



New COVID 19 Testing and Reporting Requirements

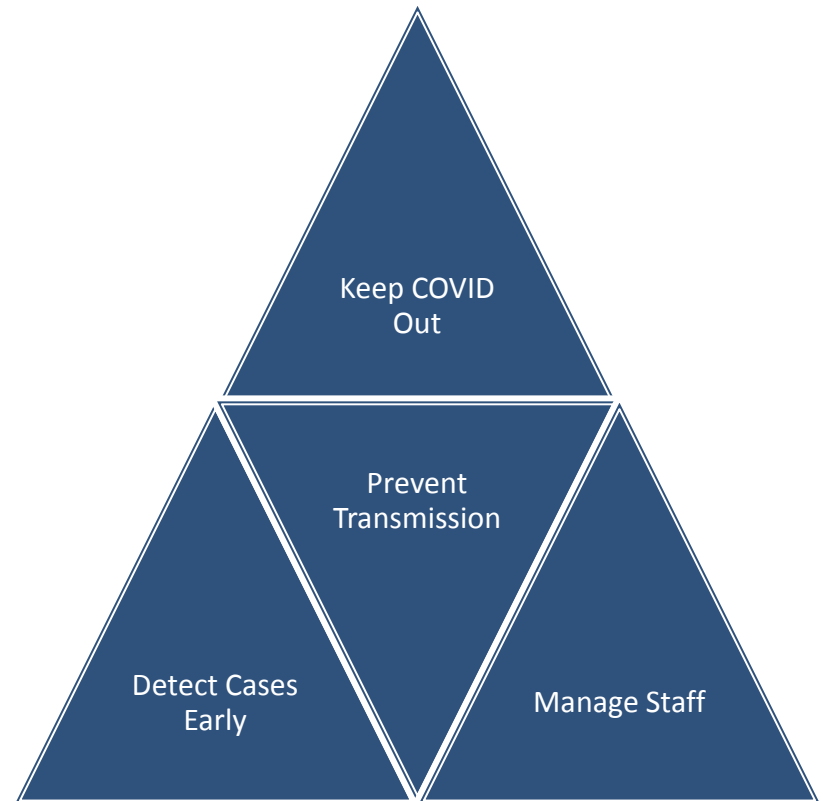


*Centers for
Medicare &
Medicaid Services*

Urgent Actions to Take

Goal:

- Reduce viral transmission (entry into and spread within the nursing home) and reduce risk of COVID complications in nursing home residents.
- Actions nursing homes can take in the next 24-72 hours to reduce the spread, and reduce risk.



Recent Actions by CMS

- Launched the National COVID-19 Training for Frontline Nursing Home Staff and Management on August 25, 2020
- Issued a third Interim Final Rule with Comment Period on August 25, 2020 that includes provisions such as:
 - Mandatory testing requirements for staff and residents in nursing homes
 - Mandatory reporting requirements for hospitals and CLIA-certified labs

National Training Program

- National COVID-19 Training for Frontline Nursing Home Staff and Management
 - The first-of-its kind scenario-based training which incorporates the most recent lessons learned from nursing homes
 - The training builds upon results of CMS nursing home inspections and the findings of epidemiological experts from the Centers for Disease Control and Prevention (CDC) who work with nursing homes.

National Training Program

CMS Targeted COVID-19 Training for Frontline Nursing Home Staff

Modules are available now, with five specific modules designed for frontline clinical staff and 10 designed for nursing home management.

Weekly Live Webinars

Live webinars are hosted every Thursday, 4-5 pm ET and you can access trainings via the Quality Improvement Organization (QIO) [QIO Program Homepage](#)

National CMS/CDC Nursing Home COVID-19 Trainings

- Module 1: Hand Hygiene and PPE
- Module 2: Screening and Surveillance
- Module 3: Cleaning the Nursing Home
- Module 4: Cohorting
- Module 5: Caring for Residents with Dementia in a Pandemic
- Module 6: Basic Infection Control
- Module 7: Emergency Preparedness and Surge Capacity
- Module 8: Addressing Emotional Health of Residents and Staff
- Module 9: Telehealth for Nursing Homes
- Module 10: Getting Your Vaccine Delivery System Ready

IFC 3 – Staff and Resident Testing

- Reminder: Regardless of the frequent of testing being performed, or the facility’s COVID-19 status, the facility should continue to screen all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors, for signs and symptoms of COVID-19.
- Facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak (as specified in the chart).

