



Notice - October 2020 COVID-19 Updates to Nursing Homes and Assisted Living Programs

(October 1, 2020)

This omnibus update to various COVID-19 guidance affecting Nursing Homes and Assisted Living Programs provided by the Maryland Department of Health (MDH) replaces all previous guidance issued by MDH regarding the following topics:

- Visitation of Residents
- Guidance for Phased Relaxation of Nursing Home and Assisted Living Program Restrictions
- Guidance on the Use of Point of Care Testing devices for COVID-19
- Standard Operating Procedure for COVID-19 RAPID ANTIGEN TESTING

Visitation for Nursing Home and Assisted Living Programs and other Restrictions Relaxation

Effectively immediately, all previous MDH guidance regarding nursing home and assisted living program visitation and reopening are rescinded, including:

- [“Guidance for Outdoor Visitation at Nursing Homes”](#)
- “Maryland Department of Health Guidance for Relaxation of Restrictions Implemented During the COVID-19 Pandemic [For both [Nursing Homes](#) and [Assisted Living Programs](#)]”

All nursing homes shall follow the Centers for Medicare & Medicaid Services (CMS) guidance on nursing home visitation regarding COVID-19 ([QSO-20-39-NH](#)). All assisted living programs should follow the same guidance in developing safe policies for their residents and visitors.

This Notice is effective immediately and shall remain in effect until it is revised or until the state of emergency has been terminated and the proclamation of the catastrophic health emergency has been rescinded.

Robert R. Neall
Secretary



Guidance on the Use of Point of Care Testing devices for COVID-19 (10/01/2020)

The U.S. Department of Health and Human Services is supplying each nursing home that has a Clinical Laboratory Improvement Amendments of 1988 (CLIA) permit with one rapid point of care diagnostic testing device (POC system) to test for SARS CoV-2 (2019 Novel Coronavirus). This guidance applies to both nursing homes and assisted living programs with a CLIA permit.

1. Updating State and CLIA Permits.

Facilities are required to expand their state and CLIA permits to address adding POC systems. A form to obtain a change form can be found at the following link: <https://health.maryland.gov/ohcq/Labs/Pages/Licensure.aspx>

Facilities that do not have a CLIA or state permit may apply for the permits by downloading the applications at: <https://health.maryland.gov/ohcq/Labs/Pages/Licensure.aspx>

Completed applications or change forms should be emailed to paul.celli@maryland.gov for questions about the application process you may also call 410-402-8045.

2. Establish a rapid point of care COVID-19 testing program.

Facilities should carefully read all inserts with the testing device and the testing kits. The facility is expected to follow those instructions when running the tests. Failure to follow the instructions may result in inaccurate test results.

Facilities should designate several staff to perform the testing and provide the required training to the staff who will perform the test.

The POC system should **not** be operated in a high traffic area. It should be set up in an area with handwashing facilities, electric and good lighting. It should not be done in nurses' stations, medication rooms, nourishment areas, staff break rooms or resident areas. The selected space should have smooth cleanable surfaces in good repair.

Testing kits may require temperature control that may require refrigeration. A thermometer scaled in 2 degree intervals shall be kept in the refrigerator and the temperature of the refrigerator shall be recorded daily before testing. Designated staff should be trained on how to run the tests and on all safety issues.

Staff should wear PPE when running the tests including a mask, face shield or goggles, gloves and gown. PPE worn while collecting or analyzing test samples should not be worn when providing resident care.

The area shall be cleaned and disinfected daily with an FDA approved disinfectant that is effective against Coronaviruses. Manufacturer's instructions for the disinfection must be followed.

Waste generated in the testing area must be considered hazardous waste and disposed of with your facility's medical waste.

For their own health, staff should not be eating, drinking or talking on the phone when performing testing.

The facility must establish a system to record and act on the results of the tests informing the facility's medical director and director of nurses so they may respond to any actionable results. The dedicated staff should be trained on that process. The process must include a system to notify the state and local health department of the results. CMS requires that all results be reported to the health department.



SOP (Standard Operating Procedure) for COVID-19 RAPID ANTIGEN TESTING (10/01/2020)

The State of Maryland Department of Health has identified point-of-care lateral flow immunoassays (rapid antigen tests) as useful diagnostic tools for COVID-19 and subsequently developed guidance for use of these tests.

