**COVID-19**

**Antigen Testing Policy**

**(12.05.2022)**

**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, Centers for Disease Control and Prevention, 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 will be implemented in addition to recommended Infection Prevention and Control measures and includes:

* To test all vaccinated and unvaccinated symptomatic residents and staff,
* To test vaccinated and unvaccinated asymptomatic residents and facility staff in facilities as part of the COVID-19 outbreak response through either a contact tracing or broad-based testing approach
* To test residents and facility staff who were exposed to persons with COVID-19 outside of the nursing home.

**Definitions**

**“Antibody (or serology) tests look for antibodies** in your blood that your immune system produced in response to SARS-CoV-2, the virus that causes COVID-19. **Antibody tests should not be used to diagnose a current SARS-CoV-2 infection or COVID-19”1**

**“Close contact** ” refers to someone who has been within 6 feet of a COVID-19 positive person for a cumulative total of 15 minutes or more over a 24-hour period.”3

“**Higher-risk exposure**” refers to exposure of an individual’s eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if present in the room for an aerosol-generating 3 procedure. This can occur when staff do not wear adequate personal protective equipment during care or interaction with an individual.”3

**Viral COVID-19 Tests:**

* **“Antigen tests** are rapid tests which produce results in 15-30 minutes. They are less reliable than NAATs, especially for people who do not have symptoms. A single, negative antigen test result does not rule out infection.  To best detect infection, a negative antigen test should be repeated at least 48 hours apart (known as serial testing). Sometimes a follow-up NAAT may be recommended to confirm an antigen test result.”2
* **“NAATs**, such as PCR-based tests, are most often performed in a laboratory. They are typically the most reliable tests for people with or without symptoms. These tests detect viral genetic material, which may stay in your body for up to 90 days after you test positive. Therefore, you should not use a NAAT if you have tested positive in the last 90 days.”2

**Outbreak- “**An outbreak investigation is initiated when a single new case of COVID-19 occurs among residents or staff to determine if others have been exposed. An outbreak investigation would not be triggered when a resident with known COVID-19 is admitted directly into TBP, or when a resident known to have close contact with someone with COVID-19 is admitted directly into TBP and develops COVID-19 before TBP are discontinued. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission.”3

**(Facility) 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.”3

**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) if necessary
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 (face shield or goggles that cover the sides of the eyes)
		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, even if mild, must be prioritized for viral testing as soon as possible
			1. Symptomatic facility staff will be immediately tested with a viral test and will be restricted from the facility pending results. “negative results from at least one viral test indicate that the person most likely does not have an active SARS-CoV-2 infection at the time the sample was collected.”4
				1. If using a NAAT, a single negative test is sufficient unless there is a high suspicion of SARS-CoV-2 infection, then maintain work restrictions and confirm with a second NAAT
				2. If using an antigen test, a negative result should be confirmed by either a negative NAAT or a second negative antigen test that is taken 48 hours after the first negative test
			2. Symptomatic residents will be placed on COVID-19 transmission-based precautions (with staff using all PPE recommended for the care of a resident with suspected COVID-19 infection) while test results are pending.
				1. It is recommended that if both COVID-19 and Influenza Viruses are co-circulating, resident should be tested for both viruses
				2. If antigen test is negative and resident is symptomatic, continue with transmission-based precautions and perform a second antigen test 48 hours after the first negative test and if negative, again 48 hours after the second negative test

If physician prefers, a confirmatory nucleic acid amplifications test (NAAT) such as reverse transcriptase polymerase chain reaction (RT-PCR) can be completed

* + - 1. For symptomatic residents and/or staff, document:
				1. Date and time of symptom identification
				2. When testing was conducted
				3. Results and when obtained
				4. Actions the facility took based upon results
	1. **Outbreak Testing**: “ An outbreak investigation is initiated when a single new case of COVID-19 occurs among residents or staff to determine if others have been exposed. An outbreak investigation would not be triggered when a resident with known COVID-19 is admitted directly into TBP, or when a resident known to have close contact with someone with COVID-19 is admitted directly into TBP and develops COVID-19 before TBP are discontinued.”3 Contact and follow recommendations of the facility’s public health authority.
		1. “Testing should begin immediately, but not earlier than 24 hours after the exposure, if known”3.
			1. Facilities have two options to conduct outbreak testing:
				1. Contact tracing
				2. Broad-based testing approach.

