CMS Testing Requirement Summary

Revised April 30, 2021

LTC Testing Requirements

Interim Final Rule with comment period will be published and effective on September 2. The Interim Rule establishes requirement to Report COVID-19 Test Results During the Public Health Emergency but best to turn to QSO-20-38-NH-Revised for the specific guidance.

QSO Memo includes Guidance to meet new testing requirements and revises the Focused Infection Control Survey tool to incorporate these new requirements as well as the requirement to have a designated infection preventionist and other COVID-19 guidance updates. (New portions of survey italicized.)

The new testing requirements of 483.80(h) will be cited under new tag F886.

Nursing homes may meet testing requirements through the use of point-of-care testing devices or through off-site laboratory testing. Only antigen tests and nucleic acid tests are acceptable; antibody tests will not meet requirements. Tests that are processed at an off-site laboratory must return results within 48 hours.

Definition of Staff

Staff are considered any individuals who are employed by the nursing home, who volunteer for the nursing home, or who provide services as part of an arrangement with the nursing home. This could include hospice workers, caregivers, or students participating in a nurse aide training and competency evaluation program. If staff receive testing off-site, such as contracted staff receiving testing through their employer, the nursing home must obtain documentation to verify that testing requirements have been met. Residents' visitors are not included in this definition.

Test Order Requirement

Recall that a nursing home must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with State law, including scope of practice laws, for COVID-19 testing. This may be accomplished through the use of physician-approved policies, such as standing orders, or other means as specified by scope of practice laws and individual nursing home policy.

Trigger Testing

Symptomatic: Nursing homes must test all staff and residents who show symptoms consistent with COVID-19 (regardless of vaccination status).

Outbreak*: Nursing homes must initiate outbreak testing procedures in response to one new confirmed case among staff or one new confirmed nursing home-onset case among residents. During outbreak testing, all residents and staff (regardless of vaccination status) must receive an initial test. Nursing homes must implement appropriate response for all who test positive,

including cohorting and implementing transmission-based precautions for residents, including those who are asymptomatic and tested positive, and restriction from work for staff, including staff who are asymptomatic and tested positive. Nursing homes must continue testing all residents and staff who test negative every 3-7 days until 14 days have passed since the last positive test result.

Exposure*: Asymptomatic staff with a higher risk exposure and patients or residents with prolonged close contact with a positive case should have a series of 2 viral tests, immediately after exposure and 5-7 days later (regardless of vaccination status).

Routine Staff Testing*

Nursing homes must conduct routine testing of all unvaccinated staff according to community prevalence. ***In order to determine testing based on community prevalence, nursing homes must monitor the nursing home site at data.cms.gov at least every other week for the positivity rate of the county in which the nursing home is located.***

If the county positivity rate increases, the nursing home must immediately increase testing for the appropriate frequency. If the positivity rate for the county decreases, the lower positivity rate must be sustained for a period of 2 weeks before the nursing home can reduce testing to the appropriate frequency. The county positivity rate will determine the frequency of routine unvaccinated staff testing as follows:

Routine Testing Intervals Vary by Community COVID-19 Activity Level

Community COVID-19 Activity	**County Positivity Rate in the Past Week**	**Minimum Testing Frequency**
Low	< 5%	Once a month
Medium	5% - 10%	Once a week*
High	> 10%	Twice a week*

*This frequency presumes availability of Point-of-Care testing on-site at the nursing home or where off-site testing turn-around time is < 48 hours.

The testing frequency outlined above represents minimum testing requirements. Nursing homes may choose to increase routine testing frequency based on other factors including state or local mandates, community prevalence in neighboring counties, or community prevalence in a county or counties where a significant portion of staff live. Since this represents the minimum testing requirements, nursing homes may choose to continue to routinely test all staff, regardless of vaccination status.

*For testing purposes, whether triggered or routine, residents and staff that have previously recovered from COVID-19 within the last 90 days should not be re-tested unless they develop symptoms consistent with COVID-19.

Staff and Resident Refusals of Testing

Nursing homes must have a plan for residents and staff who refuse testing or are unable to be tested. For symptomatic residents who decline testing or asymptomatic residents who decline testing during an outbreak, the nursing home should use a person-centered approach to address concerns and questions, provide education, and discuss potential alternatives, such as alternative specimen collection methods. If the resident continues to decline testing, the nursing home should do the following:

- For symptomatic residents, implement transmission-based precautions until the resident meets criteria for **discontinuation of transmission-based precautions**.
- For asymptomatic residents, the nursing home should exercise extreme vigilance, such as through additional monitoring, to ensure the resident maintains distance from other residents, wears a face covering, and practices effective hand hygiene until outbreak testing is complete.

