Antigen Testing Guidance

Virginia
OFFICE OF EMERGENCY MEDICAL SERVICES
Virginia Department of Health

Version 2.0

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Policy for Testing Administration by Emergency Medical Services Providers in Virginia

Purpose

This policy is designed to provide guidance to Virginia Emergency Medical Services (EMS) Operational Medical Directors (OMD), EMS agencies, and EMS providers in the development of a program for the administration of antigen tests by appropriately certified, authorized, and supervised EMS providers.

Background

The ability to conduct disease testing using methods that fall within the scope of EMS practice has not been standard practice. Events, such as the COVID pandemic, have brought to light the importance of developing processes and procedures to support the testing process.

Personnel and Responsibilities

An Operational Medical Director (OMD)/EMS Physician serves as the "prescriber" identified in the *Code of Virginia*, and as the supervising physician for the EMS providers administering tests. They are responsible for the following:

- A prescriber is a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance
- Holding a current endorsement as an EMS physician in Virginia and be affiliated with the EMS agency developing the testing program
- The OMD is ultimately responsible for the supervision of the testing program
- Providing authorization for purchase of tests and other necessary supplies for testing administration
- Ensuring appropriate physical management and handling of testing materials
- Developing/approving protocols for approval and training of testers, provision of specific testing information/education and informed consent to recipients of test,
- Developing/approving specific procedures for administration of testing and management of any testing related complications, development and approval of appropriate record keeping, reporting of test results to appropriate individuals, and implementation of an ongoing quality management program for the testing program.

Additionally, any agency participating in the testing program must hold a Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver.

Personnel Requirements

EMS providers participating in a testing program must:

- Hold a valid, unrestricted Virginia EMS certification
- Be approved by the OMD/EMS Physician to practice at the appropriate certification level
- Must be affiliated with the Virginia EMS agency developing the testing program
- Must be individually approved by their agency OMD as a tester
- Must follow protocols approved by their OMD for test administration

Procedures

The OMD must direct the development of a plan for purchase/acquisition of testing materials, including proper storage and handling of the test according to recommendations by the Centers for Disease Control (CDC) and the test's manufacturer.

- The OMD must ensure they approve each provider who will administer tests has received training in the necessary areas. These include handling of the test, specific testing protocols, and reading and recording of test administration and test results.

- The OMD/Agency will keep a written record of those providers approved to administer tests: an example is provided in Appendix A.

- The OMD must report test results to the appropriate individuals, including, but not limited to, the local health district.

- A record of tests administered and the results of those tests must be maintained by the agency.

Appendix A

I,_____, MD/DO licensed in the Commonwealth
NAME OF OMD/EMS PHYSICIAN

of Virginia do hereby authorize, _____,
NAME OF VIRGINIA LICENSED EMS AGENCY

a Virginia licensed Emergency Medical Services agency for whom I serve as an Operational Medical Director (OMD)/EMS Physician as recognized by the Virginia Office of EMS and those affiliated and certified EMS provider listed below to administer vaccines to patients in accordance with the laws and regulations of the Commonwealth of Virginia. In exercising this authority, the participants shall comply with the protocol for administration of vaccines. This medical directive also covers emergency care if it is necessary.

The participants must agree to any significant changes in the protocol.

Signatures:

Printed Name	Signature	Date (MM/DD/YYYY)
_____ Operational Medical Director	_____	_____
_____1`_____	_____	_____
_____	_____	_____
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Virginia Department of Health
Abbott BinaxNOW COVID-19 Antigen Cards Distribution

Update – December 1, 2020

The U.S. Department of Health and Human Services (HHS) distributed Abbott BinaxNOW COVID-19 Antigen Cards ("BinaxNOW") to priority populations such as long-term care facilities, home health and hospice organizations and historically black colleges and universities. Shipments were also sent to state departments of health for further distribution.

Working through the state's Unified Command, the Virginia Department of Health (VDH) disbursed portions of Virginia's allotment to priority groups, either deemed to represent vulnerable populations or those serving critical infrastructure. Organizations that have received BinaxNOW to date include:

- Virginia Hospitals and Health Care Association (100,000)
- Institutes of Higher Learning (101,200) as of 12/1 with some more on the way
- Department of Corrections (25,000)
- Department of Behavioral Health and Developmental Services facilities (15,888)
- Home Health and Hospice that did not receive HHS supplies (5,760)
- Free Clinics (3,640)

Several single requests of BinaxNOW tests (2,000 or less) intended to meet immediate needs for outbreak response, surveillance and testing of critical infrastructure, or healthcare facilities without adequate testing have also been met.

In addition, VDH Local Health Districts (LHDs) were provided 100,000 BinaxNOW tests in late November to address their immediate community needs. Based on the expected receipt of additional BinaxNOW test kits from HHS, VDH Central Office will send LHDs a second supply of tests in late December. This shipment will be approximately 1-3 times the initial shipment sent.

Other partnerships that the testing team is actively working on as of December 1 include:

- Distribution to a Retail Pharmacy, TBA (15 locations) (90,000)
- Statewide EMS Councils (Varied amounts, 1500 or less)
- Additional shipment to Free Clinics (~5,000 tests)

VDH Central Office is also beginning to engage with private provider networks to distribute BinaxNOW for use in primary care settings including pediatric practices. These partnerships will increase accessibility to priority groups to support reopening of schools, critical infrastructure, and/or meet the needs of other at-risk populations. Testing of symptomatic individuals and close contacts of COVID-19 cases will be specifically encouraged, though other groups may be included as well.

Further discussion will also be had with the Department of Behavioral Health and Developmental Disabilities to plan for BinaxNOW accessibility for residential treatment centers, as well as access to general testing for other locally operated centers such as group homes or day support programs.

The state will retain approximately 10% of its existing supplies to help support emergent needs or outbreak response.

To access the VDH's clinical and public health recommendations on use of antigen tests including the BinaxNOW, please see the Antigen Testing Recommendations. For any questions, please contact antigeninfo@vdh.virginia.gov.

Minimum Training for Antigen Testing

The links on the below page (located about halfway down the page) must be completed by EMS providers interested in conducting Antigen Testing.

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

Self-Collection

The following link provides information on the procedure for 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

Reporting

Appropriate reporting of results is required for anyone participating in antigen testing. The below links provide access to resources for reporting results. Agencies should work with their Local Health District to ensure they develop an adequate and appropriate reporting process.

If instructed by the Local Health District, please create an account in advance of testing as it can take 2-3 day to be granted access to the reporting portal:

https://www.vdh.virginia.gov/clinicians/covid-19-update-for-virginia-7/

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

Follow-Up Testing

The following link provides additional information for follow-up testing procedures.

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