

Pilot #1: Virginia K-12 COVID-19 Diagnostic Testing Pilot Program



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Overview and Requirements for Program Participation

The Virginia Department of Health (VDH) and the Virginia Department of Education (VDOE) have developed a K-12 Schools **Diagnostic Testing Pilot Program** to provide free point-of-care (POC) COVID-19 tests for school divisions and non-public schools as an additional resource to support schools. Eligible schools should be offering some level of in-person instruction or have a plan to do so during the remainder of the 2020-2021 school year. This program will help meet the important goal of ensuring same-day access to POC diagnostic testing for K-12 school teachers, staff, and/or students.

The program will provide schools with the necessary tools and information to implement POC antigen testing (using BinaxNOW Ag cards) for school staff or students with the goal of testing symptomatic persons and/or asymptomatic persons with confirmed COVID-19 exposure.

The Commonwealth will provide antigen POC tests proportional to the number of students and staff returning for in-person learning, based on the anticipated number of people that may need testing (per guidance from VDH), and as supplies allow. VDH will support the initial pilot phase of this program until June 30, 2021 and will re-evaluate future plans at that time. This program can stand alone as a school's testing regimen or can enhance an existing testing effort already implemented by the school.

This is a voluntary program; schools may opt-in to this program as an additional layer of protection. Testing is not a replacement for COVID-19 prevention practices; any testing program needs to be combined with the prevention strategies outlined in the [Interim Guidance for K-12 School Reopening](#). Furthermore, testing must be voluntary for students and staff.

Intended Use of BinaxNOW Testing:

BinaxNOW testing should be reserved for school teachers, staff, and/or students providing, supporting, or attending in-person instruction who begin exhibiting symptoms of COVID-19 while at school or who are close contacts to a known case of COVID-19. See VDH Algorithm for Evaluating a Child with COVID-19 Symptoms or Exposure and [VDH Algorithm for Evaluating Non-Critical Infrastructure Workers with COVID-19 Symptoms or Exposures](#).

Program Participation Requirements:

Schools must have the following requirements and procedures in place and relevant documentation on file prior to beginning this testing program.

1. Secure a signed order to conduct BinaxNOW testing from someone with prescriptive authority (e.g., physician) or elect to use the K-12 Statewide Standing Order and identify a super-vising licensed healthcare provider.
2. Obtain an approved CLIA certificate of waiver. Schools must apply for a CLIA certificate of waiver by completing this form: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>

This form requires an original signature and the completed form must be mailed to:

Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Richmond, Virginia 23233

3. Identify individuals who will form the testing team and develop a plan to collect samples, including processing the samples on-site and reporting results to the Virginia Department of Health.
4. Confirm ability to maintain an adequate supply of personal protective equipment (PPE) for testing team members who will be collecting and processing samples. Schools may reach out to their local emergency manager for assistance in acquiring PPE.
5. Confirm ability to properly handle and dispose of biohazard waste.
6. Ensure all testing staff have completed Abbott BinaxNOW online training modules and document training completion: <https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>
7. Obtain consent from staff and/or students (or their parents/legal guardians, as necessary). VDH has provided template consent form language and sample school community letters that schools can customize for their own use.
8. Establish procedures to offer testing to staff members or students who become ill at school in addition to any other existing procedures for isolation of a student or staff member. If a school performs in-school testing using antigen tests, there may be times when the school is advised to refer a student/staff member to obtain a confirmatory PCR test. Review the Testing Protocols and K-12 Testing Algorithm for guidance on when a tested person should obtain a confirmatory PCR test. Schools should assist in directing students/staff to testing resources in the community. See Additional COVID-19 Testing Resources in the Community for a list of available testing resources.
9. Establish procedures to notify school members that are tested, as well as the school community, including relevant follow-up actions needed to isolate any individual with positive results and plans to quarantine and contact trace as appropriate and in collaboration with the local health department.

10. Register for the VDH reporting portal and verify ability to complete VDH reporting requirements. (Schools will need to have their CLIA waiver number prior to registering.) Instructions on registering for the portal are available at: <https://apps.vdh.virginia.gov/pocreporting/login/login.aspx>. Schools should register with the portal prior to beginning any testing, since it may take several days to gain access.

Schools that require assistance with these requirements are encouraged to contact the VDH Central Office Testing Team, which can be reached at: antigeninfo@vdh.virginia.gov

Pilot Program Application Process:

A school site interested in participating in the diagnostic testing pilot program must:

1. Review the Readiness Review Checklist and certify that they have completed all the requirements (defined above).
2. Send the completed Readiness Review Checklist to the VDH Central Office Testing Team at antigeninfo@vdh.virginia.gov.

The VDH Central Office Testing Team will review the completed checklist. Upon review and confirmation by VDH, schools that meet all requirements will be enrolled in the program and receive BinaxNOW tests. VDH will also notify the local health department that serves the school division for awareness.



