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**COVID-19 Testing**

## **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> ) establishing Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents on August 25, 2020.

An update to the testing guidance includes: “CMS Updates COVID-19 Testing Methodology for Nursing Homes” on September 29, 2020: <https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes>

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 “healthcare 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 SARSCoV-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

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 RT-PCR. Thus, it may be necessary to confirm a rapid antigen test result with a nucleic acid test, especially if the result of the antigen test is inconsistent with the clinical context.”3

“The first two SARS-CoV-2 antigen tests to receive FDA EUA are authorized for testing symptomatic persons within 5 days of symptom onset and there are limited data on antigen test performance in asymptomatic persons. However, given the transmission of SARS-CoV-2 from asymptomatic and presymptomatic nursing home residents and healthcare personnel (HCP) with SARS-CoV-2 infection, CDC is providing considerations for the use of antigen tests in asymptomatic persons during this public health emergency. Facilities should be aware of the [FDA EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) for antigen [tests](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2?utm_campaign=2020-08-14%20August%2014%20Update%3A%20New%20Information%20on%20Testing%20for%20SARS-CoV-2&utm_medium=email&utm_source=Eloqua#5f37fccbef420) and potential implications for the [Clinical Laboratory Improvement Amendments (CLIA)](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA) certificate of waiver when using antigen tests in asymptomatic individuals and in persons >5 days from symptom onset.”3

The Centers for Disease Control and Prevention has provided “Guidance for SARS-CoV-2 Point-of-Care Testing, Updated November 9, 2020( <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html> ) that recommends:

* Performing a risk assessment prior to testing
* Following all manufacturer’s instructions for performing the test
* Performing regular quality control and instrument calibration consistent with the manufacturer’s recommendation
* Basic best practice approaches to testing
* Tests that can be used for Point-of-Care testing
* CLIA Certificate of Waiver requirements
* Reporting Requirements for Point-of Care Testing

**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
* 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: <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>

Centers for Disease Control and Prevention. Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. September 4, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Centers for Disease Control and Prevention. Preparing for COVID-19 in Nursing Homes; June 25, 2020; <https://cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

3Centers for Disease Control and Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. October 23, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care Testing. Updated Nov. 9, 2020: <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 and Testing Clinical Specimens for COVID-19 Updated Nov. 5, 2020: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention (CDC). Interim Infection and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19 Pandemic. Updated Nov. 4 2020: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/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>

## **Leader’s Guide**

Testing for SARS-CoV-2 (COVID-19) is essential to identify positive cases as soon as possible to implement mitigation efforts to prevent the spread of infection in the facility. Testing is also required for regulatory compliance.

There are multiple factors to consider when addressing COVID-19 testing and the role in the prevention of the spread of COVID-19 in the Long-Term Care Setting.

Policies and procedures following the guidelines provided through CMS, CDC, and State specific guidance will enable the facility to consistently implement strategies to maintain the health, safety, and welfare of residents and staff.

A solid testing plan, consistent with CMS and State guidance, identifying equipment and supply needs and acquisition, staff education and verification of competency for COVID-19 testing, reporting and documentation is essential for quality to prevent the spread of infection and compliance. Through an established policy and procedure, testing of residents and staff in accordance with guidance, will be an essential component to the COVID-19 Pandemic Plan and reopening process.

Some areas to be considered for COVID-19 Testing may include:

* Staff Resources:
* Infection Preventionist
* Licensed Nurses
* All Staff
* Administrator
* Director of Nursing Services and designee
* Education:
* Infection Control Practices and Prevention of Transmission
* Policies and Procedures for Infection Control, including COVID-19
* COVID-19 testing policies and procedures
* Proper use and application of Personal Protective Equipment
* Hand hygiene procedures
* Specimen Collection
* Use of Point-of-Care COVID-19 Antigen Testing Device
* Cleaning and Disinfection
* Reporting
* Prompt Action for positive results
* Documentation Considerations:
* CLIA Certificate of Waiver
* Employee education and competency demonstration outcomes
* COVID-19 Testing Plan
* Risk Assessment
* COVID-19 Test Results
* Resident Refusals
* COVID-19 Test Results Reporting
* Reporting
  + NHSN Reporting- COVID-19 Module for LTCF
  + CLIA requirement to report the results of all Point of Care (POC) antigen tests performed in the facility to CDC through NHSN reporting. <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>
  + CMS How to obtain a CLIA Certificate: <https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/howobtaincliacertificate.pdf>
* Monitoring and Evaluation
* Observation of staff performance with coaching as needed
* Staff interview regarding availability and use of PPE and face masks
* Observation of specimen collection
* Observation of testing performance
* Medical Record Audit for documentation of test results
* COVID-19 tracking and trending
* QAPI review and reporting

**References and Resources:**

Centers 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: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

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 Medicare & Medicaid Services. Nursing Home Reopening Guidelines for State and Local Officials; May 18, 2020. Revised 09/28/20; QSO 20-30-NH; <https://www.cms.gov/files/document/qso-20-30-nh.pdf>

Centers for Disease Control and Prevention. Preparing for COVID-19 in Nursing Homes; June 25, 2020; <https://cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

Centers for Disease Control and Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. October 23, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

Centers for Disease Control and Prevention: Testing Guidelines for Nursing Homes. Updated Oct. 16, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care Testing. Updated Nov. 9, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Disease Control and Prevention. How to Report COVID-19 Laboratory Data. Updated Nov. 2, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/reporting-lab-data.html>

Centers for Disease Control and Prevention. National Healthcare Safety Network (NHSN) LTCF COVID-19 Module: <https://www.cdc.gov/nhsn/ltc/covid19/index.html>

Centers for Disease Control and Prevention. COVID-19 Testing Resources for Nursing Homes: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/COVID-19-Testing-Resources-for-Nursing-Homes.pdf>

Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA): <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>

United States Health & Human Services. COVID-19 Pandemic Response, Laboratory Data Reporting: Cares Act Section 18115: <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>

## **Implementation Checklist: COVID-19 Testing**

| **Regulation** | **Suggested Actions** |
| --- | --- |
| **F886 COVID-19 Testing**  “§ 483.80 Infection control  § 483.80(h) **COVID-19 Testing.** 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 COVID-19 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.”  (42CFR §483.80h) | * Review for comprehensive and updated Infection Prevention and Control policies that align with current federal, state, and local health department guidance including:   + COVID-19 testing for residents, staff, vendors/contractors and volunteers   + Determination of frequency of testing   + Testing Equipment Use (Manufacturer’s recommendations)   + Specimen Collection   + Personal Protective Equipment   + Cleaning and Disinfection   + Reporting processes     - CLIA     - NHSN     - State/Local Public Health     - Resident/Resident Representative   + Process for testing procurement and supply shortages   + Documentation processes     - Testing was completed and the results of each staff test     - Testing results     - Line List     - Medical record   + Testing refusal procedures     - Resident     - Staff     - Vendor     - Volunteer * Education:   + Testing Schedule   + Specimen Collection   + Use of Testing Device   + Reporting * Incorporate education into overall facility training plan * Audit employee training and in-service records for Testing related education and verification of competency * Monitor employee performance at varied times to observe compliance with facility policies and procedures (Process Surveillance) * Complete record review to determine that documentation of testing and reporting is consistent with policy and procedure * Identify current CLIA Waiver * Evaluate staff adherence to Present findings to QAPI Committee for discussion and follow up |
| **F884: COVID-19 Reporting to NHSN**  § 483.80 Infection control. (g) COVID-19 Reporting. The facility must— (1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—  (i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;  (ii) Total deaths and COVID-19 deaths among residents and staff;  (iii) Personal protective equipment and hand hygiene supplies in the facility;  (iv) Ventilator capacity and supplies in the facility;  (v) Resident beds and census;  (vi) Access to COVID-19 testing while the resident is in the facility;  (vii) Staffing shortages; and  (viii) Other information specified by the Secretary.  (2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention’s National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.  (3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—  (i) Not include personally identifiable information;  (ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and  (iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other. | * Review and implement facility policy for reporting to NHSN including process to gather information related to:   + Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19   + Total deaths and COVID-19 deaths among residents and staff   + Personal protective equipment and hand hygiene supplies – inventory and availability   + Ventilator capacity and supplies in the facility   + Staff capacity   + Census * Identify position responsible for reporting and monitoring of related data. * Process to monitor QIES and NHSN systems for potential reporting errors and possible CMPs * Conduct process surveillance audit every 2 weeks to identify reporting is completed consistent with requirements * Evaluate staff adherence to Present findings to QAPI Committee for discussion and follow up * Review policy for notification/communication to resident, representatives and staff   + Notify by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other |
| **CLIA**  § 493.2 **Definitions.** (Modified): Condition level requirements means any of the requirements identified as “conditions” in § 493.41 and subparts G through Q of this part.  •§ 493.41 **Condition:** **Reporting of SARS-CoV-2 test results.** (New): During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.  § 493.555(c) **Federal review of laboratory requirements.** (New): (c) The organization's or State's agreement with CMS that requires it to do the following: (6) Notify CMS within 10 days of any conditional level deficiency under §§ 493.41 or 493.1100(a).  § 493.1100 **Condition: Facility administration.** (New) (a) Reporting of SARS-CoV-2 test results. During the Public Health Emergency, as defined in § 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a “SARS-CoV-2 test”) must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.  § 493.1804 **General considerations.** (Modified) (c) Imposition of alternative sanctions. (1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions. (Except for a condition level deficiency under §§ 493.41 or 493.1100(a), CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not routinely inspected for compliance with condition-level requirements.)  § 493.1834 **Civil money penalty**. (New) (d)(2)(iii) For a condition level deficiency under §§ 493.41 or 493.1100(a), a CMP of $1,000 for the first day of noncompliance and $500 for each additional day of noncompliance. | * Identify current CLIA Waiver * Identify process for reporting * Review current reporting policy and process to align with federal, state and local health department requirements * Review competency process for POC Antigen testing units and reporting processes * Process surveillance audit to identify reporting consistent with requirements * Evaluate staff adherence to Present findings to QAPI Committee for discussion and follow up * Keeps certificate information current. Notify the State Agency of any changes in ownership, name, address or director within 30 days |
| **September 29, 2020:**   Counties with 20 or fewer tests over 14 days will now move to “green” in the color-coded system of assessing COVID-19 community prevalence. Counties with both fewer than 500 tests and fewer than 2,000 tests per 100,000 residents, and greater than 10 percent positivity over 14 days – which would have been “red” under the previous methodology – will move to “yellow.”  <https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes> | * Determine a process for review of county positivity rate (roles, responsibility, data source, accountability, documentation) |
| **Centers for Disease Control and Prevention “Guidance for SARS-CoV-2 Point-of-Care Testing, Updated November 9, 2020:**  <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>  **“**Each POC test should only be used with its authorized specimen type. Proper specimen collection and handling is critical for all COVID-19 testing, including those tests performed at POC settings. A specimen that is not collected or handled correctly may lead to inaccurate or unreliable test results.”  **\*\*Risk Assessment Resource:**  <https://www.aphl.org/programs/preparedness/Documents>  /APHL%20Risk%20Assessment%20Best%  20Practices%20and%20Examples.pdf | * Perform a risk assessment before testing * Develop a system that includes:   + Follow manufacturer’s instructions for performing test   + Performs regular quality control and instrument calibration in accordance with the manufacturer’s instructions   + Follow proper manufacturer’s recommendations with use   + Follows infection prevention and control with testing   + Reads and records results   + Report all COVID-19 diagnostic and screening testing results     - Resident/Representative     - Physician     - CLIA     - NHSN |

