Public Schools of Brookline

Abbott BinaxNOW COVID-19 Rapid Antigen Test Protocol

Purpose

To facilitate the rapid identification of SARS-CoV-2 using the rapid point of care Abbott antigen card test to allow schools and districts to rapidly respond.

Protocol

Trained health staff will conduct COVID-19 antigen testing with the Abbott BinaxNOW™ COVID-19 Tests as outlined by the manufacturer, CMS, CDC and FDA.

Training

All school nurses administering or observing self-swabbing of Abbott BinaxNOW test kits within a school or district must complete all Abbott BinaxNOW training modules.

- 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

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 or observing tests for individuals.

Additionally, specifically trained nurse trainers will provide training to Brookline school nurses.

Who is eligible for the test?

Students or staff who have provided consent and who have any symptoms of an illness that develop while at school, consistent with COVID-19 according to the following guidance should be tested using the BinaxNOW test:

- Fever (100.0° Fahrenheit or higher), chills, or shaking chills
- Difficulty breathing or shortness of breath
- New loss of taste or smell
- Muscle aches or body aches
- Cough (not due to other known cause, such as chronic cough)
- Sore throat
- Nausea, vomiting, or diarrhea
- Headache when in combination with other symptoms
- Fatigue, when in combination with other symptoms
- Nasal congestion or runny nose (not due to other known causes, such as allergies)

Individuals previously diagnosed with COVID-19 are not recommended for re-testing within 90 days of the original positive test. If a previously diagnosed individual presents with symptoms, refer to their health care provider.

Positive Results

Those who test positive should be treated as a positive COVID-19 case and sent home where they must self-isolate for a minimum of 10 days.

The individual may return to school after 10 days and once they have:

- Gone for 24 hours without a fever (and without taking fever-reducing medications and
- Experienced improvement in other symptoms and
- Received clearance from public health authority

Negative Results

- The nurse completes his/her assessment of the individual
- If the individual has mild symptoms (e.g., isolated runny nose/nasal congestion, isolated headache, isolated fatigue), can return to class at nurse's discretion.
- If the minimal symptom(s) persist, the individual may be re-tested within the subsequent 3 days.
- If symptoms worsen, the individual should stay home and seek medical care and be evaluated for the need for PCR testing.

If negative test BUT exhibits any of these symptoms:

- Fever (100.0° Fahrenheit or higher), chills, or shaking chills
- Difficulty breathing or shortness of breath
- New loss of taste or smell
- Muscle aches or body aches

The student's parent/guardian, or the staff member, should be informed that the negative test is presumptive and instruct that they follow up with their healthcare provider and consider PCR testing for COVID-19. They will be dismissed from school. The individual may return to school once they 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
- Stayed out of 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; or
- Received documentation of an alternative diagnosis from a health care provider (e.g., asthma, seasonal allergies, strep throat, etc.) and have an improvement in symptoms, and have been without fever for at least 24 hours without the use of fever reducing medications

Those who test positive should be treated as a positive COVID-19 case and managed accordingly (see above).

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 contact the child's healthcare provider.

PCR test confirmation

Given the superior accuracy of PCR testing versus antigen testing, the result of a PCR test taken within 2 days of an antigen test will "override" the result of the antigen test. Consequently, a PCR test result (rather than an antigen test result) should be used to determine the proper protocol for the student or staff member when taken within 2 days of an antigen test result.

Storage and Disposal

Test kits must be stored at temperatures between 2 and 30°C (35.6 - 86°F). DPH requires the room temperature to be recorded upon test administration.

All components of this kit should be discarded in the regular trash.

Quality Control

Each box contains a positive control swab and sterile swabs that can be used as a negative control.

Perform positive and negative control tests when:

- a new Abbott BinaxNOW box is opened
- a new employee starts conducting tests

Performing the Control Test

- Ensure all test components are at room temperature (59 86°)
- Open test card just prior to use and lay it flat
- If the blue line is not present at the Control Line prior to running the test do not use and discard the test card
- Hold extraction reagent bottle vertically. Hovering 1/2 inch above the top hole, slowly add 8 drops
- Do not touch the card with the dropper tip while dispensing
- Insert positive control swab into bottom hole and firmly push upwards so that the swab tip is visible in the top hole
- Rotate (twirl) swab shaft 3 times clockwise do not remove
- Peel off the adhesive liner from the right edge of the test card
- Close and securely seal the card
- Read results in the window 15 minutes after closing the card
- Record results
- Repeat control testing procedure with a sterile swab to receive a negative result

Consent, Reporting and Documentation

This is an opt in program. All individuals being tested must have a consent.

Families and staff receive a message explaining the program and inviting them to create an account with

Project Beacon. Project Beacon is a third-party organization that created an on-line platform to compile consent for testing and consent to share test results with DPH and families. See screen shots of the steps to create an account and provide consent.

There are three ways to obtain consent to test and report results:

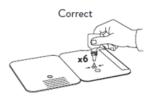
- 1. Web-based Self-registration consent: PSB sends a weblink with a unique code that will invite the user to register for a Project Beacon. Once registered, when an individual gets tested Project Beacon will provide notice to the user when a test has begun and when results are available.
- 2. Paper-based consent: For individuals who cannot interface with Project Beacon, schools can obtain consent to testing and sharing results via a paper-based consent form. The school nurse can manually import information about the test recipient and the test results into Project Beacon.
- 3. Emergency "Day-of" verbal consent:

In cases where the student's parent/guardian has not already given consent to administer the test and report results to DPH via Project Beacon, the school nurse may administer a test based upon verbal consent (i.e., over the phone) from the parent/guardian immediately prior to test administration. The parent/guardian can provide written consent by email or in person if they are on-site to pick up the student.

Performing the Test

- Gather supplies and label test card
- Ensure swab is at room temperature (59 860)
- Open the card and lay flat on table

- Look for blue control line
- Sanitize hands
- Don appropriate PPE (N95/surgical mask, eye protection, gown, gloves)
- Perform anterior nasal swab on side with drainage or congestion (if present) first
- Rotate 5 times against the nasal wall
- · Repeat on other side
- Add 6 reagent drops (hold vertically) to top hole of the swab well (do not touch card)

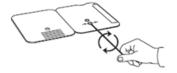


Insert the swab into the bottom hole and push up to be visible in the top hole

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Rotate 3 times clockwise



- Remove adhesive liner on the right edge of card
- · Close and seal the card
- Time for 15 minutes
- Read and record result cannot be less than 15 minutes of more than 30 minutes
- Negative single pink/purple line at the top half of the window
- Positive two pink/purple lines Specimens with low levels of antigen may give a faint sample line. Any
 visible pink/purple line is positive.
- *If no lines or just the sample line invalid, repeat test
- Doff PPE dispose in biohazard receptacle

Recording Test Results in Project Beacon

For each test, the lot number (located on the test card) and the test result should be entered as they are performed, and by no later than the end of the day. Those with user profiles will receive notification, through Project Beacon, when the test has begun and when results are ready.

In addition to automated notifications staff should personally report test results to the authorized parent/staff. Give the parent/staff the results letter.

Positive test results must also be reported to DESE - to do this, call HHS to report the results - HHS will call DESE.

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