**COVID-19 Testing**

**General Information**

**(05/26/2021)**

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**Overview and General Information**

The spread of COVID-19 from the community and within the health center is challenging. COVID-19 testing will be an instrumental aspect that will assist facilities in prompt detection of cases in order to implement actions to reduce the exposure and to halt transmission within the facility whenever possible.

The Centers for Medicare & Medicaid Services (CMS) published an interim final rule (<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-additional-policy-and-regulatory-revisions-response-covid-19> ) on August 26, 2020 and was revised on 04/27/2021 establishing Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents.

CMS has added a new requirement at F886 COVID-19 Testing to include:

“The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident’s testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.”1

CMS has indicated that “health care facilities using Point of Care COVID-19 testing devices under a CLIA Certificate of Waiver, including nursing homes, pharmacies, or other settings will be required to report test results under this regulation.”2  In addition, CMS indicates, “All CLIA-certified laboratories that perform or analyze any test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (e.g., molecular, antigen, antibody) are required to report, regardless of the type of laboratory (type of CLIA certificate) performing the testing.”2

The Centers for Disease Control and Prevention has updated reporting requirements for SARS-CoV-2 tests, updated on Jan. 7, 2020:

“Every COVID-19 testing site is [required to report](https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html) to the appropriate state or local public health department every diagnostic and screening test performed to detect SARS-CoV-2 or to diagnose a possible case of COVID-19. POC testing may be performed with a [Clinical Laboratory Improvement Amendments (CLIA)](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA)  certificate of waiver, but reporting of test results to state or local public health departments are mandated by the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

CMS-certified long-term care facilities may submit point-of-care SARS-CoV-2 testing data, including antigen testing data, to CDC’s National Healthcare Safety Network (NHSN). This CDC- and CMS-preferred pathway to submit data to CDC’s NHSN applies only to CMS-certified long-term care facilities. Test data submitted to NHSN will be reported to appropriate state and local health departments using standard electronic laboratory messages. Other types of LTC facilities may also report testing data in NHSN for self-tracking or to fulfill state or local reporting requirements, if any. While NHSN is the CDC- and CMS-preferred pathway, Medicare and Medicaid-certified LTC facilities may submit data through the other mechanisms described in the Current Methods of Submission section of [HHS Laboratory Reporting Guidance](https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf) to meet the reporting requirements.”4

Facilities will need to have knowledge regarding the types of testing. The Centers for Disease Control and Prevention indicates, “The “gold standard” for clinical diagnostic detection of SARS-CoV-2 remains laboratory-based (moderate- and high-complexity) [NAATs](https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html). Thus, it may be necessary to confirm an antigen test result with a laboratory-based NAAT, especially if the result of the antigen test is inconsistent with the clinical context.”3

“The clinical performance of diagnostic tests largely depends on the circumstances in which they are used. Both antigen tests and NAATs perform best if the person is tested when their viral load is generally highest. Because antigen tests perform best in symptomatic people and within a certain number of days since symptom onset, antigen tests are used frequently on people who are symptomatic. Antigen tests also may be informative in diagnostic testing situations in which the person has a known exposure to a person with COVID-19.”3

The Centers for Disease Control and Prevention has provided “Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing, Updated Mar. 12, 2021 (<https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html> ) that recommends:

* Performing a risk assessment prior to testing
* Use a new pair of gloves every time a specimen is collected
* Do not reuse of used test devices, tubes, solutions, swabs, lancets or fingerstick devices
* If test or components are beyond the expiration date or damaged/discolored, they should be discarded
* Storage and handling of reagents, specimens, kit contents and devices in accordance with manufacturer’s recommendations
* Discard any tests and test components that exceed the expiration date or show signs of damage or discoloration
* Don’t open reagents, test devices and cassettes until ready to test (follow manufacturer’s instructions
* Label specimen appropriately to connect specimen with person tested
* When transferring specimens from collection area to testing, follow instructions for the POC test used
* Basic best practice approaches during testing
	+ Following manufacturer’s recommendation
	+ Perform quality control and instrument calibration in accordance with the manufacturer’s recommendation
		- If quality control or calibration fails, correct issues prior to proceeding with resident testing
	+ Decontamination/disinfection
	+ Follow read and record results times
	+ Waste handling
* Tests that can be used for Point-of-Care testing
* CLIA Certificate of Waiver requirements
* Reporting Requirements for Point-of Care Testing
* Resources

**Competencies which may be associated with COVID-19 Testing include but are not limited to:**

* Understanding of COVID-19 Types of Testing
* Proper use of Personal Protective Equipment
* Knowledge of proper hand hygiene practices
* Specimen Collection
* Use of Point-of-Care Antigen Testing Equipment
* Quality Control and Calibration of Equipment
* Cleaning and Disinfection
* Reporting Antigen Testing
* Documentation

**Staff Competencies with COVID-19 Testing include but are not limited to:**

* Ability to follow proper hand hygiene practices
* Demonstration of ability to properly select and don and doff Personal Protective Equipment including proper use, removal, and storage of medical grade face masks
* Demonstration of Specimen Collection
* Demonstration of Point-of-Care COVID-19 Antigen testing
* Ability to describe actions to prevent the transmission of COVID-19 with positive results

**References and Resources:**

1Centers for Medicare & Medicaid Services. Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID19 Focused Survey Tool. QSO-20-38-NH. August 26, 2020, Revised 04/27/2021: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

2 Centers for Medicare & Medicaid Services. 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. QSO-20-37-CLIA, NH. August 26, 2020: <https://www.cms.gov/files/document/qso-20-37-clianh.pdf>

3Centers for Disease Control and Prevention. Interim Guidance for Antigen Testing for SARS-CoV-2. Updated May 13, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

4Centers for Disease Control and Prevention. SARS-CoV-2 Antigen Testing in Long Term Care Facilities. Updated Jan. 7, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes, Updated Mar. 29, 2021; <https://cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing. Updated Mar. 12, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Disease Control and Prevention (CDC). Interim Guidelines for Collecting, Handling of Clinical Specimens for COVID-19 Testing, Updated Feb. 26, 2021: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention (CDC). Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19 Pandemic. Updated Feb. 23, 2021: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

United States Food & Drug Administration (FDA). In Vitro Diagnostics EUAs: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen>

United States Food & Drug Administration (FDA). Pooled Sample Testing and Screening Testing for COVID-19: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/pooled-sample-testing-and-screening-testing-covid-19>