**References and Resources**

Centers for Disease Control and Prevention. Considerations for Interpreting Antigen Test Results in Nursing Homes. August 21, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf>

Centers for Disease Control and Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. Updated Oct. 23, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

Centers for Disease Control and Prevention. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Updated Nov. 5, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention. Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. September 4, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Centers for Disease Control and Prevention. Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes. May 19, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html>

Centers for Disease Control and Prevention. Testing Guidelines for Nursing Homes. Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel. Updated Oct. 16, 2020, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care Testing. Updated Nov. 9, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Disease Control and Prevention. COVID-19 Testing Overview. Updated Oct. 21, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>

Centers for Medicare & Medicaid Services: QSO-20-38-NH, 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. August 26, 2020: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

Centers for Medicare & Medicaid Services. CMS Updates COVID-19 Testing Methodology for Nursing Homes. September 29, 2020: <https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes>

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

Centers for Medicare & Medicaid Services: QSO-20-29-NH. Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes. May 6, 2020: <https://www.cms.gov/files/document/qso-20-29-nh.pdf>

## **COVID-19 Antigen Testing**

**Policy**

It is the policy of this facility to test residents and staff for COVID-19, based upon a facility plan that includes parameters and frequency set forth by the Health and Human Services Secretary, State guidance and local public health recommendations in accordance with current standards of practice.

**Purpose**

The purpose of testing is to enhance efforts toidentify cases of COVID-19 quickly toput in place immediate interventions to remove exposure risks for the residents and staff. Uses of antigen testing in nursing homes “should be implemented in addition to recommended IPC “Infection Prevention and Control) measures” and includes:

* To test symptomatic residents and staff,
* To test asymptomatic residents and facility staff in facilities as part of the COVID-19 outbreak response,
* To test asymptomatic facility staff without a COVID-19 outbreak as required by CMS recommendations, and
* To test residents and facility staff who were exposed to persons with COVID-19 outside of the nursing home.

**Definitions**

**Antibody Testing:** Testing from a blood test that looks for antibodies that develop several days to weeks after infection. This is not a diagnostic test.

**Diagnostic Testing**: “for SARS-CoV-2 is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.”2 The RT-PCR (reverse transcription polymerase chain reaction) molecular test detects the COVID-19 genetic material.

**Outbreak-COVID-19: “**a new COVID-19 infection in any healthcare personnel (HCP) or any nursing home-onset COVID-19 infection in a resident.”1 “Residents who were placed into Transmission-Based Precautions on admission and developed SARS-CoV-2 infection within the 14-day period after admission.”8

**Point of Care Testing** “is diagnostic testing that is performed at or near the site of resident care.”1

**Rapid Antigen Testing:** “Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection. Antigen tests are currently authorized to be performed on nasopharyngeal or nasal swab specimens placed directly into the assay’s extraction buffer or reagent.” “Antigen tests are relatively inexpensive and can be used at the point-of-care. The currently authorized devices return results in approximately 15 minutes. Antigen tests for SARS-CoV-2 are generally less sensitive than viral tests that detect nucleic acid using reverse transcription polymerase chain reaction (RT-PCR).”2

**Rapid POC Testing Devices** “are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance.”1

**Screening Testing** “for SARS-CoV-2 is intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. Screening testing is performed to identify persons who may be contagious so that measures can be taken to prevent further transmission.”2 The FDA indicates, “when screening asymptomatic individuals, health care providers should consider using a highly sensitive test, especially if rapid turnaround times are available. If highly sensitive tests are not feasible, or if turnaround times are prolonged, health care providers may consider use of less sensitive point-of-care tests, even if they are not specifically authorized for this indication (commonly referred to as "off-label"). For congregate care settings, like nursing homes or similar settings, repeated use of rapid point-of-care testing may be superior for overall infection control compared to less frequent, highly sensitive tests with prolonged turnaround times.”6

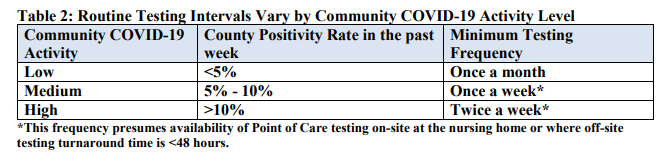
**Staff** “includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility’s nurse aide training programs or from affiliated academic institutions.”1

**Surveillance Testing** “for SARS-CoV-2 is intended to monitor for a community- or population-level infection and disease, or to characterize the incidence and prevalence of disease. Surveillance testing is used to gain information at a population level, rather than an individual level, and results of surveillance testing are only returned in aggregate to the requesting institution.”2