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff with signs and symptoms must be tested	Residents with signs and symptoms must be tested
Outbreak (Any new case arises in facility)	Test all staff that previously tested negative until no new cases are identified*	Test all residents that previously tested negative until no new cases are identified*
Routine testing	According to Table 2 below	Not recommended, unless the resident leaves the facility routinely.

IFC 3 – Staff and Resident Testing Continued

- Staff with symptoms or signs of COVID-19 must be tested and are restricted from the facility pending the results of the testing.
 - If positive: Staff should follow CDC guidelines for returning to work.
 - If negative: Staff should follow facility policies for returning to work.
- Residents who have signs or symptoms of COVID-19 must be tested.
 - While results are pending, residents should be placed on transmission-based precautions in accordance with CDC guidance.
- Staff and residents will need to be tested if there is an **outbreak** in the facility and they will need to be tested at regular intervals until the outbreak has been mitigated.
- Routine testing should be based on the extent of the virus in the community, therefore facilities should use their county positivity rate in the prior week as the trigger for staff testing frequency (as shown below).
- Other factors should also be considered, such as COVID-19 Emergency Dept. visits, the proximity of a facility to another county, and other as directed by a state.


Table 2: 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 turnaround time is <48 hours.

How to Report Testing Data

Laboratory data elements may be reported in the following ways:

- Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy. Data must be sent using existing reporting channels to ensure rapid initiation of case investigations, and concurrent reporting of results must be shared with ordering provider or patient, as applicable.
- Submit laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform) where the data will then be routed to the appropriate state and local authorities and routed to CDC after removal of personally identifiable information according to applicable rules and regulations.
- Submit laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and then to CDC as directed by the state.

Public Readiness and Emergency Preparedness Act (PREP Act)

- Authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that **provides immunity from liability** (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of **countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency** to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.
- A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

The PHS Act and the PREP Act

- On January 31, 2020, the Secretary declared a public health emergency, pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the response of the nation's health care community to the COVID-19 outbreak.
- On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID-19 (85 FR 15198 (March 17, 2020)).
- The Secretary is amending the March 10, 2020 Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act. This amendment is made in accordance with section 319F-3 of the PHS Act, which authorizes the Secretary to amend a PREP Act declaration at any time.

Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes

- Antigen tests are available with rapid turn-around-time critical to the identification of SARS-CoV-2 infection and rapid implementation of infection prevention and control strategies.
- These tests can augment other testing efforts, especially in settings where RT-PCR testing capacity is limited or testing results are delayed (e.g., >48 hours).
- In general, these POC antigen tests have a lower sensitivity, but similar specificity, for detecting SARS-CoV-2 compared to reverse-transcriptase polymerase chain reaction (RT-PCR) tests.

Considerations for Interpreting Antigen Test Results in Nursing Homes

	Positive Test	Negative Test	Additional Information
Testing of Symptomatic Residents or Healthcare Professionals (HCP):	If an antigen test is positive, no confirmatory test is necessary.	If an antigen test is presumptive negative, perform RT-PCR immediately (e.g., within 48 hours).	
Testing of Asymptomatic Residents or Healthcare Professionals (HCP) in Nursing Homes as part of an Outbreak Response	If an antigen test is positive, no confirmatory test is necessary.	If an antigen test is presumptive negative, residents should be placed in <u>appropriate precautions</u> . HCP should be allowed to continue to work with <u>continued symptom monitoring</u> . The facility should continue serial viral testing (antigen or RT-PCR) every 3-7 days until no new cases are identified for a 14-day period.	The FDA has granted Emergency Use Authorizations (EUA) to certain antigen tests for testing specimens from individuals who are suspected of COVID-19 by their healthcare provider within a number of days after the onset of symptoms, specific to each authorized test's validated performance. Facilities need to have a CLIA Certificate of Waiver to perform testing
Testing of Asymptomatic HCP in Nursing Homes without an Outbreak per CMS Recommendations	If an antigen test is positive, perform confirmatory RT-PCR test within 48 hours of the antigen test, especially in counties with low prevalence. If confirmatory test is performed, HCP should be excluded from work until confirmatory test results are completed.	If an antigen test is presumptive negative, allow HCP to continue to work. The HCP should continue to monitor for symptoms, and serial testing should continue per <u>CMS recommendations</u> .	<u>CMS recommends</u> initial testing of all HCP as part of the nursing home reopening process and serial testing of HCP at an interval based on local incidence of COVID-19.

