

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

Bureau of Infectious Disease and Laboratory Sciences

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**Memorandum**

**TO:** Community Health Center, Non-acute and Community Hospital Administrators

**FROM:** Catherine M. Brown, DVM, MSc, MPH, State Epidemiologist

 Larry Madoff, MD, Medical Director, BIDLS

**SUBJECT:** BinaxNOW Rapid Point of Care COVID-19 Testing for Community Health Centers and Non-acute and Community Hospitals

**DATE:** May 12, 2022

**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 < 30) and 99%+ specificity was observed across all groups. Further details about the study can be found here: [BinaxNOW Antigen Test General Study](https://www.medrxiv.org/content/10.1101/2021.01.09.21249499v1)

The Massachusetts Department of Public Health (DPH) is extending the time frame during which BinaxNOW test kits are being made available for use at Community Health Centers and Non-acute and Community Hospitals to respond to the ongoing demand for rapid testing. BinaxNOW tests should be utilized to provide testing to asymptomatic and/or symptomatic community members and patients at no cost to them for the period through June 30, 2022. Administration of the BinaxNOW tests may be billed to insurance, similar to other point-of-care rapid antigen tests.

The guidance below provides information to Community Health Centers, Non-acute and Community Hospitals 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 Community Health Center, Non-acute or Community Hospital requesting test kits. This guidance also clarifies that only antigen tests that are positive need to be reported to DPH’s State Laboratory.

**Use of BinaxNOW test kits by Massachusetts Community Health Centers and Community Hospitals:**

BinaxNOW tests can be utilized to provide testing to asymptomatic and/or symptomatic community members and patients. BinaxNOW test kits are **not** appropriate for broad scale asymptomatic testing of employees, other staff, or for external organizations. However, these tests may be used for testing of symptomatic employees and staff or asymptomatic employees and staff identified as close contacts. BinaxNOW tests should not be used for pre- or post-travel screening.

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

*Asymptomatic community members and patients seeking testing:*

* Those who test positive should be treated as a positive COVID-19 case; these individuals should be instructed to isolate and managed accordingly.
* 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 (or other nucleic acid amplification) test. However, individuals should be counseled that if they develop **any** symptoms of COVID-19 within several days, retesting should be considered.

*Community members, patients, and CHC and Community Hospital staff seeking testing with symptoms:* community members, patients, and staff members who have symptoms of an illness consistent with COVID-19 may be tested using the BinaxNOW test:

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| --- |
| **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 that the negative test is presumptive and the provider should follow up with the individual’s provider and order a repeat test for COVID-19[[1]](#footnote-1).
* );

*PCR test confirmation for patients, community members, and CHC or Community Hospital staff:* 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.

Consideration should be given to testing for other respiratory virus infections, especially influenza, in symptomatic people who test negative for COVID-19.

**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 providers requesting BinaxNOW test kits:**

Community Health Centers, Non-acute and Community Hospitals 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 positive test results to DPH.

Additional information about each requirement and how that requirement may be met is provided below in [Appendix A: Requirements for Community](#bookmark) Health Centers, Non-acute and Community Hospitals.

**Requesting BinaxNOW test kits**

Community Health Centers, Non-acute and Community Hospitals that currently meet all requirements outlined above may request BinaxNOW test kits through the DPH resource request process. To preserve supply and ensure BinaxNOW test kits are used appropriately, a provider may only request the number of BinaxNOW test kits that they can use through June 30, 2022. Any large quantities of tests unused as of June 30th may be subject to recollection by the DPH. A facility may request an amount of test kits equal to half the number of COVID-19 tests currently being performed each month, on average (e.g., a facility that performs 2,000 tests per month, on average, may order 1,000 tests). A facility that uses all requested tests prior to June 30, 2022 may request additional tests. Requests in excess of this amount may be considered on a case-by-case basis but must be accompanied by an explicit plan for utilization of the tests by June 30, 2022.

In order to request BinaxNOW test kits, facilities should complete [Appendix B: Resource Request Form](#bookmark1) and email the completed form to COVID19.Resource.Request@mass.gov. Delivery timelines may vary based on DPH delivery. Facilities should expect to receive requested test kits within 1 week of a request being submitted.

**Appendix A:** Requirements for Community Health Centers, Non-acute and Community Hospitals

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>

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

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.

1. **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
	+ 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](https://www.mass.gov/info-details/ppe-testing-and-vaccine-supply-resources-during-covid-19#personal-protective-equipment-(ppe)-during-covid-19-) or contact your local board of health for further information regarding the proper use of PPE.

1. **Ensuring 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](https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html).

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](https://www.fda.gov/media/141570/download). 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

1. **Reporting Test Results:**

Massachusetts Community Health Centers, Non-acute and Community Hospitals 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 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:** Resource Request Form

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

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>. [↑](#footnote-ref-1)