## **COVID-19 Antigen Testing Procedure**

**Preparation:**

1. Facility will determine capacity for testing by trained facility nurses.
   1. If additional support is necessary, contact local public health department for collaboration.
2. Facility will determine the type of Emergency Use Authorization for FDA approved viral test that will be used for testing residents and staff.
   1. If testing is sent to the laboratory, select lab that can process a large number of tests with rapid reporting of results (24-48 hours)
3. Facility will determine appropriate specimen source.
4. Supplies: Facility will obtain and maintain specimen collection kits and PPE for specimen collection.
   1. PPE includes:
      1. N95 or higher-level respirator (facemask if respirator is not available)
      2. Eye protection
      3. Gloves
      4. Gown
5. The Medical Director will order testing by standing order if permitted by State law.
6. Residents and facility staff will be prioritized for testing:
   1. **Symptomatic** **individuals** will be prioritized first for testing
      1. All facility staff and residents with signs and symptoms must be tested
         1. Symptomatic facility staff will be immediately sent home pending results. Once results received, follow facility policy on return to work. Consistent with CDC’s “Criteria for Return to Work for healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance).” <https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html>
         2. Symptomatic residents will be placed on transmission-based precautions while test results are pending.
   2. **Outbreak**: Any new cases that arise in the facility:
      1. Test all facility staff and residents that previously tested negative. All facility staff and residents that test negative will be retested every three to seven days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result.1
         1. The CDC indicates, “if testing capacity allows and does not divert staff and resources away from performing other critical IPC measures (e.g., ensuring effective implementation of [Transmission-Based Precautions](https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) for infected and potentially exposed residents), the facility should consider testing more frequently (e.g., every 3 days) for the first two weeks of the outbreak, then test less frequently (e.g., every 7 days) thereafter until no new cases are identified for 14 days.”9
      2. Facility staff and residents who test positive for COVID-10 do not need repeat testing.
         1. Residents will be placed in transmission-based precautions following CDC guidance on Discontinuation of Transmission-based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings (Interim Guidance): <https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html>
         2. Facility staff will return to work following CDC Guidance, “Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance): <https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html>
   3. **Routine Testing:**
      1. Facility Staff: Routine testing is dependent upon the extent of the virus in the community. Guidance represents minimum testing expected and can be adjusted considering other factors that could increase risk:
         1. Neighboring county with a higher positivity rate
         2. Multiple employees living in a county with a higher positivity rate
         3. Rates of emergency room visits
      2. Color coding for the CMS county positivity rate includes: Low-Green, Medium-Yellow and High-Red.
      3. If the positivity rate increases to a higher level of activity, the facility should begin testing staff as indicated in Table 2 below as soon as the criteria for higher activity is met.
      4. If the county positivity rate decreases to a lower level of activity, continue testing staff at the higher frequency level until the county positivity rate remains at the lower activity level for at least two weeks before reducing testing frequency.
      5. Asymptomatic residents will not be routinely tested
      6. Facility may consider routine testing for residents who leave the facility frequently (i.e. dialysis, chemotherapy)
      7. The Infection Preventionist or designee, will use the county positivity rate (<https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg> ) in the prior week to trigger facility staff testing frequency according to table 2 below1:



* + 1. If the facility is unable to meet the 48-hour turn-around time due to testing supply shortages, limited access, or inability of the laboratory to process the tests withing 48-hours, the facility will:
       1. Document all efforts to obtain quick turn-around test results
       2. Contact with local/state health departments
       3. Document all attempts to obtain testing supplies

1. The facility will make all attempts to provide testing that will obtain onsite rapid testing results, preferably within 24 hours.
   1. “Testing the same resident more than once in a 24-hour period is not recommended.”4
2. Testing Refusals:
   1. Facility Staff:
      1. Facility employees with signs or symptoms of COVID-19 and who refuse testing will be prohibited from entering the facility until return-to-work criteria are met.
      2. Facility employees without COVID-19 signs or symptoms who refuse routine testing (identify facility action consistent with facility occupational health policies and local jurisdiction policies)
      3. “If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed.”1
   2. Residents: Residents or the resident representative may refuse COVID-19 testing. Education will be provided to the resident/representative on the importance of testing for COVID-19, how test is performed and interventions that may need to be implemented due to refusal. An alternate specimen collection source may be discussed (i.e. anterior nares).
      1. Residents with signs or symptoms of COVID-19 who refuse testing will be placed on isolation with transmission-based precautions until criteria for discontinuing transmission-based precautions are met.
      2. During an outbreak if asymptomatic resident refuses testing:
         1. Vigilant evaluation each shift for signs and symptoms of COVID-19 will be completed and documented
         2. Resident will be instructed and observed to maintain appropriate distance from other residents
         3. Resident will be instructed and monitored for use of a face covering
         4. Resident will be instructed and monitored for appropriate hand hygiene practices
3. Priority of testing will be based upon CMS QSO-20-38-NH1:

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 above | Not recommended, unless the resident leaves the facility routinely |

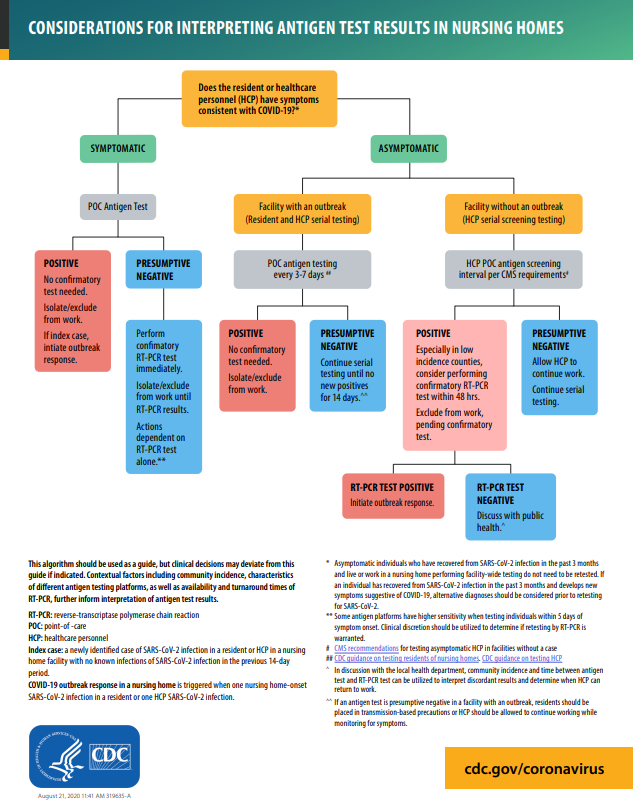
\*For outbreak testing, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. For more information, please review the section below titled, “Testing of Staff and Residents in Response to an Outbreak.”1

1. Exception to the routine testing schedule for Rural Areas: “Counties with 20 or fewer tests over 14 days will now move to “green” in the color-coded system of assessing COVID-19 community prevalence. Counties with both fewer than 500 tests and fewer than 2,000 tests per 100,000 residents, and greater than 10 percent positivity over 14 days – which would have been “red” under the previous methodology – will move to “yellow.”7
2. Documentation
   1. Documentation should include:

* Logs of county level positivity rate
* Testing schedules
* Employee testing records
* Resident testing records
* For symptomatic residents and employees:
  + Date
  + Time
  + Signs and or Symptoms
  + When testing was conducted
  + When results obtained
  + Actions taken related to test result
* Identification of a new COVID-19 Case (Outbreak)
  + Date the case was identified
  + Date all residents tested
  + Date all staff tested
  + Dates all residents retested
  + Dates all staff retested
  + Documentation of no new cases of COVID-19 among staff or residents for period of at least 14 days since most recent positive result
* Staff routine testing documentation
  + County positivity rate
  + Corresponding testing frequency identified
  + Date each positivity rate collected
  + Dates and results for all employee testing
* Shortage of testing supplies
  + For shortage of testing supplies, document:
    - Shortage
    - Attempts to order supplies
    - When the facility contacted state and local health department to assist in testing
      * Obtaining testing supplies
      * Processing test results

1. Additional Testing Considerations
   1. Staff and residents who have recovered from COVID-19 and have no symptoms (asymptomatic) will not need retesting for COVID-19 within 3 months following symptom onset.
      1. Residents or staff who show symptoms within 3 months following symptom onset of initial infection will be managed according to physician/public health recommendations.
   2. Staff and residents will be tested if symptomatic or with a COVID-19 outbreak 3 months after the date of symptom onset of prior infection or confirmed positive COVID-19 test.
      1. Review and consult with infectious diseases specialist and local public health for residents who are determined to be potentially infectious and continue transmission-based precautions.
   3. Contact State (or Local) Public Health Department for resident or staff who test positive for contact tracing
   4. Facilities may test visitors if adequate testing supplies are available
      1. Testing supplies will be prioritized for residents and staff prior to testing visitors
2. Facilities that conduct tests with own staff and equipment, including any point-or-care devices provided by the Department of Health and Human Services (HHS) must have a CLIA Certificate of Waiver.
   1. “CLIA regulations have been updated to require all laboratories to report SARS-CoV-2 test results in a standardized format and at a frequency specified by the Secretary.”5 HHS has determined that nursing homes must report point-of-care testing through the National Healthcare Safety Network (NHSN).
3. The nurse will perform hand hygiene, don full PPE, and collect specimens as soon as possible when testing is decided. Specimens will include:
   1. An anterior-nares (nasal swab) or deep nasal swab is preferred for point-of-care antigen testing
   2. A nasopharyngeal specimen (NP)
   3. An oropharyngeal specimen (OP)
4. The nurse will only use tests and test components that have not exceeded the expiration date or show any signs of compromise to the integrity of the components
5. The nurse will change gloves in between the collection of the specimen and after adding the specimen to the testing device
6. The nurse will follow manufacturer’s directions for testing in the exact order indicated (add manufacturer’s POC testing directions here)
7. The nurse will follow manufacturer’s directions for cleaning and disinfection (add manufacturer’s POC cleaning and disinfection directions here)
8. No test devices, reagent tubs, solutions or swabs will be reused.
9. Waste from testing will be handled as all other biohazardous waste.
10. Doff PPE according to PPE procedure and perform hand hygiene.
11. The nurse will document:
    1. Testing results
       1. Date
       2. Time
       3. Resident or Staff
       4. Symptoms
       5. Actions Taken
       6. Reporting

