BinaxNOW™ COVID-19 Ag Card Tests

The information re: coronavirus and related recommendations are continually changing as new information is learned, so please check the VDH.Virginia.gov website (coronavirus) frequently for updates and information. Also check the Centers for Disease Control (CDC.gov) for additional information. The CDC and VDH are the authorities with the VDH website being the Guidebook for the Commonwealth of Virginia.

DBHDS, in partnership with the Virginia Department of Health (VDH) is working to make BinaxNOW™ COVID-19 antigen tests available to providers. The initial focus will be on distribution to Community Services Boards (CSB), and both the CSB and Private Certified Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) and to other providers based on the quantity of tests in stock.

The BinaxNOW™ COVID-19 Ag Card (BD Antigen) test received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) in late August.
Additional details and FAQ on the test.

In order to be eligible to receive BinaxNOW antigen test cards, providers must meet the following requirements:

- Have a CLIA Certificate or Certificate of Waiver
- Medical provider with prescriptive authority
- Administer tests using trained staff
- Report all test results to VDH within 24 hours

Please read the linked fact sheet from VDH on the BinaxNow test and the requirements for receiving these antigen test kits for use in your facility/home, to test residents or staff - VDH BinaxNOW Overview.

Recommendations for Test Use

Recommendations for the use, evaluation, and interpretation of COVID-19 antigen tests are outlined by VDH, including the populations and circumstances where these tests should be considered. *VDH Antigen Testing Recommendations*

Obtaining Test Kits

Interested providers should submit the following information to:
https://forms.gle/TfL93Wnd51zzB2Ho7

- Provider Organization Name
- Name of Point of Contact
- Point of Contact Phone
- Point of Contact email
- CLIA Number
- Address (where test kits should be delivered)
- City
- Zip
- Number of BinaxNOW Tests Requested

Updated: 1/26/2021

ADDITIONAL INFORMATION

CLINICAL LABAORATORY IMPROVEMENT AGREEMENTS: aka CLIA certificate

- VDH/CLIA Information and please read the FAQs on this site before proceeding
- A CLIA Waiver – is one type of CLIA certificate.
- For most providers, a CLIA certificate of waiver will be the most appropriate course.
  - CMS116: CLIA Initial Application is completed and sent to VDH Office of Licensure and Certification
- Providers must have a CLIA certificate in order to administer the BinaxNOW test.
  - Providers that already have a CLIA waiver must update it to include the BinaxNOW as one of the tests being completed at the specific location.
  - Each location must be listed on the Certificate.
  - Multi-location organizations can do a multi-location request. Each location must be listed with 911 address (not P.O. Box or main office number) including phone number.
  - The application must be complete when submitted.
  - Each specific test must be listed by site: (i.e., BD Antigen testing for COVID; Blood glucose) and any other tests you perform on site.
- If a provider has an existing CLIA Certificate for the specific location the test will be administered at they can send an email to CLIALAB@vdh.virginia, and add "antigen testing for COVID" to the specific tests being conducted at that location. Be sure to include your CLIA waiver number, the Name of the location under the waiver number.
- Questions about CLIA certificates can be sent to CLIALAB@VDH.VIRGINIA.GOV

TRAINING: Test administrators must receive appropriate BinaxNow training (Modules 1-6 about midway down on this web page) and document demonstrated competency in collection and performing the test.

REPORTING REQUIREMENTS: All test results, negative and positive, must be reported to the Virginia Department of Health within 24 hours via the VDH Reporting Portal for point-of-care (POC) Covid-19-tests

- Sites conducting POC testing will need to register first to utilize the reporting portal. During this one-time registration, facilities will provide site information and select the type(s) of testing equipment utilized. When reporting results, sites will need to provide individual patient information, including demographic information, and the test result.

STORAGE AND HANDLING of BinaxNOW™ COVID-19 Ag Card

- BinaxNOW™ COVID-19 Ag Card test kits must be stored at temperatures between 35.6 - 86°F. Test components should be at room temperature (59-86°F) when the test is performed.
- Specimens should be collected with appropriate infection control precautions, including use of personal protective equipment.
    - All staff administering Abbott BinaxNOW™ COVID-19 Ag Card test kits must wear appropriate personal protective equipment (PPE) when running each test and handling patient specimens. For healthcare personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:
        - N95 mask or higher-level respirator (a surgical mask can be used only if an N95 is not available)
        - Eye protection
        - Gloves
        - Gown, when collecting specimens
    - Staff administering tests must change gloves between handling of specimens suspected of COVID-19.
- All components of the BinaxNOW™ COVID-19 Ag Card test kit should be discarded as biohazard waste according to Federal, State and Local regulatory requirements.

TESTING AND QUARANTINE: VDH and CDC continue to recommend a 14-day quarantine period after the last close contact to a person with COVID-19 as the safest option to protect HCP and patients. Please review VDH Guidance for the Duration of Quarantine for Healthcare Personnel.

OTHER RESOURCES

VDH Antigen Testing Infographic

VDH COVID-19 Testing Algorithm for Health Care Providers

Antigen Test Results and Next Steps Handouts

VDH Guidance for Healthcare Professionals

Updated: 1/26/2021