Massachusetts Department of Elementary and Secondary Education

75 Pleasant Street, Malden, Massachusetts 02148-4906

Telephone: (781) 338-3000
TTY: N.E.T. Relay 1-800-439-2370

Jeffrey C. Riley
Commissioner

Frequently Asked Questions for Phase I – Abbott BinaxNOW Rapid Point of Care COVID-19 Testing for K-12 Schools

The Massachusetts Department of Elementary and Secondary Education (DESE) in collaboration with the Massachusetts Department of Public Health (DPH) is introducing the first phase of distribution of Abbott BinaxNOW tests with an initial group of districts and schools. This FAQ document answers questions regarding protocols for using the Abbott BinaxNOW test kits, documentation and reporting requirements, and the process for implementation.

Testing Policy

Q: Who is eligible to get these tests – students, staff, or parents – and must they be symptomatic?

A: Students or staff who have any symptoms of an illness, while at school, consistent with COVID-19 according to the following guidance (previously published by DESE) should be tested using the BinaxNOW test:

- 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 *when in combination with other symptoms*
- Muscle aches or body aches
- Nausea, vomiting, or diarrhea
- Fatigue, *when in combination with other symptoms*
- Nasal congestion or runny nose (not due to other known causes, such as allergies) *when in combination with other symptoms*

Students or staff who have minimal symptoms (e.g., isolated runny nose, isolated headache, isolated fatigue, not meeting COVID-19 criteria listed above) may also be considered for testing with the BinaxNOW test.

Students or staff who are asymptomatic should not be testing using the BinaxNOW test. Students' parents/guardians are not eligible for testing through the school.

Q: Shouldn't students and staff stay home if they are experiencing COVID-19 symptoms?

A: Yes. All students and staff should follow the DESE protocol for responding to COVID-19 scenarios found here. As stated in the protocol, staff must monitor themselves for symptoms daily and students, with the assistance of families, must also be monitored daily for symptoms. Staff and students **must** stay home if feeling unwell.

However, some students and staff may experience the onset of symptoms while at school. The Abbott BinaxNOW tests will allow schools and districts to rapidly respond to these situations. Students, parents, and staff should be alerted that antigen test results are not considered diagnostic. Results are probable and confirmation of a person's COVID-19 status requires a PCR test.

Q: What happens after a positive BinaxNOW test? What about a negative one?

A: Follow-up action depends on the severity of symptoms and the result of the test. The BinaxNOW test should *not* be used for asymptomatic testing in the school.

Positive Test:

Any individual who tests positive, whether they have symptoms of an illness consistent with COVID-19 (see criteria listed above) or minimal symptoms (e.g., isolated runny nose/nasal congestion, isolated headache, isolated fatigue, not meeting COVID-19 criteria), should be treated as a positive COVID-19 case and managed accordingly (see DESE protocol for responding to COVID-19 scenarios here).

Negative Test:

If an individual with symptoms of an illness consistent with COVID-19 (see criteria listed above) has a negative test they should be sent home. The student's parent/guardian, or the staff member, should be informed that the negative test is presumptive and they should follow up with their healthcare provider and consider PCR testing for COVID-19. The individual may return to school after they 1) have obtained a subsequent negative PCR test for COVID-19, have an improvement in symptoms, and have been without fever for at least 24 hours without the use of fever reducing medications; or 2) have been removed from school for 10 days from the start of

symptoms, as long as their symptoms have improved and they have been without fever for at least 24 hours prior to their return to school without the use of fever reducing medication.

If an individual with minimal symptoms (e.g., isolated runny nose/nasal congestion, isolated headache, isolated fatigue, not meeting COVID-19 criteria) tests negative, they may return to school. The school should notify the student's parent/guardian informing them of the result and that antigen test results are presumptive (not diagnostic) and that a PCR test would be required to definitively confirm that the child does not have COVID-19. The parent/guardian should be instructed to monitor the child carefully for fever and other symptoms and if these develop, to consult the child's healthcare provider.

Communication to Parent/Guardian

The school should communicate with the student's parent/guardian after every test of a student, whether the result is positive or negative, informing them of the result, The communication should include that in a symptomatic individual, antigen test results are presumptive (not diagnostic) and that a PCR test would be required to definitively confirm that the child does or does not have COVID-19. In addition, every effort should be made to inform the individual's primary care provider of the test result, whether negative or positive.

Q: How will contact tracing work? Who is responsible for following up with the student or staff member while they are waiting for the results of their PCR test?

A: As is the case with all other COVID-19 tests conducted across the state, all contact tracing will be completed by local boards of health or the Community Tracing Collaborative on behalf of the local boards of health. Every test result must be reported to DPH which will then trigger the normal process for contact tracing. Additionally, every positive test result must be reported to DESE. While public health authorities will be responsible for contact tracing, it is imperative that schools and districts provide help as needed and advise staff, students, and parents to be aware of the possibility of calls from contact tracers.

