CMS Testing Mandate: How to Get Started

CMS Requirement

The Centers for Medicare and Medicaid (CMS) has issued an interim final rule with requirements for routine COVID-19 testing in nursing homes. CMS issued two subsequent QSO memos: QSO memo 20-38 which establishes criteria for testing and QSO memo 20-37 which contains guidance on CLIA reporting requirements for rapid antigen testing.

The interim final rule goes into effect on September 2, 2020.

When and Who to Test

There are three triggers for testing:

Symptomatic Testing: Screen all staff, residents and other visitors, and test any staff or resident with symptoms of COVID-19.

Outbreak Testing: Test 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.

Routine Testing: Test all staff based on the extent of the virus in the community based on CMS' published county positivity rate in the prior week.

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

[1] 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.

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Steps to get Started

1. Determine Testing Frequency

Providers should refer to the when and who to test section above and CMS' published county positivity rate to understand the frequency of testing.

Facilities must monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust testing frequency accordingly.

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.

2. Establish Testing Vendor

Facilities must establish a vendor to supply or perform tests. This could include commercial laboratories, public laboratories or rapid point of care (POC) antigen tests.

AHCA has a list of labs that can provide tests with a 48-hour turnaround time. Facilities should also contact their local or state health department to seek guidance.

In determining the most appropriate source, facilities should consider:

- ✓ Type of testing being used (must be antigen or molecular/PCR):
  - Important note: antibody tests cannot be used to meet this requirement.
  - While antigen tests are appropriate for use in meeting the CMS testing requirements, select states have restrictions due to their lower sensitivity. Check with your local or state health department to determine any restrictions on antigen tests.

- ✓ 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
- ✓ Staff capacity to collect specimens and/or run POC tests
    - o Using a POC antigen test does require significant staff support, both in collecting specimens and running a high volume of tests efficiently. Facilities need to ensure they have the proper staff capacity to use these devices.

3. Draft Testing Policies and Procedures

Facilities must draft policies and procedures around testing. This includes:

- ✓ When and who to test:
    - o Reference the three triggers for testing (see above)
    - o Additional testing criteria:
        - ▪ Repeat testing is not necessary for individuals who test positive
        - ▪ Individuals who have recovered from COVID-19 do not need to be tested again for 3 months unless symptomatic.
        - ▪ 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.
    - o Facility staff needing routine testing includes anyone in the building on a regular basis (staff, consultants, contractors, volunteers, students).
- ✓ What to do with results/pending results:
    - o Staff
        - ▪ Staff with symptoms must be restricted from work pending test results
        - ▪ Staff with confirmed case of COVID-19 must follow CDC's Return to Work Guidance
    - o Residents:
        - ▪ Residents with symptoms must be placed on transmission-based precautions (TBP) in accordance with CDC guidance.
- ✓ How to treat staff and resident refusals:
    - o Staff:

- Symptomatic Testing: Staff with symptoms who refuse testing cannot return until CDC's Return to Work Guidance are met.
- Outbreak Testing: Staff who refuse cannot return until outbreak testing is completed.
- Routine Testing: The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuse routine testing.

o Residents:

- Symptomatic Testing: Residents with symptoms who refuse testing are placed on TBP until the criteria for discontinuation are met.
- Outbreak Testing: Asymptomatic residents who refuse must be treated with vigilance, such as through additional monitoring, social distancing, source control masks, and effective hand hygiene until the procedures for outbreak testing have been completed.

4. Ensure Appropriate Training

Specimen Collection Training

✓ If collecting specimens and sending them out to the lab:

o Facilities should refer to CDC's guidance on collecting, handling and testing clinical specimens

o 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.

Rapid POC Antigen Test Training

✓ If performing Rapid POC Antigen Tests On-Site:

o Antigen POC tests can only be performed in a CLIA waived environment

o Undergo proper training from device manufacturer and be able to provide documentation of that training

o Contact your local or state health department for guidance on required reporting of results in CLIA waived settings.

o Facilities can refer to AHCA's member guidance on rapid POC antigen tests for more information.

5. Establish Process for Documentation

CMS laid out several documentation requirements in their guidance:

- ✓ For symptomatic testing of residents and staff, document:
  - o Date(s) and time(s) of the identification of signs or symptoms
  - o When testing was conducted and when results were obtained
  - o Actions the facility took based on the results

- ✓ For outbreak testing, document:
  - o Date the case was identified
  - o Date that all other residents and staff are tested and retested
  - o Results of all tests

- ✓ For routine testing, document:
  - o Facility's county positivity rate and testing frequency (e.g. every week)
  - o Date each positivity rate was collected.
  - o Date(s) that testing was performed for all staff
  - o Results of each test

- ✓ Document the facilities procedures for addressing refusals (see step 3).

- ✓ For facility staff tested elsewhere, documentation must be obtained showing the testing was completed under the same time frame.

- ✓ Document any issues accessing test supplies:
  - o If the facility cannot meet the 48-hour turnaround time on tests, the facility MUST document attempts to gain access, including with labs, distributers of antigen POC tests and both local AND state health departments.

6. Secure Standing Orders for Resident and Staff Testing

The facility must obtain an order from a physician, physician assistant, nurse practitioner, clinical nurse specialist or pharmacist (in accordance with State law), to do the tests for both PCR and antigen testing (including point of care (POC)) testing devices.