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Memorandum

TO: Nursing Home and Rest Home Administrators

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

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

DATE: November 23, 2020

Background

The Abbott BinaxNOW test received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) in late August. 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 7 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 $\leq$ 30) and 99%+ specificity was observed across all groups. Further details about the study can be found here: BinaxNOW Antigen Test Abstract | Graph.

The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense (DOD) recently announced an initiative to deliver Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 rapid diagnostic tests ("BinaxNOW test kits") to states. Massachusetts has been advised that it will receive approximately 2 million tests for use in priority settings, including but not limited to long-term care facilities and schools.

The Massachusetts COVID-19 Command Center, in collaboration with the Massachusetts Department of Public Health (DPH) is making BinaxNOW test kits available for use at nursing homes and rest homes (LTC facilities) for the purpose of testing visitors and symptomatic residents and staff, at no cost to the facilities.

This guidance provides information to LTC facilities on how to request BinaxNOW test kits from DPH, 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.

Use of BinaxNOW test kits in Massachusetts LTC facilities:

LTC facilities may have access to POC rapid diagnostic tests purchased directly or distributed by U.S. Department of Health and Human Services, including BinaxNOW test kits. This guidance applies only to BinaxNOW test kits supplied by DPH, and does not apply to POC rapid diagnostic tests obtained by LTC facilities from the federal government.

At this time, BinaxNOW test kits requested from DPH should be used for the purpose of testing symptomatic staff and residents at the LTC facility and for individuals entering the facility who are not regularly reporting staff (e.g., visitors). BinaxNOW test kits should **not** be used for broad scale asymptomatic testing of staff and residents.

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, managed accordingly and follow up with PCR testing for COVID-19 testing.
- 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 PCR test for COVID-19.

While waiting for the PCR test confirmation, the resident should be cared for using COVID-19 positive precautions and in a private room, if possible. Consult with DPH Epidemiology at 617-983-6800 for situation-specific considerations.

PCR test confirmation for staff and residents: given the superior accuracy of PCR testing versus antigen testing, LTC facilities should obtain a specimen for PCR testing as soon as possible after staff and residents become symptomatic. A PCR test result (rather than an antigen test result) should be used to determine the proper protocol for the resident or staff member when taken within 2 days of an antigen test result; the result of a PCR test taken within 2 days of an antigen test will "override" the result of the antigen test.

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 (e.g. a 100-bed facility can request 400 tests on a monthly basis). If a LTC facilities' 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 1 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 "BinaxNOWTM 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 here. 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 both positive and negative test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS).

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

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 one test per licensed bed, per week, rounded up to the nearest unit of 40 test kits. 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.

The document embedded below contains the maximum number of test kits permitted for each facility to request, per month:

LTC_BinaxNOW_Max OrderVolumes.xlsx

Appendix C: Resource Request Form

Date Submitted to DPH:	**OPEM 213TS – Resource Request Form – COVID19** ***Abbott BinaxNOW Test Kits***	**Page 1 of 1** **Version 10-5-20**

I. REQUESTING AGENCY POINT OF CONTACT - Please Type ALL Answers		
1. Requestor's Name (Please Print)	**2.** Title	**3.** Requestor's Phone No.
4. Requestor's Organization	**5**. Requestor's E-Mail Address	
6. DELIVERY Address (include any special instructions; such as if there is a loading dock, of if the facility needs to be contacted prior to delivery).	**7**. DPH Facility ID number	
	7. 24/7 Contact Name and Phone number for delivery issues	
	8. Hours of operations to receive delivery (for example 8:00 am – 3:00 pm M-F)	

II. REQUEST SPECIFICS - Please Type ALL Answers		
9. Order (Please complete all fields)		
No. Requested	Items Available:	Date Need, pending availability
	Abbott BinaxNOW COVID-19 Test Kit [Each kit contains test cards and swabs to conduct 40 tests, therefore, please request the total number of **kits** needed based on this quantity]	

III. Submittal Process
10.. To submit a request, please email completed form to: **COVID19.Resource.Request@mass.gov**