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Memorandum

TO: Nursing Home and Rest Home Administrators

FROM: Elizabeth Daake Kelley, MBA, MPH
Director, Bureau of Health Care Safety and Quality

SUBJECT: Antigen Rapid Point of Care COVID-19 Testing for Long-Term Care (LTC) Facilities

DATE: May 12, 2022

Overview

This guidance provides information to long-term care (LTC) facilities on how to request BinaxNOW test kits from the Massachusetts Department of Public Health (DPH), updates and clarifications to the situations in which kits requested from DPH may be used, and what documentation and protocols must be in place prior to a LTC facility requesting test kits. This updated guidance aligns reporting requirements with federal changes that only positive antigen results need to be reported to DPH's State Laboratory.

Background

The Abbott BinaxNOW test received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) in August 2020. The test is performed on a nasal swab and delivers results in just 15 minutes with no instrumentation, using lateral flow technology with observed sensitivity of 97.1% and specificity of 98.5% in a clinical study. The test was approved for detection of SARS-CoV2 in symptomatic individuals within seven days of onset of illness, but may be used "off label" in asymptomatic individuals (discussed below). The EUA allows for use in point-of-care settings that are qualified to have the test performed and are operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Within these settings, the test can be performed by a variety of trained professionals, including nurses.

The Commonwealth conducted a validation study of the performance of the Abbott BinaxNOW test in both symptomatic and asymptomatic individuals at a high throughput, drive-through, free community testing site in Massachusetts. A paired PCR result was the reference for sensitivity and specificity calculations. The BinaxNOW was found to have a very high sensitivity in adults with high viral loads,

especially those who were newly symptomatic, and a very high specificity overall. Overall, 98.6% sensitivity was observed in those with high viral levels (Ct ≤ 30) and 99%+ specificity was observed across all groups. Further details about the study can be found here: BinaxNOW Antigen Test General Study .

The Massachusetts Department of Public Health (DPH) continues to provide BinaxNOW test kits for use at nursing homes and rest homes (LTC facilities) for the purpose of testing staff who are not fully vaccinated prior to the beginning of each shift, visitors, symptomatic residents and staff, and staff who feel they are at increased risk of exposure at no cost to the facilities.

Use of BinaxNOW test kits in Massachusetts LTC facilities:

At this time, BinaxNOW test kits requested from DPH should be used for the following purposes:

- for individuals entering the facility who are not regularly reporting staff (e.g. visitors);
- testing symptomatic staff and residents at the LTC facility;
- testing asymptomatic staff and residents at the LTC facility as part of outbreak testing;
- testing direct care staff prior to beginning a shift on a unit they are not assigned;
- testing staff who are not fully vaccinated prior to beginning each shift. If staff are working two consecutive shifts then they only need to be tested prior to beginning the first shift; and
- testing for staff who feel they are at increased risk of exposure.

BinaxNOW test kits should **not** be used for broad scale asymptomatic testing of staff and residents when there are no resident or staff cases in the facility.

Situations in which BinaxNOW test kits requested from DPH may be used are described below:

Non-staff entering the building: Individuals who come inside the LTC facility for the purpose of visiting a resident, performing work, etc. This does not include regularly reporting staff. (**NOTE**: This guidance does not affect indoor visitation requirements and does not impose a requirement for visitors to LTC facilities to be tested. The most current visitation guidance for LTC facilities may be found on the DPH COVID-19 website.)

- Those who test positive should be treated as a positive COVID-19 case, be denied entry into the LTC facility, and encouraged to contact their healthcare provider.
- Those who test negative may be allowed to enter the LTC facility, provided, that they meet the screening criteria (e.g. are not exhibiting any COVID-19 like symptoms) and comply with other in-person visitation requirements such as wearing a mask and social distancing as described in the Visitation Guidance.

Residents and staff with symptoms: Residents or staff who have symptoms of an illness consistent with COVID-19 may be tested using the BinaxNOW test:

Symptoms consistent with COVID-19
• Fever (100.0° Fahrenheit or higher), chills, or shaking chills • Cough (not due to other known cause, such as chronic cough)

- Difficulty breathing or shortness of breath
- New loss of taste or smell
- Sore throat
- Headache
- Muscle aches or body aches
- Nausea, vomiting, or diarrhea
- Fatigue
- Nasal congestion or runny nose

- Those who test positive should be treated as a positive COVID-19 case and managed accordingly.
- Those who test negative should be informed that the negative test is presumptive and the LTC facility should follow up with the individual's provider and order a repeat test for COVID-19[1].

