Nursing Home COVID-19 Testing FAQs

1. Q: CMS posts county positivity rates for staff testing. What if my state or county also posts rates of COVID-19 positivity for each county?

A: If a county or state also publicly posts county test positivity rates of COVID-19 in addition to the rates posted on the CMS website (Nursing Home Data), facilities may use those rates to trigger their staff routine testing as long as they are based on a similar methodology used by the CDC and the rates are posted on the same or more frequent basis as CMS. In such cases, facilities should document the source, date, and rate used to trigger staff testing based on CMS guidance. Facilities should also continue to use the same source for determining testing (i.e., do not switch sources from week to week).

2. Q: Should nursing homes use the percent positivity rate or the color-coded positivity classification to determine their frequency for routine testing (i.e., twice a week, weekly, or monthly)?

A: A nursing home should use the color-coded positivity classification published on CMS's website to set its testing frequency, which CMS updated during the week of September 14, 2020. The indicator now includes 14 days of data instead of 7 days. Further, because there are instances where counties with high test positivity rates may reflect low testing levels rather than high levels of viral transmission, additional criteria were added to re-assign counties with low testing volume to lower nursing home staff testing tiers. Nursing homes may set their testing frequency based on the color-coded reassigned positivity classification (i.e., Green corresponds to Low, Yellow corresponds to Medium, and Red corresponds to High).

3. Q: Given CMS' modifications to the methodology for test positivity to include two weeks of data, do I still have to wait two weeks to reduce testing frequency?

A: Yes. Nursing homes should continue to wait until the county positivity rate has remained at the lower activity level for at least two weeks of data before reducing testing frequency. If, for example, your county positivity rate drops from yellow to green, you would need to wait two weeks at the "green" level before reducing your testing frequency.

4. Q: Should facilities always perform outbreak testing for all residents and staff when a new COVID-19 infection is identified?

A: In general, yes. However, there may be limited situations where it would be acceptable to not test all residents and staff that previously tested negative. For example, if the individual staff member was not exposed at work, but rather, was exposed to COVID-19 outside of work (e.g., a wedding, on vacation), and they did <u>not</u> enter the nursing home while potentially infectious, then additional interventions and testing at the facility would not be necessary while the staff member was restricted from the facility.

If testing supplies are limited, facilities should prioritize individuals with signs and symptoms of COVID-19 first, and then perform testing triggered by an outbreak focusing on individuals or units with the highest likelihood of exposure. More information on strategies can be found in CDC's <u>Clinical Questions about COVID-19</u>: <u>Questions and Answers</u> (see "Testing in Nursing Homes" section).

5. Q: Can staff be tested by a different entity than the nursing home?

A: Yes, staff can be tested at a different location or by a different entity. However, pursuant CMS memorandum QSO-20-38-NH, if staff is tested from another source, "the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency based on the county COVID-19 positivity rate." For example, a medical director or nurse practitioner who works in multiple facilities and is tested elsewhere can use those test results as documentation that testing was completed.

6. Q: Some staff or care providers do not come into the facility each week; do I have to test them at the same frequency as all staff? For example, do they need to come into the facility just to be tested?

A: It is important to remember that our requirements and policies are aimed broadly at reducing the risk of transmission of COVID-19, and facilities should implement these policies to the best of their ability. For example, staff that do not work in the facility routinely do not need to come into the facility just to be tested. In these scenarios, facilities can fit these staff into their testing schedule the next time they enter the facility.

A similar approach should be applied to how quickly facilities test staff who come to the facility infrequently. Ideally, these staff should be tested and obtain results prior to entering the facility. However, if that is not possible, such as due to a delay in test results, facilities may allow staff who do not have signs or symptoms of COVD-19 and have not had any known exposure to COVID-19 to enter the facility and work until test results are available, as long as staff have appropriate PPE and follow infection control protocols.