Use of rapid antigen tests is contingent upon implementation in appropriate clinical scenarios. Guidance is described and diagrammed herein.

Only rapid antigen tests that have received an Emergency Use Authorization (EUA) from the FDA **OR** that have been independently verified by a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory may be used. As of August 28, 2020, four separate assays have been awarded Emergency Use Authorization (EUA) through the FDA: LumiraDx, BD Veritor, Quidel Sofia and Abbott BinaxNOW.

1. Testing Requirements:

- a. All testing must be performed in compliance with the standards set forth by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), federal and state requirements.
- b. All antigen tests that currently hold an EUA are authorized for use in a patient care setting that is operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- c. Facilities will need to register with the Office of Health Care Quality (OHCQ) at <https://health.maryland.gov/ohcq/Labs/Pages/Licensure.aspx>
- d. Testing may only be performed under the direction and order of an independently licensed medical practitioner (MD/DO, PA, or NP). For the purposes of this guidance, pharmacists (based on the state's scope of practice) may also be considered independently licensed medical practitioners and may direct and order testing for COVID-19.
- e. Individuals will be required to obtain necessary training and certification provided by the manufacturer prior to performing the point-of-care testing.
- f. Testing implementation and interpretation should follow testing SOP algorithms and CMS Interim Final rule of August 26, 2020 (See below).
- g. Use of COVID-19 testing is contingent upon electronic reporting of results to the Maryland Department of Health (MDH).

- h. All patients undergoing testing must be provided with detailed instructions on test interpretation and subsequent care and isolation instructions.
- i. The ultimate implementation of, the clinical decision making from, and the reporting of COVID-19 testing, are the responsibilities of the licensed practitioner (MD/DO, PA, NP, or pharmacist) who administered the test and who is listed as the ordering practitioner for the testing procedure.

2. **Antigen Tests**

Antigen tests are relatively inexpensive and can be used at the point-of-care (POC). 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). Proper interpretation of antigen test results is important for accurate clinical management of patients with suspected COVID-19, or for identification of potentially infected persons when used for screening.

- Antigen tests are best when used with high viral shedding; probably within the first 5 days after symptom onset
- These tests should not be utilized to determine either the duration of transmission-based precautions or when HCP can return to work.

a. **Use of Antigen Tests in Congregate Settings**

In settings where large groups of individuals are expected to repeatedly congregate and social distancing may be hard to maintain (e.g., long-term care facilities, correctional institutions, shelters) the accessibility, frequency, and sample-to-answer time of antigen tests offer profound logistical benefits. Analytical limits of detection should remain a consideration, however, and the implementation of antigen testing should be considered additive to RT-PCR strategies.

For now, MDH requires continuing to use RT-PCR tests for outbreak situations, since these are settings when we need the most accurate results available to make informed decisions.

b. **Use of Antigen Tests:**

- i. Symptomatic residents and health care professionals (HCP)
- ii. Asymptomatic HCP in facilities without COVID-19 outbreak as required by Centers for Medicare & Medicaid Services (CMS) recommendations.
- iii. Other circumstances, such as testing asymptomatic residents and HCP who were exposed to persons with COVID-19 outside of the nursing home (e.g., recent hospitalization or outpatient services) or through other screening activities. **However, we recommend emphasis on maintaining infection control precautions even if the rapid antigen test is negative.**
- iv. Ambulatory settings
- v. During emergency room visits
- vi. Household contacts
- vii. School settings



Standard Operating Procedure for Point of Care Antigen Testing (10/01/2020)

1. Purpose

This Standard Operating Procedure (SOP) will establish a procedure for rapid, point-of-care antigen testing for the following populations:

- a. Long-term and post-acute care facilities
- b. Emergency and homeless shelters
- c. Patients evaluated at primary care offices and other ambulatory settings
- d. Household contacts
- e. School settings

2. Concept of Operations

MDH will provide guidance to organizations, offices, and agencies who are strategically positioned to reach the target populations for whom antigen testing is prioritized.

3. Scope

This SOP will apply to trained personnel working to identify COVID-19 infection within the target populations and settings.

