



QSO Memo 20-38-NH: Complying with 483.80(h) Testing of Staff Regulations and New F-tag (F-886)

CMS today issued a [QSO memo 20-38](#) that outlines details on how to comply with new interim final rule 483.80(h) requiring COVID-19 testing of staff. We recommend members read the entire QSO memo, as this regulation goes into effect as soon as the interim final rule is published in the Federal register. This will likely be in the next three to seven days.

Type of Tests

- Either PCR or Antigen tests can be used to comply with this regulation.
- Antibody tests do not meet the requirements under this regulation.

Facility Staff Definition

- Facility staff includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility. It also includes students in the facility's nurse aide training programs or from affiliated academic institutions.

Testing Frequency

- There are three triggers for testing: symptomatic, outbreak and routine/surveillance.
 - **Symptomatic Testing:** Test any staff or residents who have signs or symptoms of COVID-19. Facility must continue screening all staff, residents and other visitors.
 - **Outbreak Testing:** Test all staff and residents in response to an outbreak (defined any single new infection in staff or any nursing home onset infection in a resident). Continue to test all staff and residents that tested negative every three days to seven days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result.
 - **Routine Testing:** Test all staff based on the extent of the virus in the community, using CMS' published county positivity rate in the prior week as the trigger for staff testing frequency (see table below):
 - CMS will publish reports of COVID-19 county-level positivity rates [here](#).
 - Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency accordingly.
 - If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks before reducing testing frequency.
 - If a county positivity increases to a higher level of activity, the facility should immediately adjust to that testing frequency.

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 turnaround time is <48 hours.**

- Important notes on the criteria established above:
 - The guidance on frequency represents the minimum testing expected. Facilities may consider other factors.
 - State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission.
 - Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstances, such as the identification of a confirmed COVID-19 case in the facility.
 - For individuals who test positive for COVID-19, repeat testing is not recommended. Staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after the date of symptom onset.
 - Facility staff can be tested elsewhere (e.g. by another employer) **if** it is completed in the same timeframe and the results are documented by the facility.

Test Shortage/Availability

- If the 48-hour turn-around time to get tests done cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should have documentation of its efforts to obtain quick turnaround test results with the identified laboratory or laboratories **and** contact with the local and state health departments.

Refusals of Tests

Staff refusal: Facilities must have procedures in place to address staff who refuse testing.

Procedures should ensure that:

- staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met.
- If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed.
- The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuse routine testing.

Resident Refusal: Facilities must have procedures in place to address residents who refuse testing that ensure:

- residents who have signs or symptoms of COVID-19 and refuse testing are placed on TBP until the criteria for discontinuing TBP have been met.

- If outbreak testing has been triggered and an asymptomatic resident refuses testing, the facility should be extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene until the procedures for outbreak testing have been completed.

Documenting Test Results

Facilities must document the following to demonstrate compliance with this regulation:

- For symptomatic testing of residents and staff:
 - Document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- For outbreak testing:
 - Document the date the case was identified, the date that all other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests.
- For staff routine testing:
 - Document the facility's county positivity rate, the corresponding testing frequency indicated (e.g., every other week), and the date each positivity rate was collected. Also, document the date(s) that testing was performed for all staff, and the results of each test.
- Document the facilities procedures for addressing residents and staff that refuse testing or are unable to be tested and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.
- When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.
- For facility staff tested elsewhere, documentation must be obtained showing the testing was completed under the same time frame

Conducting Testing

- The facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with State law, to do the tests for both PCR and antigen testing (including point of care (POC)) testing devices.
 - Facilities may use standing orders.
- Facilities must conduct testing according to nationally recognized guidelines, outlined by the Centers for Disease Control and Prevention (CDC) and for POC testing per the manufacturers package inserts.
- 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.
- Facilities must have a current CLIA certificate appropriate for the level of testing performed within the facility.

Reporting Test Results

- Facilities conducting POC tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all individual tests completed. For additional information on reporting requirements see: [Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes.](#)
- For test results obtained from outside labs, facilities must report to CDC NHSN for all positive tests and follow local health departments.

Documenting compliance with F-886

- Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886.
- Enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.
- If 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.

COVID-19 Focused Survey for Nursing Homes

- CMS has also revised the focus surveys for nursing homes to ensure compliance with testing requirements, infection prevention standards and compliance for infection preventionists.
- Members are encouraged to review the new tool at the end of the QSO memo.

QSO Memo 20-37-NH: Requirements of Reporting by Clinical Laboratory Improvement Amendments (CLIA) Certified Labs

CMS today issued a [QSO memo 20-37-NH](#) that outlines details on CLIA requirements for the use of COVID-19 Point of Care testing devices in nursing homes based on the new **Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency**

CLIA Lab Reporting Requirements

- Nursing facilities with CLIA waivers that are performing SARS COV 2 testing are required to follow the outlined reporting requirements. Penalties will be assessed for reporting non-compliance.
- Additionally, 5 percent of Certificate of Waiver labs will receive on site surveys throughout the remainder of the PHE. The survey will determine compliance with reporting requirements and use of appropriate CLIA certificate.
- Labs failing to comply with reporting requirements will receive mandatory citation. Labs with CLIA Certificates of Waiver will receive the new D1002 tag for noncompliance with reporting SARS-CoV-2 waived testing results.
- Civil monetary penalties (CMP) will be applied in the amounts of \$1,000 for the first day of noncompliance and \$500 for each subsequent day.
- Nursing facilities not in compliance with mandatory reporting of COVID data to the CDC and NHSN will also receive a CMP starting at \$1,000 for the first occurrence and increasing by \$500 for each subsequent occurrence. Compliance with reporting requirements will be assessed weekly. Plans of correction for incidents of noncompliance are not required. This regulation will remain in place until 1 year after the end of the PHE.