**Note:** “If the facility has the ability to identify close contacts of the individual with COVID-19, they could choose to conduct focused testing based on known close contacts. If a facility does not have the expertise, resources, or ability to identify all close contacts, they should instead investigate the outbreak at a facility-wide or group-level (e.g., unit, floor, or other specific area(s) of the facility). Broader approaches might also be required if the facility is directed to do so by the jurisdiction’s public health authority, or in situations where all potential contacts are unable to be identified, are too numerous to manage, or when contact tracing fails to halt transmission.”3

1. For newly identified COVID-19 positive staff or resident that can identify close contacts:
	* + 1. Staff: Test all staff, regardless of vaccination status that had a higher-risk exposure with a COVID-19 positive individual.
				- Conduct testing “immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.”5
			2. Residents: Test all residents, regardless of vaccination status that had close contact with a COVID-19 positive individual.
				- Conduct testing “immediately (but not earlier than 24 hours after the exposure) and, if negative, again 48 hours after the first negative test and, if negative, again 48 hours after the second negative test. This will typically be at day 1 (where day of exposure is day 0), day 3, and day 5.”5
			3. It is not generally recommended to test asymptomatic staff or residents who have recovered from SARS-CoV-2 infection in the last 30 days.
				- For staff or residents who have recovered from SARS-CoV-2 infection in the past 31-90 days, it is recommended to use an antigen test
			4. “If no additional cases are identified during contact tracing or the broad-based testing, no further testing is indicated.”5
			5. If additional cases are identified, test using the broad-based approach and continue facility-wide testing every 3-7 days until there are no new cases for 14 days.
				- If antigen testing is being used, consider testing every 3 days
2. Consult with local public health department for questions/concerns
3. Facility staff and residents who test positive for COVID-19 do not need repeat testing.

**NOTE:** For additional information on contact tracing and broad-based testing: Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

* 1. **Routine Testing: “**Routine screening testing of asymptomatic staff is not longer recommended but may be performed at the discretion of the facility.”3
	2. Testing Refusals:
	3. 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. If outbreak testing has been triggered the staff member will be restricted from the building until the procedures for outbreak testing have been completed.
	4. 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.
		1. Residents with signs or symptoms of COVID-19 who refuse testing may be placed on isolation with transmission-based precautions until criteria for discontinuing transmission-based precautions are met in accordance with CDC guidance
			1. 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

**Documentation**

Documentation should include:

* Community transmission level and date
* Testing schedules for outbreak testing
* 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
* 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. Facilities that conduct tests with their 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
	2. “CMS-certified long-term care facilities may submit point-of-care SARS-CoV-2 testing data, including antigen testing data to CDC’s National Healthcare Safety Network (NHSN). This CDC- and CMS-preferred pathway to submit data to CDC’s NHSN applies only to CMS-certified long-term care facilities. Test data submitted to NHSN will be reported to appropriate state and local health departments using standard electronic laboratory messages. Other types of LTC faciities may also report testing data in NHSN for self-tracking or to fulfill state or local reporting requirements, if any. While NHSN is the CDC-and CMS-preferred pathway, Medicare and medicaid-certified LTC facilities may submut data through the other mechanisms described in the Current Methods of Submission section of HHS Laboratory Reporting Guidance to meet the reporting requirements.”6

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

**ANTIGEN POINT-OF-CARE (POC) TESTING:**

1. Collect supplies

* PPE
* Specimen test kit
1. 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)
2. 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
3. The nurse will change gloves in between the collection of the specimen and after adding the specimen to the testing device
4. The nurse will follow manufacturer’s directions for testing in the exact order indicated (add manufacturer’s POC testing directions here)
5. The nurse will follow manufacturer’s directions for cleaning and disinfection (add manufacturer’s POC cleaning and disinfection directions here)
6. No test devices, reagent tubs, solutions or swabs will be reused.
7. Waste from testing will be handled as all other biohazardous waste.
8. Doff PPE according to PPE procedure and perform hand hygiene.
9. The nurse will document:
	1. Testing results
		1. Date
		2. Time
		3. Resident or Staff
		4. Symptoms
		5. Actions Taken
		6. Reporting

**References and Resources**

1United States Food & Drug Administration (FDA) COVID-19 Basics: <https://www.fda.gov/consumers/consumer-updates/covid-19-test-basics>

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

3Centers 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. Revised 09/23/2022: <https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf>

4 Centers for Disease Control and Prevention. Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, Updated September 23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>

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

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

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

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

Centers for 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 Disease Control and Prevention. Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, Updated Sept.23, 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html>

Centers for Disease Control and Prevention. Clinical Questions about COVID-19: Questions and Answers. Updated Sept. 2022: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes>

United States Food & Drug Administration. FAQs on Testing for SARS-CoV-2, 09/27/2022: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general-screening-asymptomatic>

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

Centers for Disease Control and Prevention. Testing and Management Considerations for Nursing Home Residents with Acute Respiratory Illness Symptoms when SARS-CoV-2 and Influenza Viruses are Co-circulating, November 22, 2022: <https://www.cdc.gov/flu/professionals/diagnosis/testing-management-considerations-nursinghomes.htm>

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

United States Food & Drug Administration. COVID-19 Testing Basics. <https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics>

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>