

Executive Office of Health and Human Services

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Bureau of Health Care Safety and Quality

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**Memorandum**

**TO:** Nursing Home Administrators

**FROM:** Elizabeth D. Kelley, MPH, MBA, Director

Bureau of Health Care Safety and Quality

**SUBJECT:** Point of Care Testing Devices for Nursing Homes

**DATE:** October 5, 2020

The Centers for Medicare and Medicaid Services (CMS) recently announced a new program to send U.S. Food and Drug Administration (FDA) authorized rapid point-of-care (POC) diagnostic test equipment to nursing homes across the country. Nursing homes receiving the rapid point-of-care diagnostic test instruments will receive one diagnostic test instrument and an initial supply of testing kits.

**Indications for Use:**

The Centers for Disease Control and Prevention (CDC) has published *Interim Guidance for Rapid Antigen Testing for SARS-CoV-2* which can be found [here](https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html). As noted in the CDC guidance, antigen tests for COVID-19 are generally less sensitive than viral tests that detect nucleic acid using reverse transcription polymerase chain reaction (PCR). There are limited data to guide the use of rapid antigen tests as screening tests on asymptomatic persons to detect or exclude COVID-19, or to determine whether a previously confirmed case is still infectious. **Accordingly, at this time, antigen test results do not satisfy the testing requirements under the Department of Public Health’s (DPH) Long-term Care Surveillance Testing** [**guidance**](https://www.mass.gov/doc/updates-to-long-term-care-surveillance-testing-827/download) **or the corresponding requirements set forth in MassHealth’s** [**Provider Bulletin 148**](https://www.mass.gov/doc/nursing-facility-bulletin-148-covid-19-baseline-and-surveillance-testing-requirements-for-0/download)**:** COVID-19 Baseline and Surveillance Testing Requirements for Nursing Facilities**.**

Additionally, CMS has developed a frequently asked question webpage for use of the rapid POC diagnostic test equipment distributed to nursing homes, which can be found [here](https://www.cms.gov/files/document/covid-faqs-snf-testing.pdf). Important points from the frequently asked questions include:

* Use the instrument in a location associated with a current CLIA certificate.
* Perform a site-specific and activity-specific risk assessment to identify and mitigate

safety risks.

* Train staff on the proper use of the instrument and ways to minimize the risk of

exposures to specimens during testing. Follow manufacturer recommended procedures for decontamination after

use.

* Follow Standard Precautions when handling clinical specimens, including hand

hygiene and the use of PPE, such as laboratory coats or gowns, gloves, facemask and eye

protection.

* When using patient swabs, minimize contamination of the swab stick and wrapper by

widely opening the wrapper prior to placing the swab back into the wrapper.

* Change gloves after adding patient specimens to the instrument.
* Decontaminate the instrument after each run by using an EPA-approved disinfectant

for SARS-CoV-2. Following the manufacturer’s recommendations for use, such as

dilution, contact time, and safe handling.

**Considerations for use in Massachusetts’ Nursing Homes:**

Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest. There are limited data to guide the use of rapid antigen tests as screening tests on asymptomatic persons to detect or exclude COVID-19, or to determine whether a previously confirmed case is still infectious.

Individuals who test positive with an antigen test should be treated as a presumptive positive COVID-19 case and managed accordingly. However, until the positive result is confirmed with a PCR test, a resident with a positive antigen test result should NOT be cohorted with another COVID-positive resident or physically moved to a dedicated COVID unit. These individuals should remain in a private room on transmission-based precautions pending the results of the PCR test. This includes asymptomatic residents with a positive antigen test result in in the setting of an outbreak[[1]](#footnote-1). Staff should be excluded from work until confirmatory PCR test results are completed.

**Ordering Requirements:**

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. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual. This may be accomplished through the use of physician approved policies (e.g., standing orders).

**Reporting Requirements:**

Massachusetts nursing homes that receive rapid POC diagnostic test equipment must submit both positive and negative test results to the Department of Public Health’s Bureau of Infectious Diseases and Laboratory Sciences (BIDLS). The spreadsheet attached to this guidance (Addendum A) includes the required data variables. Please send a sample completed spreadsheet to ISIS-ImmediateDiseaseReporting@mass.gov along with primary contact details. The BIDLS team will review it, and work with your nursing home to onboard to a web-based interface which will accept manual uploads of completed spreadsheets.

DPH strongly encourages all nursing homes in Massachusetts to monitor the CMS and CDC website for up-to-date information and resources:

* CMS website: <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>
* CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html>
1. An outbreak is defined as any new case(s) of COVID-19 in a resident or staff member in a nursing home that has had no cases in the previous four weeks, excluding residents who test positive for SARS-CoV-2 within 14 days of their admission to the nursing home. [↑](#footnote-ref-1)