The nursing home should address staff who refuse testing as follows:

- For symptomatic staff, restrict the staff member from work until he/she meets **return-to-work criteria**.
- For asymptomatic staff who refuse testing during an outbreak, restrict the staff member from work until outbreak testing is complete (regardless of vaccination status).
- For asymptomatic, unvaccinated staff who refuse routine testing, refer to occupational health and local jurisdiction policies.

Procedures for When Requirements Cannot Be Met

Nursing homes that are unable to meet testing requirements due to emergency situations, such as community testing supply shortages, limited access, or inability of laboratories to process test results within 48 hours, must contact the state/local health department for assistance.

Other Testing Considerations

Consistent with **CDC recommendations**, nursing homes are not required to re-test asymptomatic individuals who have recovered from COVID-19 within the past 3 months. Testing should resume as required 3 months after symptom onset (or date of positive test if asymptomatic) of the initial illness. In other words, an individual who first showed symptoms on June 1 and was confirmed positive for COVID-19 does not need to be re-tested until after September 1, provided the individual remains asymptomatic.

Nursing homes should continue screening for fever and symptoms all residents, staff, and any visitors who may enter the nursing home, despite any ongoing testing. Nursing homes should refer regularly to the **CDC guidance** for the most up-to-date list of COVID-19 symptoms.

PPE Use for Testing

For providers collecting specimens or within 6 feet of patients suspected to be infected with SARS-CoV-2, 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.

Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, and eye protection. If needed, additional

precautions can be used, such as a surgical mask or face shield, or other physical barriers, such as a splash shield to work behind.

Change gloves after adding patient specimens to the instrument.

Training

Training on the Use of Devices Training for the use of the point-of-care devices is available online at the corresponding brand's special nursing home concierge site. For Quidel Sofia and Sofia 2 machines: https://togetheragain.quidel.com/. For BD Veritor machines: https://www.bdveritor.com/long-term-care-facilities/system-overview/.

Testing Documentation Requirements

All testing must be documented. For residents, testing must be documented in the resident's medical record. Staff testing must be documented in the personnel file. All documented test results must be maintained according to standards for personal health information (PHI). Documentation should include the following information:

- For testing of symptomatic residents/staff: date and time of symptom onset, when the resident/staff was tested, the result of the test, and actions taken.
- For testing of asymptomatic residents/staff in response to an outbreak: date the triggering case was identified, date all residents and staff were tested, dates of subsequent retests, and results of all tests.
- For routine testing of staff: applicable county positivity rate, corresponding test frequency, date the positivity rate was collected, date of rests conducted, and results.
- For any resident/staff who refuse or are unable to participate in testing: document the nursing home's policy on refusals, any residents/staff who refuse or are unable to be tested, and how those issues were addressed.

Test Result Reporting

Recall that nursing homes must report all tests conducted in the nursing home using a point-of-care testing device according to **Clinical Laboratory Improvement Amendments (CLIA) requirements**. ***This includes reporting all tests within 24 hours to the state or local health department. Nursing homes that fail to comply with CLIA reporting requirements will be imposed a Civil Money Penalty (CMP) of $1,000 for the first day of non-compliance and $500 for each additional day of non-compliance up to $10,000.***

Nursing homes must also continue reporting COVID-19 data directly to CDC through the National Healthcare Safety Network (NHSN) system on a weekly basis. Nursing homes that fail to comply with NHSN reporting requirements will be imposed a CMP of $1,000 for each week of non-compliance, with an incremental increase of $500 per week of noncompliance. So, for example, failure to report for one week will result in a $1,000 CMP. Failure to report for a second week will result in a CMP of $1,500, and a CMP of $2,000 for the third week, up to $6,500.

Lastly, nursing homes must report all positive COVID-19 test results to the state/local entity for contact tracing. Additional details covered in **QSO Memo 20-37-CLIA,NH**.

IDPH Antigen POC Testing Guidance

IDPH released LTC Antigen Testing Guidance on January 7, 2021. Key elements include:

- To perform test, must have CLIA certificate of waiver. Contact SHL at 319-335-4500 with questions.
- All staff testing must read the package insert and document that they have done so. The procedure detailed in the insert must be followed exactly and safety guidance should be followed. (LAI recommends documenting additional video training that staff may be doing about the system through the manufacturer's web site.)
- Reports of both positive and negative test results are required.
- A biosafety risk assessment must be performed before testing is performed. Use appropriate PPE to perform the test. Clean and disinfect the area around the instrument after each test.
- If a negative test result is received for a resident or staff member for whom COVID infection is highly suspected, IDPH and SHL recommend conducting a confirmatory diagnostic PCR test.