

#StayStrongNC

StrongSchoolsNC

K-12 COVID-19 Antigen Testing Pilot Application Packet

December 3, 2020

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Background

Earlier this year, the U.S. Department of Health and Human Services (HHS) and the Department of Defense (DOD) announced an initiative to deliver 150 million Abbott BinaxNOW COVID-19 Ag Card point-of-care (POC) SARS-CoV-2 rapid antigen tests across the country to schools and other targeted environments. Over the course of the year, North Carolina will obtain approximately 3.1 million tests for use in priority settings, including but not limited to public schools, including districts and charter schools. The North Carolina Department of Health and Human Services (NCDHHS) will introduce the first phase of these tests with an initial pilot group of public school districts and charter schools in collaboration with their local health departments (LHD) and, in some cases, other local partners. Local health departments in counties with participating districts and schools will receive the test kits at no cost for diagnostic testing of symptomatic and close contact students, teachers, and staff.

The Phase 1 pilot is intended for public school districts and charter schools providing any type of in-person instruction, such as full-in person (Plan A) or hybrid instructional models (Plan B) or in-person services for high needs students. The selection of districts and schools participating in Phase 1 will be based on eligibility criteria outlined in this packet. If your school or district is not selected to participate in Phase 1, please watch for additional communications regarding additional participation that will be sent out in regard to future phases.

If you have questions about any information contained in this packet that cannot be answered by the FAQ, reach out to your local health department, or contact StrongSchoolsNC@dhhs.nc.gov.

Phase 1 Pilot Requirements

The Phase 1 pilot will consist of an initial group of public school districts and charter schools in collaboration with their local health department for diagnostic testing of symptomatic and close contact students, teachers and staff. All schools and districts interested in participating in Phase 1 must be able to complete all seven (7) of the following requirements in order to receive approval from DHHS for their distribution of Abbott BinaxNOW test kits.

1. Obtain an approved CLIA certificate of waiver or partner with an entity with a CLIA certificate (see section "Obtaining a CLIA certificate" below)
2. Secure a signed physician order for testing or elect to use the statewide standing order
3. Confirm ability to maintain an adequate supply of PPE
4. Confirm ability to properly handle and dispose of medical waste
5. Ensure all testing staff have completed training modules
6. Obtain parental/guardian consent prior to testing and notify parents/guardians when testing has been performed
7. Verify ability to complete DHHS reporting requirements

Additional information about each requirement and how that requirement may be met is provided below.

Application process

A site interested in participating in the Phase 1 pilot must:

1. Review the Readiness Review Checklist, which certifies that they have completed all the requirements.
2. The site must send the checklist to their local health department.
3. The LHD will verify the completed checklist and submit the Pilot Application Form – either via online form or via fillable PDF emailed to StrongSchoolsNC@dhhs.nc.gov with the subject line "Pilot Site Completed Application."
4. NCDHHS will select qualified sites to participate in Phase 1 pilot based on satisfaction of all requirements.

Distribution process

Once pilot sites are confirmed, NCDHHS will schedule a delivery of test kits with the LHD and district/school beginning the week of December 14, 2020

Obtaining a CLIA certificate

The FDA Emergency Use Authorization for BinaxNOW supports testing in point-of-care settings operating under a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver,

Certificate of Compliance, or Certificate of Accreditation. Any site that performs laboratory testing must follow applicable regulatory requirements including federal, state, and local mandates for testing, as well as requirements for the safety and confidentiality of personal information. Use of this authorized test is limited to CLIA certified entities.

A district or school may choose to apply or utilize its own CLIA certificate or partner with an entity that has a CLIA certificate that can be extended to include the district or school. Additional details on obtaining a CLIA certificate can be found in the FAQs in this document and on the NC Division of Health Service Regulation (DHSR) CLIA website.