Facilities have the flexibility to schedule staff and resident testing in a way that best suits their needs, as long as testing is conducted according to the testing frequency indicated by their county's positivity classification and is documented. This may include a staggered approach to testing (e.g., testing multiple days per week, such as Unit A on Monday, Unit B on Tuesday, etc.) to ensure all staff are tested. Similarly, in the case of monthly testing, the facility may employ a staggered approach, such as testing a number of employees each week to meet the monthly testing frequency. If this approach is used, the facility should ensure staff are being tested in monthly intervals and testing dates tracked to ensure that all staff are tested.

We also state in QSO-20-38-NH: "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." As with most policies, CMS cannot describe every type of situation that may occur in a facility or every type of individual that provides services for residents, such as individuals that work irregular schedules or individuals that work for different types of vendors. For example, if testing resources are limited, facilities should prioritize testing an individual from a vendor that comes into the facility each week, over an individual vendor that is coming to the facility for one isolated or ad hoc service.

7. Q: What is a false positive Point of Care antigen test result and what should we do if we potentially have one?

A: A "false positive" is a test result indicating the infection is present when it is not, and can occur with all types of tests including but not limited to the point-of-care antigen tests. The CDC has provided guidance to nursing homes regarding the use of these devices. See CDC's Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes, Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, and Clinical Questions about COVID-19: Questions and Answers (see "Testing in Nursing Homes" section).

If a resident or staff has signs or symptoms of COVID-19 and the antigen test is positive, a confirmatory test (e.g., reverse-transcriptase polymerase chain reaction (RT-PCR) or different antigen test platform) is not recommended. A facility should immediately initiate outbreak response and treat the staff and resident as having COVID-19.

If a resident or staff is asymptomatic and has a positive antigen test result, then the facility should perform a confirmatory test. While the results of the confirmatory test are pending, the facility should take the following actions:

Start infection prevention steps for staff and resident:

- For any staff with pending confirmatory tests, restrict entry to the facility.
- For residents with a pending confirmatory test, the resident should be placed on transmission-based precautions (TBP).
- Asymptomatic residents should not be placed in a "COVID-19 unit or cohorted with other COVID-19 positive individuals" pending a confirmatory test result.

Delay outbreak testing pending confirmatory tests:

If the positive test would indicate an onset of COVID-19 that would trigger facility-wide outbreak testing, the facility may delay outbreak testing until the results of the confirmatory test are received. If the confirmatory test result is positive, the facility should immediately initiate outbreak testing.

Wait to initiate reporting to residents, their representatives, and families:

In cases where the confirmatory test is pending, the facility may wait until COVID-19 infection is confirmed to notify all residents, their representatives, and families as required at 42 CFR § 483.80(g)(3), unless there are three or more suspected cases within 72 hours of each other.

8. Q: What steps can be taken to reduce the potential for false-positive antigen tests?

A: False positive results can occur for a variety of different reasons and, including both inherent limitations in test performance characteristics and failure to follow manufacturer's instructions for use. Examples of issues that may result in false positive results include but are not limited to the following:

- failure to change PPE between collection of specimens from different patients
- inadequate or inappropriate sample collection
- cross-contamination with positive samples after collection

- use of inappropriate transport media
- storing a sample for longer than is recommended before testing
- interpretation of results beyond the recommended incubation time for the test
- excess blood or mucus on the swab specimen may interfere with test performance
- exposure of the test cassette to ambient environment before use

Facilities should follow the manufacturer's Instructions for Use (IFU)/package insert. Visit CDC's Guidance for SARS-CoV-2 Point of Care Testing webpage for best practices when performing these types of tests (https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html).

9. Q: What if a facility is trying to comply with the testing requirements, but is unable due to factors outside of its control?

A: We understand that some facilities may experience difficulty meeting the testing requirements. However, we expect all facilities to engage in good faith attempts to meet these requirements, such as contacting the state health and emergency management departments and testing supply vendors. If, after continuing to attempt the meet the requirements, a facility cannot due to factors outside of their control, the facility should document their attempts. Pursuant to our guidance QSO-20-38-NH, "[i]f the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources."