Algorithm for Interpreting Antigen Test Results3



**References and Resources**

3Centers for Disease Control and Prevention. Considerations for Interpreting Antigen Test Results in Nursing Homes. August 21, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf>

8Centers for Disease Control and Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. October 23 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

Centers for Disease Control and Prevention. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Updated Nov. 5, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

2Centers for Disease Control and Prevention. Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. September 4, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Centers for Disease Control and Prevention. Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes. May 19, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html>

4 Centers for Disease Control and Prevention. Testing Guidelines for Nursing Homes. Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel. Updated Oct. 16, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>

Centers for Disease Control and Prevention. COVID-19 Testing Overview. Updated Oct. 21, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>

9Centers for Disease Control and Prevention. Clinical Questions about COVID-19: Questions and Answers. Updated Nov. 6, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care Testing. Updated Nov. 9, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

1Centers for Medicare & Medicaid Services: QSO-20-38-NH, 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. August 26, 2020: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

5Centers for Medicare & Medicaid Services: QSO-20-37-CLIA, NH, 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. August 26, 2020: <https://www.cms.gov/files/document/qso-20-37-clianh.pdf>

7Centers for Medicare & Medicaid Services. CMS Updates COVID-19 Testing Methodology for Nursing Homes. September 29, 2020: <https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes>

United States Food & Drug Administration. Coronavirus Testing Basics. <https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics>

6 United States Food & Drug Administration. FAQs on Testing for SARS-CoV-2: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general-screening-asymptomatic>

United States Health & Human Services. COVID-19 Pandemic Response, Laboratory Data Reporting: Cares Act Section 18115: <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>

## **Interim Policy for Nasopharyngeal, Oropharyngeal and Anterior Nasal (nares) Swab Collection (Specimen Collection)**

**Policy**

It is the policy of this facility to collect an upper respiratory specimen for SARS-CoV-2 screening and diagnostic testing in consultation with a healthcare provider consistent with State and Federal guidance.

**Purpose**

Testing for SARS-CoV-2 (COVID-19), both diagnostic and screening based upon current State and Federal guidance, can detect current infection among residents and employees in order for prompt mitigation actions to be implemented in order to halt the transmission of COVID-19 in the facility.

\*Consider working with local and state health departments to coordinate testing through public health laboratories or work with commercial or clinical laboratories using molecular and antigen tests.1

“Antigen POC tests: These diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs”2

Upper respiratory specimens are recommended for initial diagnostic testing. The type of specimen is based upon the test used and the manufacturer’s directions. Nasopharyngeal and oropharyngeal specimens are not appropriate for self-collection.

“The following are acceptable specimens depending on the authorized SARS-CoV-2 viral test used:

* A nasopharyngeal (NP) specimen collected by trained healthcare personnel; or
* An oropharyngeal (OP) specimen collected by trained healthcare personnel; or
* A nasal mid-turbinate swab collected by trained healthcare personnel or by a supervised onsite self-collection (using a flocked tapered swab); or
* An anterior nares (nasal swab) specimen collected by trained healthcare personnel, or self-collected and observed by healthcare personnel, or by home or onsite self-collection (using a flocked or spun polyester swab); or
* Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by trained healthcare personnel; or
* A saliva specimen collected by the person being tested, either at home or at a testing site under supervision.”1

**NOTE: Anterior nares (nasal swab) may be more acceptable to residents for testing**

**Supplies:**

* Gloves
* Gown
* Facemask or N95 Respirator
* Eye Protection (face shield, eye protection that cover sides)
* Use only synthetic fiber swabs with plastic or wire shafts
  + Do not use calcium alginate swabs or swabs with wooden shafts
* Sterile transport tube containing 2-3ml of either viral transport medium, Amies transport medium or sterile saline unless otherwise designated by lab

**Procedure (If no specific Public Health directions are provided)1:**

1. Perform Hand Hygiene
2. Gather Supplies
3. Don PPE (gown, N-95 if available or facemask, eye protection, gloves)
4. Close room door
5. Limit only essential employees in room.
6. Only grasp swab by the end of the handle with gloved hand
7. Nasopharyngeal (NP) swab:
   1. Insert swab into nostril parallel to the palate until you reach resistance. The swab should reach depth equal to the distance from nostrils to outer opening of the ear.
   2. Roll the swab gently and leave the swab in place for several seconds to absorb secretions.
   3. Slowly remove swab while rotating the swab.
   4. It is acceptable, but not necessary, to collect specimens from both sides using same swab
   5. If a deviated septum or blockage is present, obtain specimen from the other nostril using the same swab
8. Oropharyngeal (OP) (throat) swab:
   1. Swab the posterior pharynx, rubbing both tonsillar pillars
   2. Avoid touching the tongue, teeth or gums
9. If both NP and OP swabs are collected, they should be combined in a single tube.
10. Anterior nares
    1. Insert entire swab tip, usually ½ to ¾ inch inside nostril and firmly sample the nasal wall by rotating the swab in a circular motion at least 4 times for about 15 seconds
    2. Collect any nasal drainage present
    3. Sample both nostrils with same swab
11. Place swabs immediately into sterile tubes that contain 2-3 ml of viral transport media, Amies transport medium, or sterile saline, unless using a test designed to analyze a specimen directly (i.e. point of care testing)4
12. For Point-of-Care Testing onsite:
    1. Gloves should be changed between specimen collection and after adding the specimen to the testing device
    2. Follow manufacturer’s directions for testing
    3. Disinfect testing device in accordance with manufacturer’s instructions
13. Remove PPE in proper sequence
14. Perform Hand Hygiene
15. Label Specimen
16. Specimen can be stored at 2-8°C for up to 72 hours after collection.
17. Disinfect room and surfaces with EPA list N disinfectant.

Note: If sending specimen to CDC, follow instructions at: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

* 1. Label specimen with the resident’s ID number (i.e. medical record number), unique CDC or state-generated NCov specimen ID
  2. Complete Specimen Submission form: <https://www.cdc.gov/laboratory/specimen-submission/form.html> and <https://www.cdc.gov/coronavirus/2019-ncov/downloads/COVID-19-Specimen-Submission-Guidance.pdf>
  3. If shipping to CDC, follow Public Health directions according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Requirements. <https://www.iata.org/en/programs/cargo/dgr/>
     1. If there is a delay in shipping, store specimens at -70°C or below.
     2. Follow Public Health directions for shipping instructions

**References and Resources**

1Centers for Disease Control and Prevention (CDC). Interim Guidelines for Collecting, Handling and Testing Clinical Specimens for COVID-19 Updated Nov. 5, 2020: <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention: Testing Guidelines for Nursing Homes. Updated Oct. 16, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>

Centers for Disease Control and Prevention (CDC). Interim Infection and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19 Pandemic. Updated Nov. 4 2020: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

2Office of the Assistant Secretary for Health (OASH), HHS.gov. SARS-CoV-2 (COVID-19) Fact Sheet. Guidance – Proposed use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19): <https://www.cdc.gov/coronavirus/2019-ncov/downloads/OASH-COVID-19-guidance-testing-platforms.pdf>

## **Billing for COVID-19 Testing**

**Medicare**

Medicare is usually the primary payer for Medicare covered testing.

Medicare covers the following diagnostic viral testing for nursing home residents consistent with “CDC Testing Guidelines for Nursing Homes”:

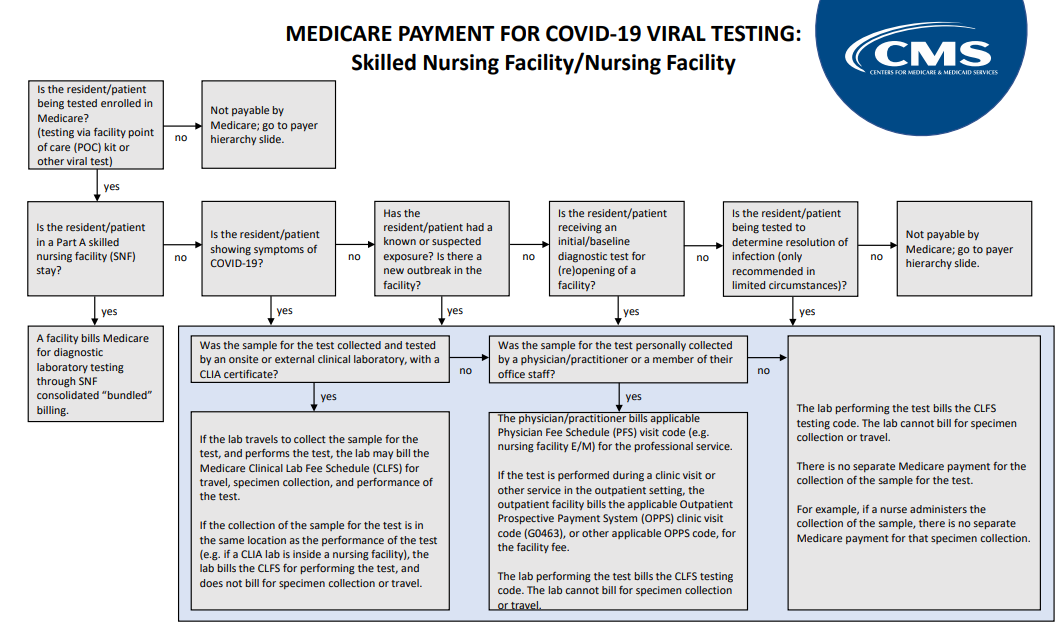
* Testing residents with signs or symptoms of COVID-19
* Testing asymptomatic residents with known or suspected exposure to an individual infected with SARS-CoV-2 including close and expanded contacts (e.g., there is an outbreak in the facility)
* Initial (baseline) testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2 as part of the recommended reopening process
* Testing to determine resolution of infection

Medicare will make payment for one diagnostic test per resident without an order from a physician, practitioner, pharmacist, or other authorized health care professional. All subsequent tests require such an order.

