shedding of RNA particles that are picked up by PCR tests, which causes false positives in the post recovery period.

Q. Can I use an antibody test to determine what staff do not have to be tested as part of this requirement?
No, antibody testing cannot be used to modify testing strategies at this time.

Q. If an individual (resident or staff) has recovered from COVID-19, do I need to continue testing them?
A. Based on CDC recommendations, individuals who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Testing should start again 3 months after the date of symptom onset.

Links to Additional Resources

AHCA Resources:
- **Testing Vendors (Labs) with 48-hour turnaround times**

- **AHCA Summary of CMS' Testing Requirements**

- **AHCA Guidance on How to Get Started with Testing**

- **AHCA Member Webinar on CMS' New Testing Requirements**

- **AHCA Member Webinar on Batch Testing with the Quidel Sofia2**

- **AHCA Guidance on Point of Care Antigen Test Devices**

- **AHCA Summary of CDC Guidance for Rapid Antigen Testing**

CDC Resources
- **Interim Guidance for Rapid Antigen Testing for SARS-CoV-2**

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

- **Considerations for Interpreting Antigen Test Results in Nursing Homes Algorithm/Decision Tree**

- **Frequently Asked Questions about COVID-19 for Laboratories: Interpreting Results of Diagnostic Tests**

CMS and FDA Resources
- **CMS Interim Final Rule**

- **CMS Sub-Regulation**
  - **QSO 20-38-NH**
  - **QSO 20-37-NH**

- **CMS COVID-19 Nursing Home Data**
  - Download the latest POC allocation list, FAQs, and county positivity rate list

- **CMS FAQ on COVID-19 testing at Skilled Nursing Facilities and Nursing Homes**

- **FDA FAQ on Testing for SARS-CoV-2**

- **CLIA FAQ**