Who Should NOT be Tested for SARS-CoV-2?

- Residents who were known to have COVID-19 on admission to the facility and were placed into Transmission-Based Precautions (TBP).
- Ideally, newly admitted patients/residents should be placed into TBP for 14 days, so would not need to be tested unless they develop symptoms (which would then trigger testing).
 - If that test is positive, TBP should continue until day 14 OR until 10 days following the positive test, whichever is longer.
 - A follow-up test is not required in order to discontinue TBPs
- HCP who have recovered from SARS-CoV-2 infection in the past 3 months and are asymptomatic should not be tested.

Policy on FDA EUA Authorized Antigen POC Tests for Inpatient Care Settings Operating under a CLIA CoW on Asymptomatic Individuals

- CMS requires facilities with a CLIA Certificate of Waiver to follow the manufacturer's instructions (Instructions For Use) when performing laboratory testing.
- CMS will temporarily exercise enforcement discretion for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals.
- **Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the FDA FAQ.**
- [Clinical Laboratory Improvement Amendments \(CLIA\) Homepage](#)

IFC 3 - New Laboratory Reporting Requirements

- All CLIA certified facilities performing SARS-CoV-2 testing are required to report all results, positive and negative, to their state or local health departments
- There is a one time, three week grace period to allow facilities time to get their systems and processes in place. The grace period begins September 2, 2020.
- Questions regarding this new rule can be sent to LabExcellence@cms.hhs.gov

IFC 3 – Enforcing Laboratory Reporting

- **CMS is continuing to assess automated methods to gather data for determining compliance with the laboratory reporting mandate. The use of available data will be augmented by the following:**
 - CLIA-certified laboratories will be identified as not reporting via survey, complaints.
 - Certificate of Waiver and Provider Performed Microscopy labs) are not routinely surveyed by CLIA. As outlined in the new rule, CLIA will be surveying 5% of these labs over the 3 years the regulation is in effect.

IFC 3 – Enforcing Laboratory Reporting

- **CMS will enforce the SARS-CoV-2 test results reporting requirement.**
- **Failure to report SARS-CoV-2 positive and negative results will result in civil money penalties of**
 - **\$1,000 for the first day of noncompliance and**
 - **\$500 for each additional day of noncompliance.**

Where to Get Help

For Resources

- CMS Emergency Resources Page
 - Recommended: Toolkit for States to Mitigate COVID-19 in Nursing Homes (updated biweekly and includes best practices for States)
- CMS Quality Safety & Oversight Memos and Guidance for State Survey Agencies and CMS Regional Offices
- CDC COVID-19 Page

Where to Get Help (cont'd)

Live Calls with CMS

- Sessions are open to members of the healthcare community and are intended to provide updates, share best practices among peers, and offer attendees an opportunity to ask questions of CMS and other subject matter experts.

To register: <https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit>

Resources

- CDC:
 - Overview of Testing for SARS-CoV-2 (COVID-19)
- FDA:
 - FAQs on Testing for SARS-CoV-2
- CMS:
 - Interim Final Rule
 - CLIA: POC Antigen Test Enforcement Discretion
 - CMS memorandum for CLIA reporting requirements
 - CMS memorandum for Nursing Home testing requirements

Thank you