Medicare does not cover non-diagnostic surveillance testing.

If Medicare is a secondary payer, the facility will need to check with the primary payer for billing guidance.

See the algorithm1 “Medicare Payment for COVID-19 Viral Testing: Skilled Nursing Facility/Nursing Facility” below for further guidance.



**Medicaid**

Medicaid may cover testing; however, facilities should direct questions regarding billing to the state-specific Medicaid agency and/or contracted Medicaid managed care plan for information on testing coverage, payment, and coding for Medicaid beneficiaries. Medicaid pays after most other payers.

**New Optional Medicaid Eligibility Group for Uninsured Individuals**

The Families First Coronavirus Response Act (FFCRA) and Coronavirus Aid, Relief, and Economic Security (CARES) Act added a new optional Medicaid eligibility group for uninsured individuals, effective March 18, 2020. Individuals eligible for this group receive a limited benefit package of services related to testing and diagnosis of COVID-19 during the public health emergency.

Additional information on eligibility, covered benefits, and federal medical assistance percentage (FMAP) for the new COVID-19 testing group is available here: https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf and here: <https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf>

**Uninsured**

The Health Resources and Services Administration (HRSA) COVID-19 Claims Reimbursement to Health Care Providers and Facilities Testing and Treatment of the Uninsured Program “provides reimbursement directly to eligible providers for COVID-19 testing and treatment services furnished to uninsured individuals. Reimbursement is generally made at the Medicare payment rate.

“To access these funds, providers must enroll in the program as a provider participant, sign the terms and conditions of the program, check patient eligibility, and submit patient information. Once they have done so, they can submit claims for direct reimbursement for COVID-19 testing and treatment services furnished to uninsured individuals on or after February 4, 2020.

“Providers must verify and attest that to the best of the provider’s knowledge at the time of claim submission, the patient was uninsured at the time the services were provided. If the provider subsequently receives reimbursement for any items from other coverage, the provider must return the payment that duplicates other reimbursement to HRSA.

“Additional information is available here: <https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions> “1

**Private Insurance**

“Section 6001 of the Families First Coronavirus Response Act (FFCRA) generally requires group health plans and health insurance issuers to provide benefits for certain items and services related to testing for the detection or the diagnosis of COVID-19 when those items or services are furnished on or after March 18, 2020, and during the public health emergency.

“Under FFCRA, plans and issuers must provide this coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements.

“Section 3201 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act amended section 6001 of the FFCRA to include a broader range of diagnostic tests that plans and issuers must cover without any cost-sharing requirements, prior authorization, or other medical management requirements.

“Section 3202(a) of the CARES Act generally requires plans and issuers providing coverage for these items and services to reimburse any provider of COVID-19 diagnostic testing an amount that equals the negotiated rate or, if the plan or issuer does not have a negotiated rate with the provider, the cash price for such service that is listed by the provider on a public website. (The plan or issuer may negotiate a rate with the provider that is lower than the cash price.)

“Additionally, during the public health emergency, section 3202(b) of the CARES Act requires providers of diagnostic tests for COVID-19 to make public the cash price of a COVID-19 diagnostic test on the provider’s public internet website or face potential enforcement action including civil monetary penalties.

“Health insurance issuers and group health plans must cover COVID-19 diagnostic testing as determined medically appropriate by the individual’s health care provider, consulting CDC guidelines as appropriate.

“Health insurance issuers and group health plans are not required to cover non-diagnostic tests (i.e., testing done for public health surveillance purposes) without cost-sharing.

“Additional information is available here, including information on which tests are required to be covered: <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf> ”2

**Additional Funding Sources**

The CDC awarded funds and provided guidance to state and local jurisdictions to help them access **CDC Preparedness and Response Supplemental Funding** as well as **CARES Act** funding in support of COVID-19 Response. “This funding may be used for a variety of activities including:

* Enhancing testing capacity.
* Establishing or enhancing the ability to aggressively identify cases, conduct contact tracing and follow up, as well as implement appropriate containment measures.
* Controlling COVID-19 in high-risk settings and protect vulnerable or high-risk populations.
* Improving morbidity and mortality surveillance.
* Working with healthcare systems to manage and monitor system capacity.”3

Facilities should contact state and local public health agencies for further information on how their state is using these funds.

The Department of Health and Human Services (HHS) through its **Provider Relief Fund** makes payments to facilities and providers to provide financial relief in response to the COVID-19 pandemic. These funds must be used for increased healthcare related expenses or lost revenue attributable to coronavirus and covers a broad range of unreimbursed expenses.

Additional information on eligibility, payment formulas, and distribution timelines is available at: <https://www.hhs.gov/coronavirus/caresact-provider-relief-fund/index.html>

**References**

1,2,3 Medicare Payment for COVID-19 Viral Testing: Skilled Nursing Facility/Nursing Facility <https://edit.cms.gov/files/document/covid-medicare-payment-covid-19-viral-testing-flow-chart.pdf>

**Resources**

CDC Testing Guidelines for Nursing Homes, Diagnostic Testing

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>

CLIA

QSO 20-06-CLIA

<https://www.cms.gov/files/document/admin-info-20-06-clia.pdf>

## **Competency Checklist for COVID-19 Testing**

**Name:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Title:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Hire Date**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **Skill Area** | | **Evaluation**  **(Check One)** | | **Method of Evaluation**  **(Check One)**  D = Skills Demonstration  O = Performance Observation  W = Written Test  V = Verbal Test | | | | **Verification**  **(Initials/Date)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Competency**  **Demonstrated/**  **Meets**  **Standards** | **Needs Additional Training** |
| **D** | **O** | **W** | **V** |
| **Policies and Procedures** | Locate written infection control policies and procedures. |  |  |  |  |  |  |  |
| Verbalizes policy for   * Specimen Collection for COVID-19 testing * Point of Care Antigen Testing |  |  |  |  |  |  |  |
| Describes facility policy on immediate mitigation actions with positive results |  |  |  |  |  |  |  |
| **Hand Hygiene** | Demonstrates hand washing with soap and water |  |  |  |  |  |  |  |
| Demonstrate hand hygiene using alcohol-based hand rub (ABHR). |  |  |  |  |  |  |  |
| **Personal Protective Equipment**  **Nursing**  **Housekeeping** | Demonstrate donning and removal (in the correct sequence) of   * Gown * N95 Respirator * Goggles or face shield * Gloves * Who to contact if additional PPE is needed |  |  |  |  |  |  |  |
| Describes facility protocol for reuse of PPE |  |  |  |  |  |  |  |
| Identify location and proper storage of Personal Protective Equipment |  |  |  |  |  |  |  |
| (Insert any State specific PPE guidance) |  |  |  |  |  |  |  |
| **Standard Precautions**  **(All Departments)** | **(Nurses)**State how the facility identifies residents to be placed in transmission-based precautions (*i.e.,* contact, droplet, airborne-if equipped in facility) |  |  |  |  |  |  |  |
| **Respiratory Hygiene/Cough Etiquette**  **(All Departments)** | Demonstrate cough etiquette and respiratory hygiene |  |  |  |  |  |  |  |
| **Environmental Cleaning**   * **Housekeeping** * **Nursing** | **Housekeeping Staff:**  Demonstrate:   * Demonstrates cleaning and disinfection of room used for testing |  |  |  |  |  |  |  |
| **Nursing:**  Demonstrate cleaning/disinfection of:   * Testing equipment consistent with manufacturer’s recommendations and product instructions |  |  |  |  |  |  |  |
| **ALL Staff**  Able to identify proper use and follow label directions for each disinfectant used by employee in the facility  (EPA List N disinfectant) |  |  |  |  |  |  |  |
| **Specimen Collection-Nasopharyngeal Swab (NP)** | * Gathers supplies   + PPE   + Synthetic fiber swabs with plastic or wire shafts unless swab provided in POC testing is required for test   + Sterile transport tube * Performs Hand Hygiene * Dons PPE in correct sequence * Close room door * Grasps swab by the end of the handle * Inserts swab into nostril parallel to palate until resistance is reached * Rolls swab gently and leaves swab in place for several seconds to absorb secretions * Removes swab slowly while rotating * If resident presents with a deviated septum or blockage, use same swab to obtain specimen from the other nostril * Promptly tests specimen using point of care antigen test device following manufacturer’s recommendations or places swab into sterile tube with viral transport medium for lab testing * If specimen is sent to offsite lab, nurse follows proper labeling and storage policy * Cleaning and disinfection according to policy and procedure:   + Machine in accordance with the manufacturers directions   + Surfaces   + Room * Doffs PPE in accordance with facility procedure * Performs Hand Hygiene * Documentation of results per facility procedure * Reports positive testing immediately for proper mitigation efforts |  |  |  |  |  |  |  |
| **Anterior Nasal Swab Specimen Collection** | * Gathers supplies * Dons PPE in correct sequence * Closes room door * Using a flocked or spun polyester swab, insert the entire absorbent tip of the swab (usually ½ to ¾ of an inch inside the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. This should take approximately 15 seconds to collect the sample. Be sure to collect any nasal drainage that may be present on the swab * Samples both nostrils with the same swab * Completes antigen test promptly following manufacturer’s recommendations * Cleaning and disinfection according to policy and procedure:   + Machine in accordance with manufacture’s instructions   + Surfaces   + Room * Doffs PPE in accordance with facility procedure * Performs Hand Hygiene * Documentation of results per facility procedure * Reports positive testing immediately for proper mitigation efforts |  |  |  |  |  |  |  |
| **Nurse** | * Demonstrates POC testing quality control and instrument calibration in accordance to the manufacturer’s instructions * Describes actions if calibration fails prior to use with another resident specimen |  |  |  |  |  |  |  |
| **Other (Describe)** |  |  |  |  |  |  |  |  |
| **Other (Describe)** |  |  |  |  |  |  |  |  |