Residents and staff without symptoms in a facility where there is at least one new resident or staff case: Residents or staff who do not have symptoms of an illness consistent with COVID-19 but live or work in a facility where there is at least one case of COVID-19 may be tested using the BinaxNOW test. BinaxNOW test kits may be used to meet the recommended all staff and resident testing following the identification of a new resident or staff case.

- Those who test positive should be treated as a positive COVID-19 case and managed accordingly.
- No further testing is required for those who test negative. If a staff member or residents develops symptoms consistent of an illness with COVID-19 then they should be retested.

Testing direct care staff before beginning a shift on a unit they are not normally assigned: Direct care staff should care for residents on the same unit or floor and not rotate to other parts of the facility. If a direct care staff member is assigned to work a shift on a unit or floor that they are not normally assigned, the facility may test the direct care worker prior to beginning their shift.

Testing staff who are not fully vaccinated prior to beginning to work a shift: If a staff member is not fully vaccinated, meaning at least two weeks after their second dose in a two-dose series, such as the Pfizer or Moderna vaccines, or two weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine, the facility must perform BinaxNOW testing on the individual prior to beginning to work a shift. If the staff member is working two consecutive shifts then they only need to have BinaxNOW testing performed on them before beginning the first shift.

Testing for staff who feel they are at increased risk of exposure: If a staff member feels they are at increased risk of exposure they may request that the facility perform BinaxNOW testing prior to beginning to work a shift, regardless of vaccination status.

[1] https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#:~:text=A%20negative%20antigen%20test%20result,alternative%20to%20confirmatory%20NAAT%20testing.

If a resident has a positive BinaxNOW test then the resident should be moved to the COVID-19 care area, and cared for using COVID-19 positive precautions. Facilities should consult with DPH Epidemiology at 617-983-6800 for situation-specific considerations.

If a staff member has a positive BinaxNOW test then they should isolate at home and follow the Isolation and Quarantine for Healthcare Personnel Guidance.

PCR test confirmation for staff and residents: Unless there are extenuating clinical circumstances (i.e. a resident has a negative antigen test but is symptomatic), a molecular or PCR test is not needed.

Temperature Controls for BinaxNOW test kits

In accordance with the BinaxNOW COVID-19 Ag Card test's instructions for use (IFU), test kits must be stored at temperatures between 2 and 30°C (35.6 - 86°F). The IFU states to ensure that the test components (Antigen card and buffer) are at room temperature (59 and 86°F) during performance of the test. DPH requires the room temperature to be recorded upon test administration. Data obtained by DPH indicates that the test's accuracy is significantly reduced when used outside of this temperature range.

Requirements for facilities requesting BinaxNOW test kits:

LTC facilities must meet the four following requirements in order to request Abbott BinaxNOW test kits from DPH:

1. Have an approved CLIA certificate of waiver;
2. Maintain an adequate supply of PPE;
3. Ensure all staff performing testing meet training requirements; and
4. Report test results to DPH.

Additional information about each requirement and how that requirement may be met is provided below in Appendix A: Requirements for LTC facilities

Requesting BinaxNOW test kits

LTC facilities that currently meet all requirements outlined above may request BinaxNOW test kits through the DPH resource request process. In order to preserve supply and ensure BinaxNOW test kits are used appropriately, a LTC facility may request BinaxNOW test kits on a monthly basis. A facility may request an amount of test kits equal to up to four times the number of licensed beds for the months of March, April, May and June, (e.g. a 100-bed facility can request 400 tests on a monthly basis). A facility was previously able to request test kits for the months of December 2020 through March 2022. If a LTC facility's prior allotment of tests has not been used or results have not been properly reported to the department a new request for test kits will not be fulfilled. Requests in excess of this amount will not be fulfilled by DPH.

> In order to request BinaxNOW test kits, facilities should complete Appendix C: Resource Request Form and email the completed form to COVID19.Resource.Request@mass.gov. Delivery timelines may vary based on DPH delivery capacity. Facilities should expect to receive requested test kits within one week of a request being submitted.