All results from the Abbott BinaxNOW test should be considered presumptive results. Individuals with symptoms who test positive and individuals who have symptoms but test negative should follow up with their healthcare provider and consider PCR testing for COVID-19. The student or staff member may return to school after they 1) have obtained a subsequent negative PCR test for COVID-19, have an improvement in symptoms, and have been without fever for at least 24 hours without the use of fever reducing medications; or 2) have been removed from school for 10 days from the start of symptoms, as long as their symptoms have improved and they have been without fever for at least 24 hours prior to their return to school without the use of fever reducing medication.

Implementation

Q: Which schools are eligible?

A: At this time only public school districts, charter schools and approved special education schools that are providing any form of in-person instruction or that will soon resume in-person instruction are eligible to participate in the program. Additionally, only schools that are able to meet all of the requirements of the program will be approved to receive distributions of the Abbott BinaxNOW test kits. DESE will prioritize schools and districts for participation in Phase 1 as necessary.

Q: How are results reported to the state?

A: Massachusetts schools that receive rapid point of care antigen tests must report all test results, positives and negatives, to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS) through the approved mechanism. Additional information about how schools are expected to report results will be provided prior to the distribution of test kits. Positive results should also be reported to DESE's Rapid Response Help Unit at 781-338-3500.

Q: Who administers the Abbott BinaxNOW tests?

A: The Emergency Use Authorization (EUA) received for the Abbott BinaxNOW test allows it to be administered by a variety of trained medical professionals, including school nurses. The test is performed on a nasal swab and delivers results in 15 minutes, requiring no instrumentation.

All staff administering Abbott BinaxNOW test kits within a school or district must complete all Abbott BinaxNOW training modules. The Abbott BinaxNOW 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. To support training of school nurses, DPH will offer train-the-trainer educational activities to school nurse leaders

participating in Phase 1. Further information regarding the availability of DPH-provided or organized training will be provided in a supplemental memo in the coming weeks.

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

It is the responsibility of the school or district to ensure that all the staff administering tests have completed the necessary training requirements.

Q: How will consent work (prior, verbal/written)?

A: DESE will work with DPH and will provide further information on the consent and authorization that must be obtained by schools and districts administering Abbott BinaxNOW test kits. This consent process, which will include options for electronic or paper consent forms, will include obtaining signatures from students' parents/guardians consent prior to administering the tests to students.

Additionally, DESE will work with DPH to provide sample notification forms that may be used to inform parents/guardians when a student has received an Abbott BinaxNOW test while at school. The notification form will also serve to inform parents/guardians on what next steps they should take, depending on the child's rapid test results.

Schools should watch for additional information from DESE and DPH regarding consent and notification. Once this process has been finalized, schools should review the guidance and ensure they are able to obtain consent from students' parents/guardians prior to beginning testing.

Q: Do I need a standing order to perform these tests? How can I get one?

A: Yes, the district or school must have a standing physician order in place prior to requesting test kits from DPH. Districts and schools may obtain a standing order from a school physician or local board of health medical director.

DPH has drafted a model standing order which can be used by districts or schools to request a standing order from a school physician or local board of health medical director. The model standing order can be found here: https://www.doe.mass.edu/covid19/BinaxNOW/

Q: What should I know about the CLIA Certificate of Waiver process?

A: 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 If applicable, a school district may apply for one CLIA Certificate of Waiver that would include all schools in the district. 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. The Facility Address must be the physical address of a location that is performing testing even if you are applying for multiple site designation.
- In section II, please select "Certificate of Waiver" if you will be performing only the Abbott BinaxNOW COVID-19 Ag Card test.
- In section III, please select "26-School/Student Health Service."
- In section V, please select "Yes" if you are applying as a school district and have more than one school in your district.
    - In #1 in section V, please select "No" (unless there are plans to test at temporary locations).
    - In #2 in section V, please select "Yes" if criteria are met and provide requested information for each location/school.
    - In #3 in section V, please select "No."
    - Please note that only one of the multiple site criteria may be selected.
- In section V, please select "No. If no, go to section VI" if you are applying as a school at a single site.
- In section VI, please enter "Abbott BinaxNOW COVID-19 Ag Card Test" and provide the Estimated Total Annual Test Volume. If any additional CLIA-waived tests will be performed the specific test system information should be included in this section.
- Please completely fill out the other sections, as applicable, including the laboratory director signature section.

If you are only performing testing on students and staff, then you do not need to obtain a state clinical laboratory license in addition to a CLIA certificate.

Please send the completed application to The Clinical Laboratory Program at CLIALab@mass.gov. Should 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

Q: Are there requirements around the storage or disposal of tests?

A: All staff administering the tests should follow the instructions provided on the Abbott BinaxNOW package insert regarding specimen collection, handling, transport and storage as is detailed here: https://www.fda.gov/media/141570/download

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.

See the Abbott BinaxNOW package insert for instructions on its proper use. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Schools and districts should have a plan on how they will dispose of the biohazardous waste prior to implementation of the testing program. It is recommended that schools and districts work with their facilities managers and if necessary, their local board of health to determine an appropriate process for the removal of waste.