**References and Resources:**

Centers for Disease Control and Prevention. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19, Updated Nov. 5, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19). Information for Healthcare Providers. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care Testing. Updated Nov. 9, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Medicare & Medicaid Services. QSO-20-38-NH. August 26, 2020: 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: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

Centers for Medicare & Medicaid Services. Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes: <https://www.cms.gov/files/document/covid-faqs-snf-testing.pdf>

Centers for Medicare & Medicaid Services. CMS Updates COVID-19 Testing Methodology for Nursing Homes, Sept. 29, 2020: <https://www.cms.gov/newsroom/press-releases/cms-updates-covid-19-testing-methodology-nursing-homes>

Quidel. Sofia SARS Antigen FIA Resources: <https://www.quidel.com/node/8736>

BD Veritor™ System for Rapid Detection of SARS-CoV-2: <https://www.bd.com/en-us/offerings/capabilities/microbiology-solutions/point-of-care-testing/bd-veritor-plus-system-for-rapid-covid-19-sars-cov-2-testing>

**\*I certify that I have received orientation in the above-mentioned areas.**

**\*Employee:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

**Initials**  **Signature**  **Date**

**Evaluator/Trainer:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

**Initials Signature Date**

***(PLACE IN EMPLOYMENT FILE)***

## **Training Plan – COVID-19 Testing**

|  |  |  |
| --- | --- | --- |
| Training Name: COVID-19 Testing | | |
|  | **❑ Training ❑ Simulation ❑ Workshop 🗹 Presentation** | |
| *Training Objectives* | Attendees will verbalize the reasons COVID-19 testing is done in the facility  Attendees will describe the types of COVID-19 testing  Attendees will identify PPE necessary for testing  Attendees will verbalize immediate follow-up for positive COVID-19 test results | |
| *Connection to Overall Project Goals* | This training is part of the overall project to educate and support nursing facility operators and staff regarding COVID-19 testing in accordance with regulatory compliance and best practices | |
| *Participants:*  *Who should attend?* | For the purposes of this education, we will refer to the regulations and CDC guidance for COVID-19 testing for employees and residents  Education is offered in slide presentation form with speaker’s notes for use by each facility.  Participants:  Nursing Staff-RN, LPN, Nursing Assistant  Interdisciplinary Team | |
| **What training should they attend before this one?** | No pre-requisite |
| **What training should they attend after this?** | Annually, new licensed nurse hire and as needed |
| *Facilitators:*  *(How many trainers should participate and whom?)* | ***One presenter will be needed to facilitate the presentation, discussion and post-test*** | |
| *Logistics Requirements* | *What is needed?* | Communication slide presentation  Attendance Sheet |
| Room for training  Projector  Screen or other blank light-colored surface | Room for training  Projector  Screen or other blank light-colored surface |

**TRAINING RESOURCES**

**References and Resources**

Centers for Disease Control and Prevention. Considerations for Interpreting Antigen Test Results in Nursing Homes. August 21, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/hcp/nursing-home-testing-algorithm-508.pdf>

Centers for Disease Control and Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. Updated Oct. 23, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

Centers for Disease Control and Prevention. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Updated Nov. 5, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Centers for Disease Control and Prevention. Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. Updated Sept. 4, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

Centers for Disease Control and Prevention. Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes. May 19, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html>

Centers for Disease Control and Prevention. Testing Guidelines for Nursing Homes. Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel. Updated Oct. 16, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html>

Centers for Disease Control and Prevention. COVID-19 Testing Overview. Updated Oct. 21, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html>

Centers for Disease Control and Prevention. Guidance for SARS-CoV-2 Point-of-Care Testing. Updated Nov. 9, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

Centers for Medicare & Medicaid Services: QSO-20-38-NH, 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. August 26, 2020: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

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

United States Food & Drug Administration. Coronavirus Testing Basics. <https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics>

United States Food & Drug Administration. FAQs on Testing for SARS-CoV-2: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general-screening-asymptomatic>

## **POST TEST – COVID-19 Testing**

|  |  |
| --- | --- |
| **Question: True or False?** | **Answer** |
| 1. If I have no signs/symptoms of COVID-19 I do not need to be tested |  |
| 1. If I was tested last month at my doctor’s office, I do not ever have to be tested again as long as my test was negative |  |
| 1. Even one new case of COVID-19 for staff or resident is considered an outbreak |  |
| 1. The prevalence of COVID-19 in the county will dictate the testing frequency for routine testing |  |
| 1. All staff or residents with signs/symptoms of COVID must be tested |  |
| 1. The results of all testing done in the facility must be reported per regulatory guidelines |  |

Employee Printed Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Employee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## **POST TEST – COVID-19 Testing Answer Key**

|  |  |
| --- | --- |
| **Question: True or False?** | **Answer** |
| 1. If I have no signs/symptoms of COVID-19 I do not need to be tested | **False**. Staff must be tested if symptoms, if an outbreak according to requirements and routinely based upon County positivity rate |
| 1. If I was tested last month at my doctor’s office, I do not ever have to be tested again as long as my test was negative | **False.** Staff must be tested if symptoms, if an outbreak according to requirements and routinely based upon County positivity rate |
| 1. Even one new case of COVID-19 for staff or resident is considered an outbreak | **True.** |
| 1. The prevalence of COVID-19 in the county will dictate the testing frequency for routine testing | **True.** Minimum testing frequency is determined by low, medium or high community COVID-19 Activity |
| 1. All staff or residents with signs/symptoms of COVID must be tested | **True** |
| 1. The results of all testing done in the facility must be reported per regulatory guidelines | **True** |

## **COVID-19 Outbreak Investigation and Management**

**Policy**

It is the policy of this facility to recognize and contain COVID-19 outbreaks and outbreak measures will be instituted whenever there is evidence of an outbreak as outlined below.

The Infection Preventionist, or designee, will conduct the COVID-19 outbreak investigation and has the authority to implement and/or direct outbreak measures to control possible transmission. These actions will be carried out in coordination with the Medical Director, administration, and medical staff as well as state and local health agencies. In the absence of the Infection Preventionist, the Director of Nursing or the Assistant Director of Nursing or designee will conduct the investigation.

Appropriate notifications to the Medical Director, Administrator, all departments, attending physicians, state and local agencies, and resident representatives will take place as soon as possible after the outbreak has been identified.

Outbreak monitoring and reporting will continue until the outbreak has resolved. The facility will send all appropriate reports to state, local health department agencies and National Healthcare Safety Network (NHSN) in accordance with State and Federal requirements.