Securing a signed physician order

The Abbott BinaxNOW test must be ordered by a healthcare professional. North Carolina has a statewide standing order which authorizes individuals to obtain a SARS-CoV-2 diagnostic test at a testing site. The pilot site may use this standing order, or pilot sites may consider obtaining a standing order from a school physician or local board of health medical director.

Maintaining an adequate supply of PPE

All staff administering Abbott BinaxNOW test kits must wear appropriate personal protection equipment when running each test and handling patient specimens. For personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:

- A surgical or procedural mask (a fit-tested N95 or higher level respirator can be used if available)
- Eye protection
- Gloves
- Gown, when collecting specimens

Pilot sites must be able to maintain an adequate supply of PPE as is required to administer tests as needed.

Ensuring all staff complete training requirements

All staff administering Abbott BinaxNOW test kits within a school or district must complete all Abbott BinaxNOW training modules available here. 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 tests on individuals.

It is the responsibility of the entity holding the CLIA certificate of waiver (i.e., district, school, or CLIA-certified partner) to ensure that all the staff administering tests have completed the necessary training requirements.

Obtaining consent from parents/guardians and notifications around testing

Sites administering Abbott BinaxNOW tests kits must establish consent and notification processes for all parents/guardians prior to beginning testing. Sites administering Abbott BinaxNOW test kits must obtain parental/guardian consent before performing a test on a student. Sites must also notify parents/guardians when a student has received an Abbott BinaxNOW test while at school, the result of the test, and next steps they must take to ensure follow-up, dependent on the child's test results.

Verifying ability to complete all reporting requirements

All positive and negative test results must be reported daily as part of required reporting of COVID-19 diagnostic tests. The most current reporting requirements and methods of reporting of COVID-19 diagnostic tests are described in the NC Administrative Code Emergency Rule and the associated NCDHHS guidance for reporting results.

Disposal of medical waste

All components of the BinaxNOW test kit, as well as gloves used by personnel administering the tests and any grossly contaminated PPE, should be discarded as biohazard waste according to federal, state, and local regulatory requirements. Sites administering tests must have a means to appropriately package, transport, and dispose of medical waste.

Readiness Review Checklist

An applicant must review, complete, and send this checklist to their local health department. Sites will then coordinate with the LHD to submit a pilot application to NCDHHS on their behalf.

Please direct questions to your local health department or to StrongSchoolsNC@dhhs.nc.gov.

- ☐ **CLIA certificate of waiver:** The site has received a CLIA Certificate of Waiver OR has identified an entity with a CLIA Certificate to perform tests
- ☐ **Provider Order:** The site has acquired a signed standing order for COVID-19 testing with the Abbott BinaxNOW from a physician or has elected to use the statewide standing order.
- ☐ **PPE:** The site has acquired an adequate supply of PPE and will be able to procure additional PPE as is needed. Additionally, the appropriate staff that will be administering the Abbott BinaxNOW test have reviewed CDC guidance on the use of PPE.
- ☐ **Training requirements:** The site has ensured that all staff members who will be administering Abbott BinaxNOW test kits have completed all necessary training modules.
- ☐ **Consent and notification processes:** The site has identified consent and notification processes for all parents/guardians prior to beginning testing with any students.
- ☐ **Reporting requirements:** The site has trained all necessary staff on how to appropriately report test results daily to state or local public health.
- ☐ **Medical waste management:** The site has a mechanism to safely dispose of used testing material.
- ☐ **Ongoing Requirements**: The site will adhere to the following requirements, that will be ongoing through the pilot:
  - Testing personnel will adhere to the written Instructions for Use (IFU) provided by the manufacturer in the test package insert.
  - The site will ensure DHHS has up-to-date information on test administrators and testing locations.
  - The site will abide by the infectious waste disposal criteria.
  - The site will have all individuals being tested, or his/her parent/guardian, sign an authorization for testing.
  - The site will submit all required data elements to DHSS at least every 24 hours.
  - The site will retain documentation related to this testing program for at least two years.
  - The site will review and stay up-to-date on NCDHHS's "Considerations For COVID-19 Testing of Adults and Children Who Work at or Attend a K-12 School."