4. Procedure

a. Organizational Information

- i. Trained personnel will screen individuals to determine if the person needs a COVID-19 test (PCR, point-of-care, etc.)
- ii. The U.S. Department of Health and Human Services (HHS) will be providing testing kits and supplies directly to the nursing homes.
- iii. Manufacturers will be providing all necessary training and technical support with the initial setup and any follow up needed, including the transmission of test results.

b. Screening for Symptoms

- i. Trained staff determines if person is asymptomatic or symptomatic
 - (A) Symptomatic person may include those with fever $> 100.4^{\circ}\text{F}$, severe sore throat, loss of taste or smell, shortness of breath, cough, congestion or runny nose, or muscle aches

- (B) Alternate symptoms including headache, nausea, vomiting, and diarrhea, and others that have been identified as potential COVID-19 symptoms and may prompt further screening, action, or investigation.
 - ii. Staff personnel will let the individual know if they are eligible for testing based on the SOP for rapid COVID-19 antigen testing and CMS interim final rule of August 26, 2020.
- c. **Approved for testing and testing protocol**
 - i. Trained personnel perform a rapid, point-of-care antigen test and provide the patient with the results.
 - ii. Trained personnel obtain subsequent sample for RT-PCR testing if indicated.
 - iii. Prior to ending the visit, trained personnel reiterate protective measures and follow the SOP for Rapid COVID-19 testing regarding need for repeat testing.
- d. **Follow-up/closure**
 - i. Staff ensures that results are submitted for each rapid, point-of-care antigen test performed for COVID-19 to the Maryland Department of Health (MDH).
 - ii. Negative cases: Follow SOP algorithm for COVID-19 rapid antigen testing.
 - iii. Confirmatory testing with molecular testing: Follow SOP algorithm for COVID-19 rapid antigen testing

5. **Testing of symptomatic residents or healthcare providers (HCP):**

- a. Some antigen platforms have higher sensitivity when testing individuals within 5 days of symptom onset. Clinical discretion should be utilized to determine if individuals who test negative on such platforms should be retested with RT-PCR.
- b. Symptomatic residents and HCP should be kept in transmission-based precautions or excluded from work until RT-PCR results return.
- c. If an individual has recovered from SARS-CoV-2 infection in the past 90 days and develops new symptoms suggestive of COVID-19, alternative diagnoses should be considered prior to retesting for SARS-CoV-2.

6. **Testing of asymptomatic residents or HCP in nursing homes and assisted living programs as part of an outbreak response*:**

- a. If an antigen test is positive, consider confirming with a RT-PCR test.
- b. Residents who test positive should be placed in transmission-based precautions, and HCP should be excluded from work.