10. Q: Do individuals providing emergency medical services (EMS) need to be tested?

A: While the regulations require facility staff, including individuals providing services under arrangement to be tested, it is a high priority for EMS staff to attend to the emergency which they were called to address. Therefore, in emergencies, facilities should allow EMS personnel to enter the facility immediately without being tested or screened. This practice should also be applied to other emergency personnel, such as police or firefighters.

Personnel who are providing non-urgent transportation (e.g., for scheduled medical appointments) are considered to be providing services under arrangement and should be tested at a frequency consistent with the facility's routine testing frequency.

11. Q: What does the 48-hour turn-around time mean?

A: A 48-hour turn-around time noted in QSO-20-38-NH refers to the time between when the specimen is collected and when the test result is received by the nursing home. However, it is important to remember that the intent of the 48-hour timeframe is for rapid identification of COVID-19 cases to prevent and limit transmission of the virus. CMS expects facilities to focus on obtaining test specimens and results as quickly as possible, to enable prompt action to prevent transmission not necessarily exactly meeting the 48-hour timeframe. For example, if a facility receives test results back in 50 or 52 hours, which enables the facility to implement the necessary actions to prevent the spread of COVID-19, this would be

acceptable. If the 48-hour turn-around time cannot be met due to community testing supply shortages, or limited access to or inability of laboratories to process tests within 48 hours, the facility should conduct testing using available resources, notify the local and state health departments, document its efforts to obtain quick turnaround test results with the identified laboratory or laboratories, and continue to seek resources to enable testing according to the guidance. We expect facilities to make a good faith effort to meet the 48-hour turnaround time and document their effort.

12. Q: When a facility admits a new resident with COVID-19, does that trigger outbreak testing?

A: No. Outbreak testing is only triggered when a new case of COVID-19 is identified in the facility among residents or staff that were not previously known to have COVID-19. Nursing home-onset COVID-19 refers to COVID-19 infections that originated in the nursing home. Pursuant CDC's <u>Testing Guidelines for Nursing Homes</u> (see definitions at bottom of page), it does not refer to:

- Residents who were known to have COVID-19 on admission to the facility and were placed into appropriate Transmission-Based Precautions to prevent transmission to others in the facility.
- Residents who were placed into Transmission-Based Precautions on admission and developed COVID-19 infection within 14 days after admission.

For example, facilities with dedicated units or floors for accepting COVID-19 admissions do not need to engage in outbreak testing when an individual with COVID-19 is admitted. Similarly, COVID-19-only facilities would not fall into the criteria of outbreak testing, since all of the admissions to the facility are residents with confirmed COVID-19. Routine testing of staff should still be conducted at the testing frequency that corresponds with the facility's county positivity rate classification.

Additional Resources:

- CMS memorandum for nursing homes: <u>Interim Final Rule (IFC)</u>, <u>CMS-3401-IFC</u>, <u>Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool (8/26/20)
 </u>
- CMS memorandum for Clinical Laboratory Improvement Amendment (CLIA) laboratory reporting requirements: <u>Interim Final Rule (IFC)</u>, <u>CMS-3401-IFC</u>, <u>Updating Requirements for Reporting of SARS-CoV-2 Test Results by CLIA of 1988 Laboratories</u>, and <u>Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (8/26/20)</u>
- CMS: FAQs About COVID Testing in Skilled Nursing Facilities (PDF) (8/5/20)
- CDC: COVID-19 Testing Resources for Nursing Homes
- FDA: FAQs on Testing for SARS-CoV-2
- CMS (CLIA) FAQ on antigen testing of asymptomatic individuals: <u>Point of Care Antigen</u> Testing FAQ (8/31/20)

| • | CMS memorandum for nursing homes: <u>Nursing Home Visitation - COVID-19</u> (9/17/20) |
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