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 and 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.

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.

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<table>
<thead>
<tr>
<th>Community COVID-19 Activity</th>
<th>County Positivity Rate in the past week</th>
<th>Minimum Testing Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>&lt;5% (less than 5%)</td>
<td>Once a month</td>
</tr>
<tr>
<td>Medium</td>
<td>5%-10%</td>
<td>Once a week</td>
</tr>
<tr>
<td>High</td>
<td>&gt;10% (more than 10%)</td>
<td>Twice a week</td>
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</tbody>
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Steps to Get Started

- Determine Testing Frequency
- Establish Testing Vendor
- Draft Testing P&Ps
- Proper Training
- Process for Documenting
- Secure Standing Orders
1. Determine Testing Frequency

Test frequency is determined by the facilities’ county positivity rate. 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

This could include commercial laboratories, public laboratories or rapid point of care (POC) antigen tests. AHCA has a list of labs that providers can refer to, and facilities should also contact their local or state health department.

In determining the most appropriate source, facilities should consider:

- Type of testing being used
  - Must be antigen or molecular/PCR (antibody testing does not meet this requirement)
  - Check with your local/state health department for any restrictions

- 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
Components of your testing policy and procedure document may include:

- **Purpose of the testing policy**, such as: *To decrease the chance of COVID-19 from entering the nursing home, detect cases quickly, take action to mitigate and reduce risk of exposure/transmission consistent with CMS’ regulatory guidance under F-886*

- **Definitions**
  - Who is covered under “staff”
  - What is defined as an “outbreak”

- **Type of testing used and in what situations**
  - Reference the three triggers for testing (see above)
  - Include any limitations or requirements imposed by your state health department
  - Required turnaround time (48 hours) and what happens if it can’t be met
  - How doctors’ orders are obtained

- **Routine testing of staff:**
  - Process for monitoring county positivity rate and modifying frequency
    - Reference data source you are using
  - Frequency to test staff that work less frequently than testing requires (e.g. how often to test staff who work 1x/week when the facility is testing 2x/week)
  - How to document results for individuals tested at another source

- **Symptomatic testing of staff and residents:**
  - Screening and testing process for staff and residents for signs or symptoms

- **Outbreak testing of staff and residents:**
  - What triggers outbreak testing
  - Frequency of outbreak testing (refer to CDC or health department guidance)
    - 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.

- **What to do with results/pending results:**
  - Staff
    - Staff with symptoms must be restricted from work pending test results
    - Staff with COVID-19 must follow CDC’s [Return to Work Guidance](#)
  - Residents:
    - Residents with symptoms must be placed on transmission-based precautions (TBP) in accordance with [CDC guidance](#)

- **Reporting test results**
Requirement to report all POC results to CDC’s NHSN
Requirement to report all testing results from PCR and POC testing to NHSN
Any additional state reporting requirements

Documentation of testing
- CMS’ documentation requirements (see below)
- Document resident results in the EMR
- Documentation process for employee and contractor results

How to treat staff and resident refusals:
- 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.
- 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.

Specimen Collection Training
- If collecting specimens and sending them out to the lab:
  - Refer to CDC’s guidance on collecting, handling and testing clinical specimens
  - 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.
  - Workers handling collecting/handling specimens from potentially infected individuals are considered very high exposure risk per OSHA’s Occupational Risk categorization.
- If performing Rapid POC Antigen Tests On-Site:
  - Facility must have a CLIA waiver
  - Staff must undergo and document training from device manufacturer
  - Results must be reported to NHSN, per HHS guidance
    - Check with your local or state local/state health department for additional reporting requirements
  - Refer to AHCA/NCAL member guidance on rapid POC antigen tests

4. Ensure Appropriate Training
CMS laid out several documentation requirements in their guidance:

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

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

- **For routine testing, document:**
  - Facility’s county positivity rate and testing frequency (e.g. every week)
  - Date each positivity rate was collected.
  - Date(s) that testing was performed for all staff
  - 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:
  - If the facility cannot meet the 48-hour turnaround time on tests, document attempts to gain access, including with labs, distributors 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.