Pilot Application Form

For Local Health Departments

Once a site submits their completed checklist to their local health department, the LHD should work with the site complete the pilot application form – either via online form or via fillable PDF emailed to StrongSchoolsNC@dhhs.nc.gov with the subject line "Pilot Site Completed Application."

Frequently Asked Questions

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Q1: Who is eligible to participate in the K-12 antigen testing pilot?

A: Public school districts and charter schools providing any type of in-person instruction – including full, in-person (Plan A) or hybrid instructional models (Plan B) or in-person services for high-needs students – are eligible to participate in the program, and may collaborate with a local partner (such as their local health department, a health care provider, or another type of partner) to implement the pilot. Pilot participants must be able to meet all of the requirements of the program in order to be approved to receive the Abbott BinaxNOW test kits. These requirements are outlined in the K-12 COVID-19 Antigen Testing Pilot Requirements and Readiness Review Checklist.

Q2: How do pilot sites report test results?

A: North Carolina pilot sites that receive Abbott BinaxNOW test kits must report all test results to NCDHHS or to their local health department. The most current reporting requirements and methods of reporting of COVID-19 diagnostic tests are described in the NC Administrative Code Emergency Rule and the associated NCDHHS guidance for reporting results.

Q3: What training is required to administer these tests? Do the tests require a medical professional to administer them?

A: No, test administrators do not need to be medical professionals. The Emergency Use Authorization (EUA) received by the Abbott BinaxNOW rapid antigen test allows it to be performed by a person who receives a specific training, described below.

All staff administering Abbott BinaxNOW test kits at a pilot site must complete all Abbott BinaxNOW training modules. The Abbott BinaxNOW training modules can be found here and are listed below:

- 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.

Further information about the proper use of the Abbott BinaxNOW test kits can be found on the package insert and here. This includes information regarding specimen collection, handling, transportation, and storage.

It is the responsibility of the entity holding the CLIA certificate of waiver (i.e., district, school, or CLIA-certified partner) to ensure that all the staff administering tests have completed the necessary training requirements.

Documentation or records of satisfactory completion of training should be maintained by the school, district or partner organization performing tests.

Staff who have questions or concerns about the administration of the test can always utilize these direct links to Abbott support: 800-257-9525 8:00 am – 8:00 pm Monday through Friday or ts.scr@abbott.com

Q4: Who is eligible for testing at a pilot site?

A: Public or charter school students and staff at pilot sites who have symptoms of an illness consistent with COVID-19 according to DHHS screening guidance, or are close contacts of someone with COVID-19 (based on the CDC definition of close contacts) can be tested using the Abbott BinaxNOW antigen test.

Q5: Is parental/guardian consent required to administer a COVID-19 test to a child?

A: Yes. Sites administering Abbott BinaxNOW tests kits must identify consent and notification processes for all parents/guardians prior to beginning testing and must obtain parental/guardian consent before performing a test on a student.

Additionally, schools and districts must send notification forms to inform parents/guardians when a student has received an Abbott BinaxNOW test while at school and the result of the test. The notification form also serves to inform parents/guardians on what next steps they must take to ensure follow-up, dependent on the child's test results.

Q6: What happens after a positive or negative Abbott BinaxNOW rapid antigen test?

A: See the information below, as well as referring to the DHHS flowchart on using and interpreting antigen test results here.

Positive Test:

Any individual experiencing COVID-19 symptoms for 7 days or less who tests positive, should be treated as a positive COVID-19 case and managed accordingly (see DHHS protocol for responding to COVID-19 scenarios here).

