VDH Abbott BinaxNOW Train the Trainer

TRAIN Course ID: 1094542

November 16, 2020

VDH VIRGINIA DEPARTMENT OF HEALTH
Protecting You and Your Environment

Agenda

Introduction: Linda Anthony

Abbott BinaxNOW Overview: Gail Ryan

Clinical Training: Dr. Sulola Adekoya

Local Distribution of BinaxNOW: Chris Patterson

Q & A: Please enter questions in the chat. The Testing Team will answer questions throughout the presentations.

BinaxNOW Train the Trainer Dates

BinaxNOW training with Abbott Rep Gail Ryan will be offered three days. This is a train the trainer course.

- Monday 11/16/20 10AM-11AM
- Wednesday 11/18/20 10AM-11AM (External partners may attend)
- Thursday 11/19/20 1PM-2PM (External partners may attend)

Go to http://va.train.org/ to register for one of the three sessions.

If you are dialing-in to this meeting, please email Joe Colantuoni at jcolantuoni@deloitte.com to document your attendance.

External partners: To schedule future training, please contact:
Dr. Arman Davani, Arman.Davani@vdh.virginia.gov
Antigen Testing Training Coordinator

Next Steps for Local Health Districts

- Trained Trainers will train local staff (LHDs/MRC/VDH Contractors)
  - Abbott Training Modules will be located in TRAIN - Course Training # 1094708 - will be emailed after the training
- Complete the Train the Trainer Training
  - Document Training and Proficiency
  - Complete the Competency Checklist
- Conduct Quality Assurance monthly

Training Resources

Abbott Training link:
https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

Self Collection:
https://www.fda.gov/medical-devices/letters-health-care-providers/recommendations-providing-clear-instructions-patients-who-self-collect-anterior-nares-nasal-sample?utm_medium=email&utm_source=govdelivery

VDH Reporting:
https://www.vdh.virginia.gov/clinicians/covid-19-update-for-virginia-7/
https://apps.vdh.virginia.gov/pocreporting/login/login.aspx

Follow up testing:
https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Abbot BinaxNOW
Train the Trainer Training

Gail Ryan
Technical Consultant, Abbott Rapid Testing

Rapid Antigen COVID-19 Testing Training

Sulola Adekoya, MD MPH

Rapid Antigen COVID-19 Testing

- Standing Order
- LHD Staff Training Requirements
- CLIA Requirements
- Patient Consent
- Testing Conditions and Considerations
- Results Interpretation
- Reporting Results
- Quality Assurance

Rapid Antigen COVID-19 Testing

COVID-19 Specimen Collection and Rapid Point of Care Testing - Standing Order

- Clinician Order is required prior to performing test
- Standing Order has been updated for Rapid POC Testing:

  This standing order authorizes specific Virginia Department of Health (VDH) staff or Medical Reserve Corps (MRC) trained personnel to collect anterior nasal swabs for the purpose of performing rapid, point of care (POC) antigen testing for the detection of SARS-CoV-2 (the virus that causes COVID-19).

Standing Order
Who can collect specimens?

VDH and MRC Personnel Authorized to Collect Anterior Nasal Specimens:

- Registered Nurses (RNs)
- Licensed Practical Nurses (LPNs) serving under the supervision of an RN, physician (MD or DO), or Nurse Practitioner (NP)
- Pharmacists serving through a special authorization
- Nurse Midwives, Nurse Anesthetists, and other Nurse Practitioners, who are not Family Nurse Practitioners or who are acting on behalf of VDH and are not within their practice agreements, are to collect specimens under their RN license.
- Active duty Virginia National Guardsmen based on their existing protocols
- Collecting nasal swabs is not within the scope of practice of Certified Nursing Assistants (CNAs)

** Excerpt from Standing Order*

Standing Order
Who can perform the test?

VDH and MRC Personnel Authorized to Perform Rapid, Point of Care Antigen Testing:

- Any individual *within their scope of practice* to perform waived laboratory tests
- Received appropriate training
- Demonstrated competency to their supervisor or the CLIA Lab Director
- Training and competency must be documented, per agency policy.

Rapid Antigen COVID-19 Testing
Staff Training Requirements

- All approved VDH/MRC staff must be appropriately trained to collect anterior nasal swabs.
  - Documentation must be maintained in personnel file.
- All individuals *within their scope of practice* to perform waived laboratory testing must be appropriately trained.
- Training Modules are available on TRAIN.
- Competency must be verified by competent trainer, by performing the testing procedure outlined by Abbott.
  - Signed Competency Checklist should be maintained in employee's personnel file *(see Nasal Swabbing Procedure and Performance of BinaxNOW™ COVID-19 Ag Card Competency Checklist)*

Rapid Antigen COVID-19 Testing
CLIA Requirements

- Each site performing testing must have a CLIA waived/PPM certificate.
- Districts must update their CLIA certificate to include BinaxNOW Rapid Antigen Point of Care testing *(see guidance document)*.
  - Districts with an existing CLIA Certificate are asked to email their CLIA # and COVID testing method to CLIALAB@vdh.virginia.gov. It will be added to the test menu in their system.
  - If Districts plan to conduct antigen testing at other locations, the Multi-Site exception can be added to their CLIA certificate by selecting "yes" on #1 under Section V on the CMS116 *(see guidance document)*.

Rapid Antigen COVID-19 Testing
Consent

- Consent must be obtained prior to testing.
- Use ***updated*** COVID-19 Free-of-Charge Testing Encounter and Consent Form, available in both English and Spanish.
- There is **no** charge for testing.
- Complete symptom review is **required** for Antigen POC Testing.
- Verbal consent is acceptable.
- Check off the type of testing: Antigen / Point of Care Testing.

Rapid Antigen COVID-19 Testing
Consent Form Updates

Patient is a close contact to COVID-19 case for ≥15 minutes over 24 hours period ☐Yes ☐No	
Symptomatic: ☐ Yes ☐ No **IF SYMPTOMATIC CHECK ALL THAT APPLY (Required for Antigen Testing)**	
☐ Cough (new onset or worsening of chronic cough)	☐ Fever: Subjective *(felt feverish)* ***OR*** Temperature >100.4°F (38°C)
☐ Chills or rigors	☐ Headache
☐ Muscle aches	☐ Sore throat
☐ Fatigue or malaise	☐ Runny nose
☐ Shortness of breath	☐ Chest pain
☐ Abdominal pain or tenderness	☐ Nausea or vomiting
☐ Diarrhea (3 or more loose stools/24-hr period)	☐ Loss of appetite
☐ Loss of taste/smell	☐ Other:_____

Signature of Person Obtaining Consent (Required) **Signature of Witness (Needed for verbal consent only)**

PCR Testing			Antigen/Point of Care Testing
Lab Corp	**DCLS**	**UVA**	
☐L139900 ☐NP or ☐OP	☐87252 ☐NP or ☐OP	☐U0002 ☐NP or ☐OP	☐BinaxNOW **or** ☐Other_____ ☐Nasal Swab **or** ☐Other_____
CODING FOR CE			
Subprogram Code: OC	**Diagnosis Code:** Z1159 for Asymptomatic		**Diagnosis Code:** Z20828 for Contact with or Suspected Exposure

☐**Negative Result – No additional follow-up needed** ☐**Negative Result – Follow-up needed (see exception notes)**
☐**Positive Result – Follow-up needed (see exception notes)**

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Rapid Antigen COVID-19 Testing Key Considerations

- Test kits must be stored at 2°-30° degrees Celsius. If refrigerated leave out for 1 hour prior to performing test.
- Testing should be performed at 15°-30° degrees Celsius (room temperature).
- Use expiration date **outside of the box** (*box contents may have various expiration dates, but use by expiration on outside of box*).
- **Label each test:**
  - Write the patient's name on the test kits **BEFORE** beginning the test by using the lines on the right side of the front of the card

    OR
  - If using patient labels, place on the shaft of the swab, to identify the patient prior to testing.

Rapid Antigen COVID-19 Testing Key Considerations cont'd

- Test immediately upon swab collection (recommended)

  OR

- Use Abbott Swab Transport Tube (DO NOT return swab to paper packaging) to hold swabs if not testing right away – **must test within one hour, if using tubes**.
- Set timer, test must be read *no earlier than* 15 minutes and *no later than* 30 minutes.
- All reagents, swabs, and test cards must be discarded in **red biohazard bags**.
- Maintain a testing log and retain for 2 years as a laboratory record (see COVID-19 Lab Tracker)

Rapid Antigen COVID-19 Testing
COVID-19 Lab Tracker

COVID-19 Lab Tracker

DATE	PATIENT NAME	DOB	GENDER	RACE	ETHNICITY	ADDRESS	PHONE NUMBER	SYMPTOMS	RESULT	ENTERED IN PORTAL
			☐M ☐F	☐American Indian or Alaskan Native ☐Asian ☐Black or African American ☐Native Hawaiian or Other Pacific Islander ☐White ☐Other Race ☐Unknown ☐Refused to Answer	☐Hispanic ☐Non-Hispanic			☐Yes ☐No	☐Positive ☐Negative	

Rapid Antigen COVID-19 Testing

Results Interpretation for Symptomatic and Asymptomatic Persons

https://www.vdh.virginia.gov/coronavirus/antigen-testing-recommendations/

Table 1:	Symptomatic person (test close to onset of symptoms)	Asymptomatic person with close contact to COVID-19 case	Asymptomatic person without close contact to COVID-19 case
Test Result			
Positive	• Current infection • Prompt isolation until no longer contagious by timed-based strategy	Current infection • Prompt isolation until no longer contagious by time based strategy	Presumptive current infection • Prompt isolation while awaiting confirmatory test result • Confirm positive result with a PCR test done in a high-complexity CLIA-certified laboratory+* • Patients with positive confirmatory test should isolate until no longer contagious by time-based strategy

