Abbott BinaxNOW in Residential Congregate Care Programs: Instructions and Guidance

December 17, 2020

Purpose

The following document outlines instructions for organizations operating Covered Programs, as defined in the EOHHS Congregate Care Surveillance Testing Guidance, (hereafter "organizations" or "congregate care organizations") who elect to receive Abbott BinaxNOW tests. Please note that organizations who elect to receive Abbott BinaxNOW tests will not be eligible for the other testing access options outline in the aforementioned guidance.

Overview

The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense (DOD) recently announced an initiative to deliver 150 million Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 rapid diagnostic tests ("BinaxNOW test kits") to strategic environments. Massachusetts has been advised that it will receive approximately 2 million tests for use in priority settings, including priorities identified by the Governor. Beginning January 1st, 2021, the Executive Office of Health and Human Services (EOHHS) in collaboration with the Massachusetts Department of Public Health (DPH) will allow organizations operating residential congregate care Covered Programs ("residential congregate settings"), as defined by the EOHHS Congregate Care Surveillance Testing Guidance ("Surveillance Testing Guidance"), to request Abbott BinaxNOW tests for the purpose of meeting surveillance testing objective. Participating organizations will receive the test kits at no cost, and in most cases, administer the test using existing staff resources.

This memo provides those organizations with an overview of the use of Abbott BinaxNOW test kits in residential congregate care settings and information regarding the documentation, reporting requirements, and protocols required prior to receiving test kits. Additionally, the last page of the memo includes a Readiness Review Checklist that must be completed by organizations operating Covered Programs in order to request distribution of Abbott BinaxNOW test kits.

Additional details on the Abbott BinaxNOW test on the can be found on the Abbott BinaxNOW webpage and in the product documentation.

Use of Abbott BinaxNOW test in residential congregate settings:

Organizations which elect to receive BinaxNOW test kits should carefully consider the risks and benefits of using this test for surveillance testing when compared to a molecular test, such as those offered by the vendor specified in the EOHHS Congregate Care Surveillance Testing Guidance. Additional information regarding the performance of the Abbott BinaxNOW test can be found in Appendix B: Abbott BinaxNOW Performance

BinaxNOW test kits requested from DPH should only be used in accordance with the recommendations for surveillance testing, with frequency based on county positivity rate, as detailed in the EOHHS Congregate Care Surveillance Testing Guidance. Additional detail regarding the application of this guidance to in the context of Abbott BinaxNOW tests is below:

Asymptomatic individuals, testing in accordance with the Surveillance Testing Guidance:

- Those who test positive should be treated as a positive COVID-19 case; these individuals should be instructed to isolate for a minimum of 10 days
- Those who test negative should be informed of their test result. Negative tests in asymptomatic individuals do not need to be confirmed by a PCR test. However, individuals should be counseled that if they develop **any** symptoms of COVID-19 within several days, testing should be performed with a PCR test.

Individuals with symptoms testing in accordance with the Surveillance Testing Guidance: staff and residents 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;
- Those who test negative should be informed of the test result. A provider may decide to order a confirmatory PCR test if there is strong clinical suspicion of COVID-19, including if there was known close contact (i.e., 15 minute or more of contact at less than 6 feet of distance or being coughed or sneezed upon by, or caring for a COVID-positive individual);
- Limited data on the ability of a negative BinaxNOW test to exclude COVID-19 in children 18 and under are available. Clinicians may choose to follow-up negative BinaxNOW tests in symptomatic children with a PCR.

PCR test confirmation for patients and community members: When a PCR test is indicated for confirmation, the result of a PCR test taken within 2 days of an antigen test will "override" the result of the antigen test in situations where the test results are different. Antigen positive individuals should not routinely try to get a PCR test in the hope of testing negative.

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 to receive BinaxNOW tests:

Organizations electing to receive Abbott BinaxNOW tests must complete all five of the following requirements in order to receive approval from EOHHS for their distribution of Abbott BinaxNOW test kits.

1. Obtain an approved CLIA certificate of waiver
2. Secure a signed physician order for testing
3. Confirm ability to maintain an adequate supply of PPE
4. Ensure all testing staff meet training requirements
5. Verify ability to complete DPH reporting requirements

Additional information about each requirement and how that requirement may be met is provided below in Appendix A: Requirements for Residential Congregate Care Providers. Once complete, organizations should complete Online Readiness Review Checklist.