Control measures include:

* Identifying space in the facility that will be dedicated to care for residents with confirmed COVID-19
* Identify dedicated, essential staff to work the COVID-19 floor, unit, or wing
* Single/private room for resident new admissions and readmissions for 14-day quarantine
* Single/private room for residents exposed to COVID-19 for 14-day quarantine
* Testing
* Reporting
* Active screening of staff, visitors, vendors
* Resident screening and monitoring
* Management/restricted of communal areas for dining and activities
* Physical/Social Distancing
* Personal Protective Equipment
* Universal Source Control
* Hand Hygiene
* Physical/Social Distancing
* Visitation restriction during outbreaks
* Cleaning and Disinfection

An interdisciplinary evaluation of the COVID-19 outbreak will be completed, and findings and recommendations will be presented at the quarterly Quality Assurance Committee meeting.

**Definitions**

The Centers for Medicare & Medicaid Services indicates, “An outbreak is defined as a new COVID-19 infection in any healthcare personnel (HCP) or any nursing home-onset COVID-19 infection in a resident.”1

\*\*Please check with your State specific guidance for COVID-19 Outbreak in Nursing Facilities

**Goal of COVID-19 Outbreak Investigation and Management**

The goal of outbreak investigation and management is to rapidly identify any new cases of COVID-19, prompt resident placement in isolation on the COVID-19 designated unit/area, begin outbreak testing and follow facility systems to stop any further spread of COVID-19 in the facility.

**COVID-19 Outbreak Prevention:**

All residents and healthcare personnel will be educated on COVID-19 to include:

* COVID-19 and signs/symptoms
* Personal Protective Equipment (PPE)
* Resident placement
* Universal Source Control
  + Healthcare personnel
  + Residents
* Physical/Social Distancing
* Respiratory Hygiene and Cough Etiquette
* Visitation Policies and Procedures
* Communal Dining and Activity Areas
* Hand Hygiene
* Testing
* Reporting
* Active screening of staff, visitors, vendors
* Resident screening and monitoring
* Cleaning and Disinfection

**COVID-19 Outbreak Prevention Measures for Healthcare Personnel**

1. Healthcare Personnel must be screened upon entrance to the facility. Healthcare Personnel with fever and/or signs or symptoms of COVID—19 are restricted from work and will be tested for COVID-19
   * If testing results indicate COVID-19 is confirmed, employee will follow the CDC guidance on “Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection”
2. Healthcare Personnel routine testing to be completed based upon the Community COVID-19 Activity Level in accordance with CMS Guidance1:
   * See COVID-19 Antigen Testing Policy and Procedure

**COVID-19 Outbreak Measures for Residents**

In the event of an outbreak or suspected case, the DON, Infection Preventionist, Administrator and Medical Director will be contacted to direct the process:

1. All facility residents
   * Screening (identify facility policy, i.e.3 times/day) for fever and signs/symptoms of COVID-19 and potential exposure
2. New Admissions/Readmissions
   * Private/Single room in a separate observation area for 14 days under monitoring and evaluation to identify evidence of COVID-19
   * Testing at the end of the 14-day observation period can increase certainty that resident is not infected3
   * “A resident who is admitted to the facility with COVID-19 does not constitute a facility outbreak.” Resident should be placed onto the COVID-19 designated unit/area and placed on isolation.1
3. Rapid identification that an outbreak exists.
   * Symptomatic resident
   * Testing consistent with CDC and CMS guidance
4. To implement immediate response:
   * Symptomatic Resident:
     + Prompt testing
       - POC Rapid Antigen
       - PCR-RT (with lab able to provide results in less than 48 hours)
     + Place resident in a private room in separate observation area awaiting results
   * Resident Confirmed COVID-19 Positive:
     + Isolation on dedicated COVID-19 wing/unit
     + Full Personal Protective Equipment (PPE) to prevent the spread of the COVID-19 outbreak:
       - Gloves
       - Gown
       - Eye Protection
       - N95 or higher respirator
     + Implement dedicated, essential staffing on COVID-19 wing/unit
   * Roommates of Residents Confirmed COVID-19 Positive:
     + Resident should be placed in a private room and observed under quarantine for 14 days.
       - Full PPE for all employees entering room
         * Gloves
         * Gown
         * Eye Protection
         * N95 or higher respirator
   * All Residents:
     + During a facility outbreak, full PPE for the care of all residents:
       - Gloves
       - Gown
       - Eye Protection
       - N95 or higher respirator
     + Outbreak testing of all residents previously tested negative until no new cases identified
       - “For outbreak testing, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of 3 COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result.”1
         1. The CDC indicates, “if testing capacity allows and does not divert staff and resources away from performing other critical IPC measures (e.g., ensuring effective implementation of [Transmission-Based Precautions](https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) for infected and potentially exposed residents), the facility should consider testing more frequently (e.g., every 3 days) for the first two weeks of the outbreak, then test less frequently (e.g., every 7 days) thereafter until no new cases are identified for 14 days.”2
         2. When testing of asymptomatic residents is completed as part of an outbreak response, “if an antigen test is positive, no confirmatory test is necessary. Residents should be placed in transmission-based precautions.”4
   * Communal dining and activities will be halted during an outbreak
   * Physical/Social distancing will be practiced by all staff and residents whenever possible
   * Universal source control
     + Residents
     + Employees
   * Visitation restriction during outbreak with exception of compassionate care situations

**COVID-19 Outbreak Measures for Healthcare Personnel (Employees)**

1. **Healthcare Personnel** must be screened upon entrance to the facility. Employees with fever and/or signs or symptoms of COVID—19 are restricted from work and will be tested for COVID-19.

* If testing results indicate COVID-19 is confirmed, employee will be sent home and facility will follow the CDC guidance on “Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection”
* All healthcare personnel that previously tested negative will be tested followed by retesting every 3-7 days until testing identifies no new cases for at least 14 days since the most recent positive results.1
  + - “If testing capacity allows and does not divert staff and resources away from performing other critical IPC measures (e.g., ensuring effective implementation of [Transmission-Based Precautions](https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) for infected and potentially exposed residents), the facility should consider testing more frequently (e.g., every 3 days) for the first two weeks of the outbreak, then test less frequently (e.g., every 7 days) thereafter until no new cases are identified for 14 days.”2

1. **Dedicated and Essential Staffing**
2. **Education:** Orientation of new employees and routine education should include:

* COVID-19 signs and symptoms, description of what a COVID-19 “outbreak” is, their role in an outbreak and methods of prevention
  + Hand hygiene
  + COVID-19 Active Screening
    1. Employees
    2. Residents
    3. Visitors
    4. Others
  + Personal Protective Equipment
    1. All residents
    2. Residents on quarantine
    3. On COVID-19 designated unit/wing
  + COVID-19 observation and quarantine for new admissions, readmissions and residents exposed to COVID-19
  + Placing residents with confirmed COVID-19 on the COVID-19 designated unit/wing
    1. Assessment for change of condition related to COVID-19
  + Reporting symptoms of COVID-19 to the Infection Preventionist or Nurse Manager promptly.
    1. Residents
    2. Employees (will need to leave facility immediately upon identification of symptoms and testing directions)
  + Cleaning and Disinfection

1. **Monitoring/Surveillance**
   * Routine daily screening and ongoing monitoring of resident condition with cares for signs and symptoms of COVID-19 will be done by the frontline staff with cares.
   * Surveillance, logging, and mapping by the Infection Preventionist or member of the Infection Control team to determine any trends for action and for future analysis.
   * A system for the Infection Preventionist to monitor COVID-19 outbreaks in the community using the COVID-19 county positivity rate on the COVID-19 Nursing Home Data site ( <https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg> ) and communicate with public health agencies for pertinent information regarding infections or outbreaks identified in the community or any other significant findings.
2. **Enforce Compliance**
   * It is the responsibility of all employees to comply with facility infection prevention and control policies and procedures:
     1. Hand Hygiene
     2. Standard and Transmission-based Precautions
     3. PPE
     4. Respiratory Hygiene and Cough Etiquette
     5. Equipment and Environment
        1. Disinfection and appropriate product use
   * The Infection Preventionist, Supervisors and managers will be accountable for assuring staff, resident, and visitor compliance.
   * If non-compliance is identified through process surveillance, further actions may be taken by the Infection Preventionist or administration.
3. **Notify State and Local Health Officials**
   1. As required by State Law, Public Health Codes or Ordinances, report COVID-19 cases to public health agencies as soon as possible.
      1. CLIA Reporting
      2. State Requirements
      3. NHSN Reporting
   2. Report measures the facility has taken to prevent further spread within the facility and to (or from) the community.
   3. Seek assistance from public health if needed.
4. **Continue to Monitor**

* Identify any new signs, symptoms and/or cases of COVID-19.
* Determine if there are additional lab results or new information that would assist to identify common causes.

