**COVID-19 Testing**

**General Information**

**(12/05/2022)**

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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 a revised interim final rule (<https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf> ) on September 23, 2022, establishing Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents. Facilities “are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary.”1 Updates to this guidance include:

* “Routine testing of asymptomatic staff is no longer recommended but may be performed at the discretion of the facility.
* Updated recommendations for testing individuals who have recovered from COVID-19.” 1

Additional guidance includes, “Residents who have signs or symptoms of COVID-19, regardless of vaccination status, must be tested as soon as possible. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with CDC guidance. Once test results are obtained, the facility must take the appropriate actions based on the results.”1 “Staff, regardless of vaccination status, with signs or symptoms must be tested.”1 Outbreak investigation and testing is initiated when a single new case of COVID-19 occurs among residents or staff to determine of other have been exposed.”1

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, providers may choose 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. 2

“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 they are symptomatic. Although antigen tests generally have lower sensitivity compared to NAATs, they can also be used to test for infection with specific attention to the context in which they are used”2

The Centers for Disease Control and Prevention has provided “Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings, Updated Apr. 4, 2022: (<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 from a different person
* Do not reuse of used test devices, tubes, solutions, swabs, lancets or fingerstick collection devices
* Store all reagents, specimens, contents of the kit and test devices in accordance with the manufacturer’s instructions
* 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
* 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
    - If processing multiple specimens in batches, follow manufacturers recommendation on the testing process and change gloves before putting new specimens in the testing device
  + Decontamination/disinfection per manufacturer’s recommendations with appropriate EPA disinfection
  + Always follow read and record results times
  + Waste handling consistent with all other biohazardous waste in the laboratory
* Only use tests that can be used for Point-of-Care testing
* Follow CLIA Certificate of Waiver requirements
* Follow Reporting Requirements for Point-of Care Testing

**NOTE:** Monitor for ALL updates and requirements related to the end of the Public Health Emergency in relation to reporting of COVID-19 testing

The Centers for Disease Control and Prevention, in “How to Report COVID-19 Laboratory Data, announces HHS and CDC revisions that took place effective April 4, 2022, that indicates that “Reporting of negative results for non-NAAT tests (rapid or antigen test results) is no longer required. However, testing sites must still report data for all positive diagnostic and screening testing completed for each individual test.”3 In the event that the resident has a positive antigen test, and then has a negative PCR test that is performed within 2 calendar days of each other, this will be excluded from the positive test count.

“CMS-certified long-term care (LTC) facilities can submit point-of-care SARS-CoV-2 testing data, including antigen, antibody, and nucleic acid amplification test (NAAT) 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 LTC facilities. Test data submitted to NHSN will be reported to appropriate state, tribal, local, and territorial health departments using standard electronic laboratory messages. Other types of LTC facilities can also report testing data in NHSN for self-tracking or to fulfill state or local reporting requirements, if any.”4

**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. Revised 09/23/2022: <https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf>

2Centers for Disease Control and Prevention. Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community. Updated Apr. 4, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

3Centers for Disease Control and Prevention. How to Report COVID-19 Laboratory Data. Updated Apr. 4, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html#who-must-report>

4Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Rapid Testing Performed in Point-of-Care Settings. Updated Apr. 4, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic), Updated Sept. 23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

Centers for Medicare and Medicaid Services. Long Term Care Survey Pathway Infection Prevention, Control, and Immunizations (CMS-20054) Updated 10/2022:

Available for download at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Nursing-Homes>

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>

Centers for Disease Control and Prevention (CDC). Interim Guidelines for Collecting, Handling of Clinical Specimens for COVID-19 Testing, Updated July 15, 2022: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention. COVID-19 Testing: What You Need to Know, Updated September 28, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Rapid Testing in Point-of-Care Settings, Updated Apr. 4, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.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>