Distribution Process:

Each organization electing to receive BinaxNOW tests must complete the Online Readiness Review Checklist in order to certify that all the requirements have been completed. Once submitted, the organization will then be directed to coordinate with DPH to schedule a delivery of test kits. Deliveries will be made to a **single location specified by the organization**; organizations operating multiple sites will not be able to designate multiple delivery addresses.

Organizations which elect to receive BinaxNOW test kits will receive a fixed supply of test kits based on the number of staff and residents served in the Covered Programs it operates. Organizations should note that the number of BinaxNOW tests received may not be enough to perform multiple rounds of testing in response to new positive cases. Insurance is required to cover testing that is deemed medically necessary, as defined in DOI guidance. This includes close contacts of confirmed or clinically diagnosed COVID-19 cases.

Appendix A: Requirements for Residential Congregate Care Providers

1. Obtaining a CLIA certificate

Organizations which do not already possess a CLIA Certificate will need to submit an application and obtain one prior to receiving BinaxNOW tests. 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, we are sharing some information that may help you fill out your CLIA application if your facility does not already have a CLIA Certificate of Waiver or other appropriate CLIA certificate:

- In section I, please select "Initial Application" and under "Other Changes (Specify)" fill in "COVID 19" to alert the Clinical Laboratory Program that your application is a part of this distribution effort.
    - For the section requesting the Name/Credentials of the Director please input the individual who will have responsibility for oversight of the testing and ensuring compliance with CLIA requirements. Examples would be the facility director or medical director, if available.
- In section II, please select "Certificate of Waiver" if you will be performing only the Abbott BinaxNOW COVID-19 Ag Card test or other CLIA-waived tests.
- In section III, please select the item most descriptive of your facility type. If none of the existing categories describe your organization, please select "29- Other (Specify)" and write in "Congregate Care."
- In section IV, please select the box in the top-right corner which indicates testing will occur 24/7
- In section V, please select "No" and go to section VI. Organizations which plan to distribute Abbott BinaxNOW tests to multiple sites for testing (e.g., to each group home) should still select "No." Applying as a single site indicates that the organization applying accepts the responsibility for the correct use of the Abbott BinaxNOW tests.
- In section VI, please enter "Abbott BinaxNOW COVID-19 Ag Card Test" and provide the Estimated Total Annual Test Volume. If additional CLIA-waived tests will be performed, the test and specific test system information should be included in this section.
- Skip sections VII and VIII
- Complete sections IX and X

Please completely fill out the other sections, as applicable, including the laboratory director signature section.

Pursuant to the Public Health Order titled "ORDER OF THE COMMISSIONER OF PUBLIC HEALTH: CLIA-WAIVED COVID-19 TESTING IN CONGREGATE CARE SITES," congregate care settings may conduct CLIA-waived COVID-19 tests of their staff and residents without applying for or receiving state clinical laboratory licensure, subject to the requirements of the Public Health Order.

Please send the completed application, signed by the laboratory director (or owner) to The Clinical Laboratory Program at CLIALab@mass.gov and include your facility name in the subject line.. If you have any questions you may contact the Clinical Laboratory Program at (617) 660-5385.

A resource you may find helpful is this Quick Start Guide from CMS: https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf

2. Securing a signed physician order

The Abbott BinaxNOW test must be ordered by a physician. The organization must have a standing physician order in place prior to requesting test kits from DPH. Organizations may obtain a standing order from the organization's medical director, other provider, or local board of health medical director.

EOHHS has drafted a model standing order which can be used by organizations to request a standing order. The model standing order can be found on the webpage which hosts this document.

3. 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.

Organizations must be able to maintain an adequate supply of PPE as is required to administer tests as needed.

4. Ensuring all staff complete training requirements

All staff administering Abbott BinaxNOW test kits within a 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 – NOT REQUIRED, as the Navica App should not be used

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 provider 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

5. Verifying ability to complete all reporting requirements

Organizations participating in this initiative must report all test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS).

Additional information about how organizations will report test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences will be provided in a supplementary memo prior to the distribution of test kits.

Appendix B: Abbott BinaxNOW Performance

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. 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 operators.

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.