1. **Re-evaluate and Modify**

* The Infection Preventionist and facility leadership will identify any additional necessary modifications, or any measures as needed, for example:

1. Possible closure of a unit or the facility to new admissions or transfers out (except in a medical emergency)
2. **Resolve**

* When there have been no new cases as a result of testing employees and residents as a response to an outbreak for at least 14 days, discuss with the Medical Director and Public Health to determine if the outbreak resolved.
* Employees will not return to work until employee meets CDC Guidance on “Criteria for Return to Work for Healthcare Personnel with SARS-CoV-2 Infection (Interim Guidance). <https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html>
* Report resolution to appropriate public health agencies.

1. **Analyze Data and Plan for the Future**

* The Infection Preventionist will compile data gathered during the COVID-19 outbreak and examine for possible improvement opportunities in identification and management of the outbreak.
* The Infection Preventionist will develop a written report of the COVID-19 outbreak details. The report will identify possible strategies that could be implemented to prevent future outbreaks or improve the process.

1. **Report**

* The Infection Preventionist will outline the report to the Quality Assurance Committee and determine actions to take that may assist prevent or control in the future.
* Develop a plan to implement process improvement activities.
* Report the findings to all department managers and employees. Feedback is a critical factor in staff satisfaction and performance improvement.

**References and Resources**

1Centers for Medicare & Medicaid Services: QSO-20-38-NH, 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. August 26, 2020: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

2Centers for Disease Control and Prevention. Clinical Questions about COVID-19: Questions and Answers. Updated October 5, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes>

3Centers for Disease Control and Prevention. Preparing for COVID-19 in Nursing Homes. June 25, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

4 Centers for Disease Control and Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. Updated October 23, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

## **COVID-19 Outbreak Management Checklist**

The below is a checklist of steps recommended to be completed by the organization related to a COVID-19 Outbreak Management. This checklist was designed to provide a preparation and management for a COVID-19 outbreak. This resource can provide leadership, clinical and staff actions in accordance with organization policy and procedures, federal requirements and state/local public health department.

| **Action Steps** | **Completed** | | **Follow Up Actions** |
| --- | --- | --- | --- |
| **Yes** | **No** |
| **COVID-19 Outbreak Preparation and Management Plan should include the following:** | | | |
| 1. Infection Preventionist designation and authority |  |  |  |
| 1. Identify and designate space in the facility that will be dedicated to care for residents with confirmed COVID-19 |  |  |  |
| 1. Determine dedicated and essential staffing plan |  |  |  |
| 1. Prepare a “COVID-19 Outbreak Investigation and Management Policy and Procedure” |  |  |  |
| 1. Prepare a plan for active screening    1. Employee    2. Resident    3. Visitors    4. Vendors |  |  |  |
| 1. Prepare an interdisciplinary leadership plan for resident placement    1. Develop the plan    2. Determine staff role for implementation of resident placement decisions (including off hour decision process)       1. Isolation       2. Quarantine       3. Co-horting       4. PPE       5. Signage |  |  |  |
| 1. Implement the process for isolation/quarantine in single/private room and process for observation and monitoring of new admissions and readmissions for evidence of COVID-19    1. Full PPE upon entering room       1. Gloves       2. Gown       3. Eye Protection       4. N95 or higher equivalent (mask if no N95 available) |  |  |  |
| 1. Implement the process for placement in private room to quarantine on isolation and care of residents exposed to COVID-19    1. Full PPE upon entering room       1. Gloves       2. Gown       3. Eye Protection       4. N95 or higher equivalent (mask if no N95 available) |  |  |  |
| 1. Implement a separate space in the facility that can be dedicated for the care of residents who are confirmed to be positive for COVID-19.    1. Dedicated staff    2. Eliminate non-essential staff from space/unit |  |  |  |
| 1. Prepare an emergency staffing plan in the event of a COVID-19 outbreak |  |  |  |
| 1. Prepare a plan for employees exposed to COVID-19 |  |  |  |
| 1. Prepare a plan for employee with COVID-19    1. Exclude from work - quarantine    2. Return to work |  |  |  |
| 1. Universal source control    1. Employees    2. Residents |  |  |  |
| 1. Identify Personal Protective Equipment Supply    1. PPE Burn Rate Calculator    2. Put policies/procedures in place for use and optimization    3. Determine documentation process for PPE optimization decisions |  |  |  |
| 1. All Staff Education    1. Orientation    2. COVID-19    3. PPE, Hand Hygiene, etc.    4. Cleaning and Disinfection    5. Employee Health |  |  |  |
| 1. Prepare Testing Procedures consistent with State, CMS and CDC guidance: <https://www.cms.gov/files/document/qso-20-38-nh.pdf> |  |  |  |
| 1. Create a list of emergency contacts:    1. Local Public Health Department contact    2. State Health Department contact    3. Acute Care Partner contact(s)    4. Vendor emergency contact(s)    5. Staffing agency contact(s) |  |  |  |
| **COVID-19 Outbreak Plan** | | | |
| 1. Resident Confirmed COVID-19: Immediate isolation in private room (or cohort residents with COVID-19 confirmation) with door closed on COVID-19 unit/dedicated space.  * Implement transmission-based precautions (COVID-19) * Full PPE   + Gloves   + Gown   + Eye Protection   + N95 or higher respirator |  |  |  |
| 1. Implement dedicated, essential staff on COVID-19 unit |  |  |  |
| 1. Health Department notification |  |  |  |
| 1. Implement COVID-19 Outbreak testing for employees and residents consistent with CMS guidance: <https://www.cms.gov/files/document/qso-20-38-nh.pdf> |  |  |  |
| 1. Complete clinical assessment of resident  * Document in medical record |  |  |  |
| 1. Complete Notifications (Physician, resident, representative) and document in the medical record |  |  |  |
| 1. Document on 24 Hour Report |  |  |  |
| 1. Add to resident line list |  |  |  |
| **Communication Plan – Confirmed COVID-19** |  |  |  |
| 1. Resident representative will be informed of COVID-19 Status |  |  |  |
| 1. Local/Health Public Health Department |  |  |  |
| 1. The facility will inform all residents and their families and/or representatives of COVID-19 outbreak status in facility |  |  |  |
| 1. Employee Communication |  |  |  |
| 1. Medical Director will be promptly informed |  |  |  |
| 1. CLIA Reporting – COVID-19 testing in facility |  |  |  |
| 1. NHSN Reporting |  |  |  |
| 1. Other: |  |  |  |
| **Disinfection Criteria** | | | |
| Equipment   1. Dedicated or disposable patient-care equipment should be used    1. If equipment must be used for more than one resident, it will be cleaned and disinfected before use on another resident, according to manufacturer’s recommendations using EPA-registered disinfectants against COVID-19: <https://www.epa.gov/newsreleases/epa-releases-list-disinfectants-use-against-covid-19> |  |  |  |
| 1. Cleaning and disinfecting room, high touch areas and equipment will be performed using products that have EPA-approving emerging viral pathogens: <https://www.epa.gov/newsreleases/epa-releases-list-disinfectants-use-against-covid-19> |  |  |  |
| **Staff Re-Education (reinforce infection control protocols)** | | | |
| The facility will re-educate employees and reinforce:   * COVID-19 Signs and Symptoms * Active Screening process * Hand Hygiene practices * Cough Etiquette and Respiratory Hygiene * Resident placement and Transmission Based Precautions * Appropriate utilization of PPE * PPE Sequencing specific for COVID-19 * Optimization protocols for PPE * Isolation, room logs * Consistent staff assignment * Staff roles and responsibilities |  |  |  |

***NOTE: The situation regarding COVID-19 is still evolving worldwide and can change rapidly. Stakeholders should be prepared for guidance from CMS and other agencies (e.g., CDC) to change. Please monitor the relevant sources regularly for updates.***

**References and Resources**

Centers for Medicare & Medicaid Services: QSO-20-38-NH, 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. August 26, 2020: <https://www.cms.gov/files/document/qso-20-38-nh.pdf>

Centers for Disease Control and Prevention. Clinical Questions about COVID-19: Questions and Answers. Updated Nov. 6, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes>

Centers for Disease Control and Prevention. Optimizing Personal Protective Equipment (PPE) Supplies. Updated July 16, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>

Centers for Disease Control and Prevention. Preparing for COVID-19 in Nursing Homes. June 25, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html>

Centers for Disease Control and Prevention. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes. Updated October 23, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html>

**FDA Resources:**

Emergency Use Authorizations: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

**CMS Additional Resources**

Long term care facility – Infection control self-assessment worksheet: https://qsep.cms.gov/data/252/A.\_NursingHome\_InfectionControl\_Worksheet11-8-19508.pdf

Infection control toolkit for bedside licensed nurses and nurse aides (“Head to Toe Infection Prevention (H2T) Toolkit”): https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment

Infection Control and Prevention regulations and guidance: 42 CFR 483.80, Appendix PP of the State Operations Manual. See F-tag 880: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf