

VIRGINIA DEPARTMENT OF HEALTH
LOCAL HEALTH DISTRICT GUIDANCE FOR USE AND SECONDARY DISTRIBUTION
ABBOTT BINAXNOW COVID-19 ANTIGEN TEST CARDS
December 1, 2020

Local Health Districts (LHDs) have received a shipment of the Abbott BinaxNOW antigen test cards from the Virginia Department of Health (VDH) central office. Districts can decide how they wish to use their supply. Each box contains supplies for 40 tests, which districts may distribute to local partners. The purpose of this document is to provide guidance and steps for local health districts to use for district testing events and sharing with local partners. Please refer to [VDH Interim COVID-19 Antigen Testing Recommendations](#) for guidelines on the clinical use of antigen testing.

VDH has identified priority groups for use of the BinaxNOW test. Use this as a guide to determine appropriate secondary distribution of your supply. LHDs will decide which local partners are to receive an allotment of their supply.

I. [Priority Groups Identified in Virginia](#)

- **Vulnerable populations:** Low income, people of color, uninsured/underinsured, individuals with disabilities or access and functional needs, limited access to care (rural residents, etc.).
- **Individuals at higher risk of illness or death** from COVID-19 due to age, medical conditions, etc.
- **Residents and staff of congregate care settings:** Skilled nursing and assisted living facilities, behavioral health facilities, correctional institutions, etc.
- **Students, staff and faculty of educational institutions:** Child care, pre K – grade 12, colleges and universities.
- **People involved in areas of critical infrastructure** important to the state’s recovery and reopening.

II. [Facility Requirements for Receiving Abbott BinaxNOW COVID-19 Ag Test Cards](#)

LHDs must ensure their partners are aware of the requirements and agree to meet them prior to providing them a supply of test cards

- Medical provider with prescriptive** authority to order the test and provide follow up. A standing order is acceptable. When LHDs are working with external partners, encourage use of the partner’s prescriptive authority.
- CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation** for the facility providing the test. If unsure of whether the facility has, or can obtain, such a certificate, please contact clialab@vdh.virginia.gov. Facilities can obtain a certificate of waiver to provide only the COVID-19 waived tests. For existing certificates, facilities must update their CLIA Certificate to include antigen testing as one of its COVID testing methods on the menu of testing. To update the test menu for existing certificates, the CLIA # and the additional test method (antigen) should be emailed to clialab@vdh.virginia.gov. A facility can provide multi-site testing, but must have that added to their CLIA certificate. **LHDs must obtain the CLIA number for the partner entity for entry into the REDCap [VDH Antigen Testing Survey](#).**

- ❑ **Report all positive and negative test** results to VDH within 24 hours through the [VDH POC Reporting Portal](#) for point-of-care (POC) COVID-19 tests.
- ❑ **Patients cannot be charged for the testing kit**, but the testing entity may charge an administrative, office visit, or other fees, as deemed appropriate. Entities who choose to charge a fee must determine the appropriate CPT code(s).
- ❑ **Test operators must receive appropriate BinaxNOW training and document proficiency.** Records must be maintained by the entity conducting the test. [Abbott BinaxNOW POC Testing Training](#) is required prior to performing testing. If you would like to schedule a **Train the Trainer class** with an Abbott representative, please contact antigeninfo@vdh.virginia.gov.
- ❑ Share [Interim COVID-19 Antigen Testing Recommendations](#) to provide VDH's current recommendations regarding the use, evaluation, and interpretation of COVID-19 antigen tests.

III. [LHD Steps to Distribute BinaxNOW to Local Partners](#)

- **Population:** Determine if the requesting partner serves a priority group, as noted above. LHD management may make exceptions.
- **Eligibility:** Verify the partner meets ALL the requirements for eligibility to receive the test kits and provide the resources as identified in **Section II**.
 - Discuss required reporting of all positive and negative results within 24 hours through the [VDH POC Reporting Portal](#). Explain that **negative** results can be reported in aggregates, as opposed to individual entries. Positive results must be entered individually.
 - Partner must have VDH POC Reporting Portal access *prior to* administering antigen tests (this can take 2-3 days).
- **Documentation:** Document eligibility requirement responses and distribution information in the REDCap [VDH Antigen Testing Survey](#). The central office uses this tool to track secondary distribution at the district level. A copy of this survey will be emailed to you for your records, A Memorandum of Agreement (MOA) is not required. Districts may forward a copy of the survey email to the receiving entity for documentation purposes, if desired.

IV. [LHD Steps for Internal Use of BinaxNOW](#)

- Ensure use in priority populations (e.g. congregate living settings, outbreaks, jails, education, critical infrastructure, homeless populations) or other populations, as determined by district management.
- Examples of antigen testing use include testing of symptomatic people, or people who are close contacts to a known COVID-19 positive case. Antigen testing has been successfully used in outbreak response to get rapid results of positive cases while awaiting PCR testing. Please follow [interim clinical recommendations for antigen testing use and results interpretation](#).
- Document training and proficiency. LHD antigen testing training documents include [competency checklists](#), [quality control](#), [quality assurance](#), [standing order](#), consent forms in [English](#) and [Spanish](#), [COVID-19 Lab Tracker](#), and more. All of these documents are available on the VDH website under [Antigen Testing Training](#).
- Report all positive and negative test results to VDH within 24 hours, either using VEDSS or the Point of Care (POC) Test Reporting Portal. The VDH COVID-19 POC Portal will be available for LHD registrations beginning Wednesday, 12/02/2020. Districts may contact pocreporting@vdh.virginia.gov for information on registering. Registration requires CLIA

certificate information. If you do not know where this information is, check with your lab manager or nurse manager.

- Update CLIA certificate to include rapid antigen point-of-care testing to their menu of tests. For Districts performing testing outside of the LHD, a multisite exception must be added to the CLIA Certificate (see guidance [here](#) and the [CLIA CMS116 Form](#)). **Health Districts should have an individual CLIA Certificate for each health department location within the District.**
- Questions about CLIA should be sent to clialab@vdh.virginia.gov.

The central office will distribute one additional round of BinaxNOW to all local health districts the week of December 14th. Amounts to be dispersed will be 1x-3x the original disbursement.

V. Clinical Laboratory Improvement Amendments (CLIA) Information

The BinaxNOW COVID-19 Ag Card has been authorized by the FDA under an Emergency Use Authorization for use at the Point of Care, i.e., in patient care settings operating under a **CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation**.

To get a CLIA Certificate, the [CMS116: CLIA Initial Application](#) is completed and sent to the VDH - Office of Licensure and Certification. After the application is processed, a CLIA number is generated and emailed to the facility contact and testing may begin. The Certificate of **Waiver fee is \$180 for the 2 year** certificate and can be paid on-line at pay.gov once the CLIA number is emailed. (The VDH - Office of Licensure and Certification does not process CLIA monies.)

There are no qualifications or credentials required to be the **director on a CLIA Certificate of Waiver**; however, the director is usually someone in leadership. The director ensures that the regulations are followed (i.e. only waived testing is performed, the manufacturer instructions are followed, and test results are reported to the health department).

VI. Ordering Extra Positive Control Swabs and Transport Tubes

Training and quality control require the use of several positive control swabs. Each box of 40 test cards contains only one Positive Control Swab. Additional Positive Control Swabs may be ordered, along with the Abbott Swab Transport Tube Accessory Pack by contacting antigeninfo@vdh.virginia.gov.

VII. RESOURCES

[VDH COVID-19 Antigen Testing Algorithm](#)

[Abbott BinaxNOW POC Testing Training](#) (videos are about halfway down the page)

[Guidance for Self Collection](#)

If you have any additional questions, please contact VDH at antigeninfo@vdh.virginia.gov.