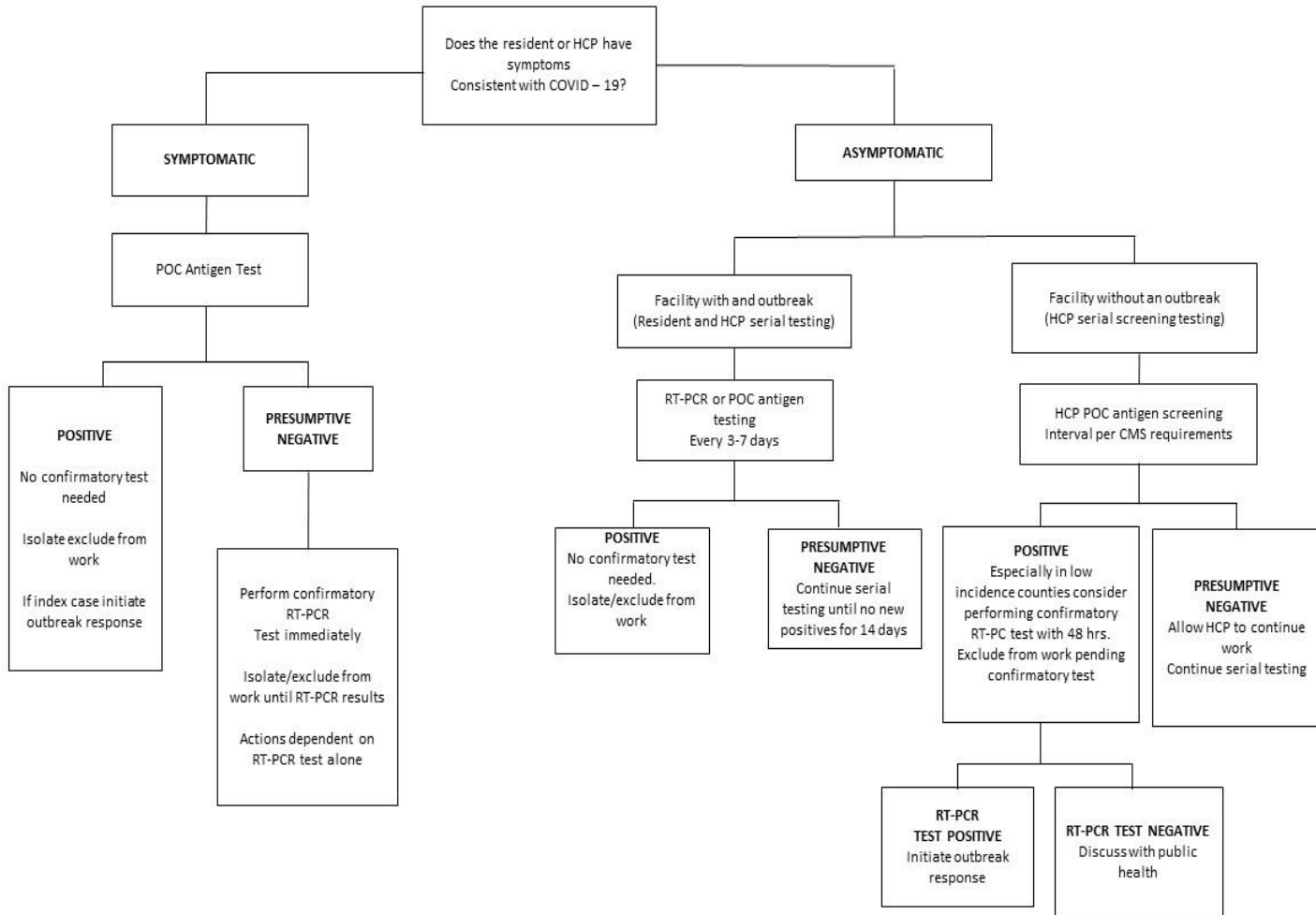
- c. If an antigen test is presumptive negative, residents should continue appropriate precautions for facilities with an outbreak.
- d. HCP should be allowed to continue to work with continued symptom monitoring. The facility should continue serial viral testing (RT-PCR) every 3-7 days until no new cases are identified for a 14-day period.
- e. Asymptomatic individuals who have recovered from SARS-CoV-2 infection in the past 90 days and live or work in a nursing home or assisted living performing facility-wide testing should not be tested for SARS-CoV-2.

Note: MDH requires using RT-PCR testing during an outbreak

7. Testing of asymptomatic HCP in nursing homes and assisted living programs without an outbreak:

- a. If an antigen test is positive, perform confirmatory RT-PCR test within 48 hours of the antigen test, especially in counties with low prevalence. HCP who test positive by rapid antigen test must be excluded from work unless they receive a confirmatory negative PCR.
- b. If the confirmatory RT-PCR test is positive, continue excluding the HCP from work until they meet criteria to discontinue isolation, and initiate an outbreak response including facility-wide testing of all residents and HCP.
- c. If the confirmatory RT-PCR test is negative, discuss results with the local health department to determine how to interpret the discordant results and next steps. The incidence of SARS-CoV-2 infection in the local community can help interpret the likelihood of a false positive antigen test. The time between antigen test and RT-PCR test should also be considered. If RT-PCR is performed >48 hours after an antigen test, it is possible that the viral dynamics have changed during the time between antigen and RT-PCR and testing. Therefore, the antigen test may indicate a true infection even if the RT-PCR is negative.
- d. If an antigen test is presumptive negative, allow HCP to continue to work. The HCP should continue to monitor for symptoms, and serial testing should continue per CMS recommendations.
- e. HCP who have recovered from SARS-CoV-2 infection in the past 90 days and are asymptomatic should not be tested for SARS-CoV-2.

Decision Guide



CMS interim final rule of August 26, 2020

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