Massachusetts Department of Elementary and Secondary Education

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Jeffrey C. Riley
Commissioner

MEMORANDUM

To:	Superintendents, Charter School Leaders, and Leaders of Educational Collaboratives and Approved Special Education Schools
From:	Jeffrey C. Riley, Commissioner of Elementary and Secondary Education
Date:	October 23, 2020
Subject:	Phase I – BinaxNOW Rapid Point of Care COVID-19 Testing for K-12 Schools

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The U.S. Department of Health and Human Services (HHS) and the 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 to schools and other strategic environments. Over the course of the school year, Massachusetts will obtain approximately 2 million tests for use in priority settings including but not limited to public districts, charter schools, educational collaboratives, and approved special education schools. The Department of Elementary and Secondary Education (DESE) in collaboration with the Department of Public Health (DPH) is seeking to introduce the first phase of these tests with an initial group of districts and schools. Participating districts and schools will receive the test kits at no cost, and in most cases, administer the test using existing staff resources.

This memo provides a brief overview of the Abbott BinaxNOW test kits, the documentation, reporting requirements, protocols for use of these tests, and the process for requesting test kits. Phase I is intended for districts and schools providing any type of in-person instruction, such as full-in person or hybrid instructional models or in-person services for high needs students. If your district or school is providing such services and is interested in participating, we strongly encourage you to fill out the brief survey below to register for this initiative and attend an optional informational webinar on Wednesday, October 28 from 12-1pm.

Survey Link
https://survey.alchemer.com/s3/5975124/Phase-I-Abbott-BinaxNOW-Testing-Survey
Please complete the survey by close of business on October 30 if you are interested in participation.

Optional Informational Webinar
Date: Wednesday, October 28, 2020
Time: 12-1pm

https://us02web.zoom.us/j/88558148716?pwd=VEUvM2xJckhtVUFxeDJseW5Md004QT09

Meeting ID: 885 5814 8716
Passcode: 098244
One tap mobile
+16465588656,,88558148716# US (New York)

Overview of the Abbott BinaxNOW test

Abbott BinaxNOW Test

The Abbott BinaxNOW test received Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) in late August. The test is performed on a nasal swab and delivers results in 15 minutes with no instrumentation. The FDA approved the test for detection of SARS-CoV-2 in symptomatic individuals within 7 days of onset of illness. 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[1], including school nurses and other school-based health professionals.

Documentation, Reporting Requirements and Protocols

Obtaining a CLIA certificate

To administer the test in a school setting, a district or school must apply for one CLIA Certificate of Waiver.[2] Districts and schools in Phase I will be supported in their application of a CLIA Certificate of Waiver, as necessary, to accelerate their access to this testing opportunity.

Reporting Requirements

Massachusetts districts and schools participating in this initiative must report test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS) at 617-983-6800 and report positive test results to DESE's Rapid Response Help Unit at 781-338-3500.

Indications for Use

The Centers for Disease Control and Prevention (CDC) has published *Interim Guidance for Rapid Antigen Testing for SARS-CoV-2* which can be found here.

Use of Abbott BinaxNOW test in Massachusetts' schools[3]

The Abbott BinaxNOW test can be used in the following situations:

- Students and staff with symptoms consistent with COVID-19.[4]

1 Health professionals, including school nurses, will complete comprehensive training before administering this test. While additional information about training is forthcoming, training videos, modules and frequently asked questions for the Abbot BinaxNOW test are available here: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

2 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

3 Schools and districts must obtain proper authorization and consent for administration of the BinaxNOW test to students and staff.

4 A list of symptoms consistent with COVID-19 can be found in the Protocols for Responding to COVID-19 Scenarios guidance document: https://www.doe.mass.edu/covid19/on-desktop/protocols/

- Students and staff with minimal symptoms (e.g., isolated runny nose, sore throat, abdominal pain without fever, not meeting symptoms consistent with COVID-19).
- The Abbott BinaxNOW test is **not to** be used for broad scale asymptomatic testing in the school at this time.

Requesting Testing Kits

Ordering Requirements

The Abbott BinaxNOW test must be ordered by a healthcare professional. The district or school must have a standing order in place prior to requesting test kits from DPH. Districts and schools may consider obtaining a standing order from a school physician or local board of health medical director.

Conclusion

If your district or school is providing any form of in-person instruction (full in-person, hybrid or services solely for high needs students), you are well positioned to participate in Phase I of this testing opportunity. We hope you will complete this survey by October 30 to indicate your interest in participating.