DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health

COVID-19 RAPID ANTIGEN TESTING FOR CONGREGATE SETTINGS

The U.S. Department of Health and Human Services (HHS) has committed to sending 290,000 Abbott BinaxNOW COVID-19 point-of-care antigen tests to the State of Delaware. The rapid point-of-care tests, which can diagnose coronavirus infection in as little as 15 minutes, are being distributed by the State to support our overall testing strategy, including to support infection prevention measures within congregate settings such as emergency and homeless shelters.

All testing must be performed in compliance with standards set forth by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as well as the FDA Emergency Use Authorization (EUA). CLIA certification may be sought at https://www.cms.gov/files/document/laboratory-quick-start-guide-cms-clia-certification.pdf).

Supplies must be ordered through the Department of Health and Social Services. SHOC request form may be sought at : .https://coronavirus.delaware.gov/wp-content/uploads/sites/177/2020/10/SHOC-Resource-Request-Form.pdf

Biomedical waste must be properly disposed of. Further information may be sought at: https://dnrec.alpha.delaware.gov/waste-hazardous/management/infectious/.

Facilities must have a plan to isolate antigen-positive individuals as “probable” cases and not cohort with other probable or confirmed positive individuals until confirmatory testing is completed.

Facilities must have the ability to obtain, order, and send confirmatory PCR samples from antigen-positive individuals.

Testing may only be performed under the direction and order of an independently licensed medical practitioner (MD/DO, DMD/DDS, PA, or APRN).

The ultimate clinical decision making from, implementation of, interpretation of, and reporting of COVID-19 antigen tests are the ultimate responsibility of the licensed practitioner (MD/DO, DMD/DDS, PA, APRN, or pharmacist) by whom the tests are administered and who is listed as the ordering practitioner for the testing procedure. DPH guidance for test implementation and interpretation is listed below (See Appendix A).

Use of point-of-care COVID-19 antigen testing is contingent upon reporting of results to the Delaware Division of Public Health via the results logging portal, access to which can be

requested by emailing Dhss_Dph_RedcapAccess@delaware.gov (note underscores). COVID-19 remains a reportable disease and failure to report may result in adverse action.

All patients undergoing testing must be provided with detailed instructions on test interpretation and subsequent care and isolation instructions

General Operating Procedures

I. Purpose

General Operating Procedures for Rapid Point-of-Care Antigen Testing using Abbott BinaxNOW for screening testing of asymptomatic individuals is detailed herein and diagrammed in Appendix A. Testing is to be used **in conjunction with** other known effective non-pharmaceutical interventions, including maintenance of social distancing, mask wearing, and strict handwashing.

II. Concept of Operations

Congregate settings will perform screening testing of facility staff to more rapidly identify asymptomatic carriage of SARS-CoV-2 and to mitigate the spread of COVID-19.

III. Procedure

1. **Organization information**
    a) Personnel should review online training, available at:
        1. https://whitehatcom.com/alere_binax
        2. https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

2. **Approved for testing and testing protocol**
    a) Trained personnel performs a rapid point-of-care antigen test and provides patient with results.
        1. Testing may be performed by properly trained non-clinical personnel.
    b) Prior to allowing individual into setting, trained personnel reiterate protective measures.
    c) Confirmatory PCR testing must be obtained, ordered, and sent on any antigen-positive individuals.

3. **Follow-up/closure**
    a) Staff ensures that results are submitted for each rapid point-of-care antigen test performed for COVID-19 to the Division of Public Health within 24 hours.
    b) Negative cases should continue with previously-recommended PCR testing cadence.

c) Positive cases must be isolated distinct from other individuals pending confirmatory PCR testing.

Guidance for Asymptomatic Staff Screening Within Congregate Settings (Appendix A)