

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:** Massachusetts Healthcare Providers

**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 Provider Settings

**DATE:** May 13, 2021

**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 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 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 Abstract](https://www.mass.gov/doc/binaxnow-antigen-test-abstract/download) | [Graph](https://www.mass.gov/doc/binaxnow-antigen-test-graph/download).

The Massachusetts COVID-19 Command Center, in collaboration with the Massachusetts Department of Public Health (DPH) is making BinaxNOW test kits available for use in all provider settings to maximize availability of testing.

The guidance below provides information to providers on how to request BinaxNOW test kits from DPH and what documentation and protocols must be in place prior to requesting test kits.

**Use of BinaxNOW test kits in provider settings**

This guidance applies only to BinaxNOW test kits supplied by DPH and does not apply to POC rapid diagnostic tests obtained from the federal government, manufacturers, or other sources.

Requested BinaxNOW tests should be utilized as clinically indicated to provide testing to asymptomatic and/or symptomatic patients at no cost to them.

**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:**

Providers 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 all test results to DPH.

Additional information about each requirement and how that requirement may be met is provided below in [Appendix A: Requirements for BinaxNOW Testing in Provider Settings](#bookmark).

**Requesting BinaxNOW test kits**

Providers that currently meet all requirements outlined above may request BinaxNOW test kits through the DPH resource request process. To start, providers will be able to request up to 10 kits of 40 tests each per provider; a provider that uses all requested tests may request additional kits.

In order to request BinaxNOW test kits, providers 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 capacity. Providers should generally expect to receive requested test kits within 1 week of a request being submitted.

**Appendix A:** Requirements for BinaxNOW testing in Provider Settings

1. **Obtaining a CLIA certificate:**

For providers 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 (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](https://www.mass.gov/doc/updated-comprehensive-personal-protective-equipment/download) or contact your local board of health for further information regarding the proper use of PPE.

1. **Ensuring staff complete training requirements**

All providers administering Abbott BinaxNOW test kits 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 before 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.

Providers 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:**

Providers 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 providers 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** |