GETTING STARTED WITH COVID-19 POINT OF CARE (POC) ANTIGEN TESTING

Overview of COVID-19 Point of Care (POC) Antigen Tests

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Overview of COVID-19 Point of Care (POC) Antigen Tests
This document provides a step-by-guide to get started with Point of Care (POC) COVID-19 antigen testing. Currently, the Virginia Department of Health (VDH) offers one type of prescription antigen test:

Abbott BinaxNOW COVID-19 Antigen (Ag) Card – A self-contained antigen test that uses a card and does not require a separate analyzer device. For more information about this product, see https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html.

Step-by-Step Process for Providers

Step 1: Obtain CLIA Certification
The Abbott BinaxNOW COVID-19 Antigen Card is a CLIA-waived test. Therefore, the facility performing the test needs a current CLIA Certificate of Waiver, CLIA Certificate of Compliance, or a CLIA Certificate of Accreditation. A CLIA certificate must be obtained before BinaxNOW supplies can be shipped from VDH to the receiving facility.


The CMS-116 requires an original signature; therefore, the completed form must be mailed to:

Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Richmond, Virginia 23233
If you have an existing CLIA certificate, you do NOT need to obtain another one. You will need to notify the VDH Office of Licensure and Certification that the practice/organization will be performing COVID-19 antigen testing. Please email CLIAlab@vdh.virginia.gov with the practice name and CLIA number stating you will be performing COVID-19 antigen testing, and the specific test you will use.

**Step 2: Prescriptive Authority Needed for POC Antigen Tests**
The Abbott BinaxNOW COVID-19 Ag Card is a prescription item; therefore, a medical provider with prescriptive authority must order the test, review the results, and take appropriate medical action, as indicated, for the person tested. If an organization doesn’t have, or work with, a medical provider with prescriptive authority, you will need to partner with one.

**Step 3: Train Staff/Volunteers to Perform the POC Antigen Test**
Abbott offers online training for its antigen test. It is important that any training that is done be documented; records need to be kept by the employee and their employer.

**Abbott BinaxNOW Training:** This can be done online or by a live webinar. If people wish to take both trainings, which is not required, they can. Online training materials are available at https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html. For questions about Abbott training or to arrange a live webinar, please contact antigeninfo@vdh.virginia.gov.

**Step 4: Register the facility in the VDH COVID-19 POC Reporting Portal**
VDH has established a secure, electronic COVID-19 POC Reporting Portal, which can be found at https://apps.vdh.virginia.gov/pocreporting/login/login.aspx. Please register your facility/testing site.

**Step 5: Order and Perform Antigen Tests**
To order BinaxNOW cards, please complete the following order form: https://forms.gle/3o1dNSLusNi7w6Sq8.

**Step 6: Report COVID-19 Antigen Test Results to VDH**
Per the federal CARES Act, all test results (both positive and negative) must be reported to VDH within 24 hours of receipt. This is done by secure electronic reporting through the VDH portal (https://apps.vdh.virginia.gov/pocreporting/login/login.aspx).

For 1-page patient handouts about what antigen test results mean and next steps, see the VDH Antigen Testing Results and Next Steps Handout. For forms in languages other than English, see: https://www.vdh.virginia.gov/coronavirus/resources-and-support/.
Resources

Guidance Documents

- VDH Interim COVID-19 Antigen Testing Recommendations
- VDH Antigen Testing Results and Next Steps Handout
- Abbott BinaxNOW COVID-19 Antigen Card Training Materials
- VDH Interim COVID-19 Testing Guidance for Healthcare Providers
- Epidemiology terminology about test performance
- VDH COVID-19 Molecular and Antigen Testing Algorithms for Healthcare Providers
- Personal Protective Equipment (PPE) Guidance for Rapid Antigen Point of Care Testing

CLIA Certificate Resources

- How to Obtain a CLIA Certificate of Waiver - Brochure
- CLIA CMS-116 Form Application for Certification

Templates

- Antigen Results Letter for LHDs
- COVID-19 Testing Consent Form - English
- COVID-19 Testing Consent Form - Spanish
- COVID-19 Lab Tracker for Testing Facilities
- COVID-19 Specimen Collection and Rapid Point of Care Testing Standing Order