**BinaxNOW Training and Testing Protocol Attachment D**

**l. Purpose**

To ensure guidance is being followed in an effort to trace, contain, and combat the spread of COVID - 19. Serial testing can be completed on staff members and others using the BinaxNOW point of care antigen test to help detect infection earlier and exclude them from the workplace or other congregate settings, thus preventing disease transmission and subsequent outbreaks.

**II. Requirements to Administer the BinaxNOW Antigen Test**

1. A CMS - 116 CLIA Certificate of Waiver is required to administer the BinaxNOW COVID – 19 antigen test. A Clinical Laboratory Improvement Amendments (CLIA) number must be assigned prior to performing a BinaxNOW point of care test. To access the certificate of waiver, go to <https://www.alabamapublichealth.gov/providerstandards/clia.html>, click on Click on [CMS.gov/CLIA](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index?redirect=/CLIA), under the tree on the left side of the page, click on “How to Apply for a CLIA Certificate, including International Laboratories”. Scroll to the bottom of the page to Downloads and click on [CMS 116 (PDF)](https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf). Complete the fillable form, print and email to the local state agency contact for CLIA amendments at [CLIAAlabama@adph.state.al.us](mailto:CLIAAlabama@adph.state.al.us).

**NOTE:** If an entity has an existing CLIA number and plans to add additional sites to administer the

test, Section V. Multiple Sites must be completed on the CMS 116 application for multiple site

testing.

# Serial and Non-Serial Testing for COVID -19

* 1. Staff members who perform duties at sites such as Universities, Assisted Living Facilities, Long Term Care Facilities, schools, clinics, and interacting with community customers should provide serial testing on a weekly basis.
  2. Organizations can also administer non serial testing for others within their organization such as university students, clinic patients, or staff members.
  3. The NAVICA App is a mobile phone app feature that may be used for people to receive their test results on their personal phones. A requirement to use the optional NAVICA App is for the organization to download the administrative app from the BinaxNOW training website to an Apple iPad. See the website below for further instructions. [https://www.globalpointofcare.abbott/en/support/product-installation-training/navica- brand/navica-binaxnow-ag-training.html](https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-%20brand/navica-binaxnow-ag-training.html).
  4. A designee within each organization will determine the weekday that each of their staff members will be tested weekly. If a staff member does not report to work on the designated test day, they must be tested on the day they return to work prior to reporting to assigned duties. Thereafter, they will resume testing on their designated day.
  5. Positive test results should be reported online in the COVID – 19 Report Card.

A symptomatic person who has a positive result should be entered

into the COVID – 19Report Card.

If an asymptomatic person has a positive test, or a symptomatic person has a negative test result, the results must be confirmed with a rt PCR test. Positive reflex rt – PCR test results must be reported into the online COVID -19 Report Card.

Click on the following website <https://www.alabamapublichealth.gov/covid19/healthcare.html>, then, click on [COVID - 19 REPORT Card,](https://epiweb.adph.state.al.us/redcap/surveys/?s=WK7TY9PT7J) complete the information and submit.

# Training for Administration of the Test

* 1. Staff administering the BinaxNOW test must complete the BinaxNOW training videos on the

website, htttps://[www.globalpointofcare.abbott/en/support/product-installation-training/navica-](http://www.globalpointofcare.abbott/en/support/product-installation-training/navica-)

brand/navica-binaxnow-ag-training.html. The training consists of six training modules, helpful

documents, and a FAQ page. See attached quick reference guide (attachment 1).

The NAVICA App is a mobile phone app feature that may be used for people to receive their test results on their personal phones. A requirement to use the optional NAVICA App is for each organization to download the administrative app from the BinaxNOW training website to an Apple iPad. See the website below for further instructions. [https://www.globalpointofcare.abbott/en/support/product-installation-training/navica - brand/navica-binaxnow-ag-training.html](https://www.globalpointofcare.abbott/en/support/product-installation-training/navica%20-%20brand/navica-binaxnow-ag-training.html)

* 1. Complete the *BinaxNOW COVID - 19 Ag Card – Training Checklist* under the supervision of a

designee (attachment 2).

# Administration and Logging Results of the Test

* 1. If applicable, results will be sent to the staff members using the NAVICA App.
  2. Test results must be logged on the BinaxNOW COVID – 19 Ag Card Internal

Controls and Patient Record. In addition, the External Control Log must be

completed when a new kit is opened (attachment 3).

* 1. A daily temperature log must be maintained. Store kit at 2-30°C. Ensure all components are at room temperature before use (Attachment 4).

   

Attachment 1 Attachment 2 Attachment 3 Attachment 4

Note: These attachments are available on the website under Helpful Documents

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