Table 1:	Symptomatic person (test close to onset of symptoms)	Asymptomatic person with close contact to COVID-19 case	Asymptomatic person without close contact to COVID-19 case
Test Result			
Negative	No antigens were detected • Confirm negative antigen result with a PCR test done in a high-complexity CLIA-certified laboratory+ • Prompt isolation while awaiting confirmatory test result	• No antigens were detected • Close contacts who test negative must still complete 14 days of quarantine. • Obtain COVID-19 PCR test if person develops symptoms	No antigens were detected • No additional case follow-up necessary • Reinforce prevention measures

Rapid Antigen COVID-19 Testing Reporting Results to Patients

- All patient results (positive and negative) should be documented on the Consent/Encounter Form. This will become the Medical Record.
- Any positive results, or negative results that require follow up, should be given by a Nurse or NP. Patient education and guidance should be given and documented on an Exception Note, and attached to the Consent/Encounter Form.
- Negative results that do not require follow up can be given by non-licensed designated staff.
- Follow Up PCR Testing may be necessary, depending upon the interpretation of the results.

Test Result Notification Letter

INSERT DISTRICT LETTERHEAD HERE

COVID-19 Test Record

_____ had a COVID-19 test performed by the local health
(Print Patient Name)

department. Specific information about the test is documented below.

Date of test:_____

Result of test: ☐Negative ☐Positive

Type of test: ☐Antigen ☐Molecular (PCR) ☐Other_____

_____ _____
(Printed Name of Test Administrator) (Signature of Test Administrator)

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Rapid Antigen COVID-19 Testing
Reporting

- Report **BOTH** positive and negative results within 24 hours using the VDH's Reporting Portal for Point-of-Care (POC) Test Results:

  https://apps.vdh.virginia.gov/pocreporting/login/login.aspx.

  - This site may be used to meet the rapid reporting requirement for POC tests and allows for aggregating negative results for high-volume sites. Positive results must be reported as a single entry.
  - VDH portal is connected to VEDSS (no need to report separately in VEDSS)
- Test Results should be recorded in the **COVID-19 Lab Tracker** – the Tracker serves as a CLIA Log and facilitates data entry into the Portal.

Rapid Antigen COVID-19 Testing
COVID-19 Lab Tracker

COVID-19 Lab Tracker

DATE	PATIENT NAME	DOB	GENDER	RACE	ETHNICITY	ADDRESS	PHONE NUMBER	SYMPTOMS	RESULT	ENTERED IN PORTAL
			☐M ☐F	☐American Indian or Alaskan Native ☐Asian ☐Black or African American ☐Native Hawaiian or Other Pacific Islander ☐White ☐Other Race ☐Unknown ☐Refused to Answer	☐Hispanic ☐Non-Hispanic			☐Yes ☐No	☐Positive ☐Negative	

Rapid Antigen COVID-19 Testing Quality Assurance Recommendations

- All staff have completed skills check off for Nasal Swab Collection and Testing for BinaxNOW™ COVID-19 Ag Card test and/or training on other testing methods checklists completed.
- All staff have PPE appropriate for the test site as recommended by the CDC and established by VDH.
- Using the Nasal Swab checklist or other approved testing method checklist, observe at least 50% of the persons performing testing at 1 test site per month.
- Monitor for critical gaps
- Ensure results are reported within 24 hours using VDH's Reporting Portal for Point-of-Care (POC) Test Results.
- Remember to perform Quality Control on new shipment of BinaxNOW COVID-19 Ag Cards, or when a new untrained operator performs the test.
- ***Refer to QA Document in training materials***

Training Resources

Training Checklist, Procedural, QC, and QA Guidance:

- Nasal Swabbing Procedure and Performance of BinaxNOW TM COVID-19 Ag Card
- PPE Guidance For Rapid Antigen Point-of-Care Testing
- BinaxNOW™ COVID-19 Ag Card Quality Control Procedure
- Quality Assurance Checklist for BinaxNOW™ COVID-19 Ag Card Testing

Forms for Antigen Testing:

- Standing Order for Rapid Antigen Testing
- COVID Testing Encounter & Consent Form

Results Guidance:

- COVID-19 Lab Tracker
- Antigen Testing Results Letter for patients

CLIA Resources:

- CLIA Updates for Antigen Testing
- CMS116 Form (CLIA Application for Certification Form)

https://www.vdh.virginia.gov/emergency-preparedness/training-education/

Local Distribution of Abbott BinaxNOW

REDCap Presentation

Chris Patterson
Assistant State Planning & SNS Coordinator
VDH Office of Emergency Preparedness

Questions About Antigen Testing

Clinical and Technical Questions:
Dr. Sulola Adekoya: sulola.adekoya@vdh.virginia.gov
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Antigen Testing Dissemination Strategy:
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Antigen Training:
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Logistics (RedCAP/BinaxNOW Distro):
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