Pilot #1: K-12 Diagnostic Testing Process: Protocol and Roles/Responsibilities

About the Test:

Abbott BinaxNOW is a POC antigen test that uses a nasal swab for sample collection and can return test results in about 15 minutes. These tests are most accurate when administered to symptomatic individuals. The sample is taken with an anterior nasal swab (i.e., swabbing about 0.5 inches into the nostril). Individuals who perform or observe testing must complete online training modules and be under the supervision of a licensed healthcare provider. Samples may be self-collected by an adult staff member or a child who is deemed able to follow the directions, while visually monitored by trained testing team members. Young children or those with disabilities may require assistance from their parent/ legal guardian to collect the specimen.



Healthcare professionals and trained testing team members must be stocked with appropriate personal protective equipment (PPE) – gloves, gowns, face protection (shield or goggles), and masks (N95 or surgical masks, not cloth masks). Nasal swabs should be processed in the test card as quickly as possible after collection.

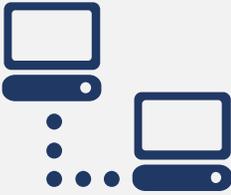
Allocation and Distribution of Tests:

Approximately 2 million BinaxNOW tests have been allocated to Virginia from the U.S. Department of Health and Human Services. VDH and the Virginia Department of Emergency Management are coordinating allocation and distribution to school divisions and other partners. Upon verification by VDH, schools that opt-in to this voluntary program and submit documentation that they meet all criteria for participation will receive POC antigen tests. VDH will ship BinaxNOW tests and will continue to distribute allocations upon request until supplies are diminished or June 30, 2021. Future allocations and distribution processes might be adjusted depending on usage, district needs, and historical information.

A further breakdown of school responsibilities and available resources is below:

What is the requirement?	Who is responsible for executing the requirement?	What resources could schools use to fulfill the requirement?
<p>1. Partner and coordinate with a person with prescriptive authority to write the order for the test, authorize collection, and manage reporting and results follow-up.</p>  <p>Or utilize the K-12 Statewide Standing Order and identify the supervising licensed healthcare provider.</p>	<p>Individuals who can write an order include:</p> <ul style="list-style-type: none"> Local healthcare provider School-contracted healthcare provider 	<p>Schools might consider:</p> <ul style="list-style-type: none"> School-contracted physician Partnership/ agreement with local pediatrician Local health department Other contracts <p>The K-12 Statewide Standing Order can be found here.</p>
<p>2. Obtain a CLIA certificate of waiver to analyze samples.</p> 	<ul style="list-style-type: none"> School submits application 	<ul style="list-style-type: none"> The form to apply for the CLIA certificate of waiver can be found here: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf Schools may contact CLIALab@vdh.virginia.gov with any questions related to the CLIA certificate of waiver.

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<p>3. Develop a plan to collect samples from staff and/or students.</p>  	<ul style="list-style-type: none"> School identifies individuals who will conduct testing. A licensed healthcare provider must conduct testing or provide supervision for individuals who will conduct testing. Individuals who conduct sample collection do not need to be medical professionals, but must complete Abbott BinaxNOW online training modules. In many cases, a student or staff member may self-collect the sample while supervised by a trained individual. 	<p>Individuals who conduct/observe sample collection might include:</p> <ul style="list-style-type: none"> School team Outside community support Private contractors 	<p>6. Collaborate with VDH to report test results.</p> 	<ul style="list-style-type: none"> School reports test results to VDH through the VDH reporting portal. 	<p>Schools can report electronically through the VDH Reporting Portal. Additional information and the link to register for the portal can be found here: https://apps.vdh.virginia.gov/pocreporting/login/login.aspx</p> <p>VDH will also hold training sessions on reporting for participating schools.</p>
<p>4. Obtain consent from staff and/or students (or their parents, where applicable) to conduct testing (testing must be voluntary; schools may not make it mandatory).</p>	<ul style="list-style-type: none"> School collects signed consent and maintains record of consent. 	<p>VDH has provided template consent form language and sample school community letters that schools can customize for their own use.</p>	<p>7. Work with VDH to establish and implement follow-up protocols for each test result (including case investigation, contact tracing, and mitigation).</p> 	<ul style="list-style-type: none"> School coordinates with ordering provider or supervising licensed healthcare provider (if using K-12 Statewide Standing Order) on follow-up care for individuals testing positive. School works with local VDH resources on containment and mitigation practices. 	<p>Individuals who support follow-up activities might include:</p> <ul style="list-style-type: none"> Local healthcare provider School-contracted healthcare provider School staff in collaboration with local health district Private vendor VDH specialized strike teams
<p>5. Establish and implement procedures to refer certain persons for confirmatory testing if needed.</p> 	<ul style="list-style-type: none"> Depending on the test result, certain individuals may be advised to seek confirmatory PCR testing. The school should assist by connecting the individual with resources to find testing in the community. 	<p>Schools should refer to the Testing Protocols for guidance on when to refer an individual for confirmatory testing. VDH has developed a resource for schools that overviews testing options in the community, available here.</p> <p>Local health department resources may also assist in providing guidance on specific cases.</p>			