Negative Test:

If an individual with symptoms of an illness consistent with COVID-19 according to DHHS screening guidance has a negative test, they should be sent home. The parent/guardian should be informed that the negative test is presumptive, and they should follow up with their healthcare provider for a confirmatory PCR testing for COVID-19. The student 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 mild symptoms not included in the screening checklist (e.g., isolated runny nose, sore throat, abdominal pain without fever,) tests negative, they may return to school. A communication should be sent to the parent/guardian informing them of the result the parent/guardian should be instructed to monitor the child carefully for fever and other symptoms and if these develop, to refer to the child's healthcare provider. A follow-up PCR test may be indicated.

Communication to Parent/Guardian

After every test, positive or negative, communication should be sent to the parent/guardian informing them of the result.

Q7: Who is responsible for following up with the student or staff member after test results, and contact tracing (if applicable for a positive test)?

A: As is the case with all other COVID-19 tests completed across the state, all contact tracing will be initiated by the local health department. Every test result must be reported to the local health department or DHHS which will then trigger the normal process for contact tracing. While local health departments 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.

Q8: Does a pilot site need a standing order to perform these tests?

A: Yes, the Abbott BinaxNOW rapid antigen tests must be ordered by a healthcare professional. North Carolina has a statewide standing order which authorizes individuals to obtain a SARS-CoV-2 diagnostic test at a testing site. The pilot site may use this standing order, or pilot sites may consider obtaining a standing order from a school physician or local board of health medical director.

Q9: How can a pilot site obtain a CLIA certificate of waiver?

A: The FDA Emergency Use Authorization for BinaxNOW supports testing in point-of-care settings operating under a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Any site that performs laboratory testing must follow applicable regulatory requirements including federal, state and local mandates for testing, as well as requirements for the safety and confidentiality of personal information. Use of this authorized test is limited to CLIA certified entities. 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 one:

- In section I, select “Other Changes (Specify)” and fill in “COVID 19” to alert our program that your application is a part of this distribution effort
- In section II, select “Certificate of Waiver”.
- In section III, select “26-School/Student Health Service”

- In section V, select “Yes” if you are applying as a school district and have more than one school in your district.
    - In #1 in section V, select “No” as each school may act as a temporary testing location should there be a need to test students, teachers, or staff.
    - In #2 – “Yes,” and #3, “No”
- In section V, select “No. If no, go to section V1” if you are applying as a school at a single site.
- In section VI, enter “BinaxNOW COVID-19 Ag Card”
- Completely fill out the other sections, as applicable.

Please also include information about other medical tests, including any other COVID-19 tests, you may be performing at this location and provide specifics on these test systems. Please send the completed application to NCDHHS Division of Health Service Regulation/CLIA Certification at DHSR.CLIA@dhhs.nc.gov or via fax to (919)733-0176. If you have any questions, please contact DHSR at (919) 815-4620.

Q10: What are the requirements around the storage or disposal of the Abbott BinaxNOW tests?

A: All staff administering the tests must 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. All components of this kit should be discarded as biohazard waste according to federal, state and local regulatory requirements.

Q11: What are the requirements around PPE with the Abbott BinaxNOW tests?

A: All staff should follow standard precautions when running each test and handling clinical specimens. For personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:

- A surgical or procedural mask (a fit-tested N95 or higher-level respirator can be used if available)
- Eye protection
- Gloves
- Gown, when collecting specimens

Staff administering tests must change gloves between handling of specimens suspected of COVID-19. Additionally, when using patient swabs, minimize contamination of the swab stick and wrapper by widely opening the wrapper prior to placing the swab back into the wrapper. Visit the CDC website for PPE guidance or contact your local health department for further

information regarding the proper use of PPE. Schools and districts must be able to maintain an adequate supply of PPE as is required to administer tests as needed.

Q12: How can I contact Abbott directly with any additional questions?

A: Abbott customer support can be contacted at 800-257-9525 from 8:00 am – 8:00 pm Monday through Friday, or via email at ts.scr@abbott.com