Appendix A: Requirements for LTC facilities

1. Obtaining a CLIA certificate:

For facilities that do not yet have a CLIA certificate, the application for a CLIA Certificate (CMS Form 116) can be found here:
https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf

For your convenience, the below information may help you fill out your CLIA application if your facility does not already have one:

- In section I, please select "Other Changes (Specify)" and fill in "COVID 19" to alert our program that your application is a part of this distribution effort
- In section II, please select "Certificate of Waiver".
- In section III, please select "27-Skilled Nursing Facility/Nursing Facility"
- In section V, please select "Yes" if you are applying as a company and have more than one LTC facility in your organization.
    - In #1 in section V, please select "Yes" as each LTC facility may act as a temporary testing location should there be a need to test residents or staff.
    - In #2 and #3 in section V, please select "No".
- In section V, please select "No. If no, go to section V1" if you are applying as a single facility at a single site.
- In section VI, please enter "BinaxNOW™ COVID-19 Ag Card"
- Please completely fill out the other sections, as applicable.

Please also include information about other tests you may be performing at this location and provide specifics on the test systems.

If you are only performing COVID-19 testing pursuant to a CLIA certificate of waiver then you may not need to obtain a state clinical laboratory license, the state clinical laboratory program will follow up with you, as appropriate.

Please send the completed application to The Clinical Laboratory Program at clialab@mass.gov.

Should you have any questions, please contact the Clinical Laboratory Program at (617) 660-5385.

2. Maintaining an adequate supply of PPE

All staff administering Abbott BinaxNOW test kits must wear appropriate personal protective equipment (PPE) when running each test and handling patient specimens. For healthcare personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:

- N95 mask or higher-level respirator (a surgical mask can be used only if an N95 is not available)
- Eye protection
- Gloves
- Gown, when collecting specimens

Staff administering tests must change gloves between handling of specimens suspected of COVID-19. Refer to DPH Comprehensive PPE Guidance or contact your local board of health for further information regarding the proper use of PPE.

3. Ensuring staff complete training requirements

All staff administering Abbott BinaxNOW test kits within a LTC facility must complete all Abbott BinaxNOW training modules. The training modules can be found here.
The Abbott BinaxNOW training modules include:

Module 1: Getting Started
Module 2: Quality Control
Module 3: Specimen Collection and Handling
Module 4: Patient (Individual) Test
Module 5: Navica Admin App

These modules provide a detailed step-by-step guide to the test process. All the modules should be completed in their entirety prior to staff performing test on individuals.

It is the responsibility of the LTC facility to ensure that all the staff administering tests have completed the necessary training requirements. Staff administering tests must watch the Abbott BinaxNOW video training modules as part of their attestation prior to ordering tests.

Additionally, further information about the proper use of the Abbott BinaxNOW test kits can be found on the package insert and on the FDA website. This includes information regarding specimen collection, handling, transportation, and storage.

Staff who have questions or concerns about the administration of the test can utilize these direct links to Abbott support: 800-257-9525 8:00 am – 8:00 pm Monday through Friday or ts.scr@abbott.com.

4. Reporting Test Results:

Massachusetts LTC Facilities that receive any rapid POC antigen test equipment must report positive test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS).

Results of positive BinaxNOW tests should be reported to DPH using Casetivity, with "BinaxNOW COVID Antigen" in the "Test" field. If your facility does not have access to Casetivity, you will need to gain access by sending an email to ISIS-ImmediateDiseaseReporting@mass.gov and following the instructions you receive.

DPH strongly encourages all facilities 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/hcp/facility-planning-operations.html

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- HHS website: https://www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html

Additionally, please visit DPH's website that provides up-to-date information on COVID-19 in Massachusetts: https://www.mass.gov/2019coronavirus.

Appendix B: Maximum Order Volumes

Maximum order volumes for LTC facilities requesting BinaxNOW test kits from the Department of Public Health are calculated based on the number of licensed beds at each facility. Facilities are permitted to receive up to four tests per licensed bed, per month, rounded up to the nearest unit of 40 test kits. A facility may request an amount of test kits equal to up to four times the number of licensed beds for the months of March, April, May and June. Tests are distributed in kits containing 40 tests per kit, and shipments will only be made in units of entire test kits.

Facilities which request fewer than the maximum order volume of test kits per month are **not eligible** to receive additional test kits the following month.