STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Deidre S. Gifford, MD, MPH
Acting Commissioner

Ned Lamont
Governor

Susan Bysiewicz
Lt. Governor

HEALTHCARE QUALITY AND SAFETY BRANCH

BLAST FAX 2020-100

TO: Home Health Agencies

FROM: Acting Commissioner Deidre S. Gifford, MD, MPH

CC: Deputy Commissioner Heather Aaron, MPH, LNHA
Adelita Orefice, MPM, JD, CHC, Senior Advisor to the Commissioner
Barbara Cass, RN., Branch Chief, Healthcare Quality and Safety Branch
Donna Ortelle, Section Chief, Facility Licensing and Investigations Section

DATE: October 29, 2020

SUBJECT: BinaxNOW COVID-19 Antigen Cards

The Connecticut Department of Public Health (DPH) will be distributing rapid BinaxNOW COVID-19 Antigen CARDS for use with nasal swab specimens for COVID-19 testing. These can be used for routine screening of staff working in long term care facilities, or for testing of symptomatic individuals.

The BinaxNOW™ COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. Distribution is related to Home Health Agencies (HHAs) and Hospices that maintain a CLIA Certificate of Waiver. An active CLIA Certificate of Waiver is required before conducting POC antigen testing, and the attached attestation form must be submitted to **DPH.FLISLab@ct.gov**

For those HHA's and Hospices who do not currently hold a certificate of waiver, please complete the FDA-EUA form (link below) and CMS-116 application for a CLIA Certificate of Waiver found at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf Submit questions related to the CLIA certificates to dph.flislab@ct.gov.

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Affirmative Action/Equal Opportunity Employer

DPH is discussing distribution locations (PODs) similar to personal protective equipment (PPE) distribution for the BinaxNOW™ COVID-19 Antigen Cards. More information will be forthcoming.

IMMEDIATE ACTION:

1. The agencies interested should review the attached guidance; an addendum specifically addressing the BinaxNOW™.
2. Agencies will need to have an ordering provider who will be responsible for ordering these tests and staff trained in collecting the specimens appropriately (must follow manufacturer's instructions, viewing their videos is HIGHLY recommended). For additional support, please contact the Abbott Rapid Diagnostics Technical Support Services Team at 1-800-257-9525 between 8am-8pm EST Monday - Friday or by emailing ts.scr@abbott.com.
3. For additional training videos and documents, please visit the BinaxNOW™ COVID-19 AG Card and NAVICA™ App Set-Up and Training portal.
4. Agencies must have an infrastructure for reporting ALL results (positive and negative) to DPH via *electronic* means (see guidance).
5. Agencies will need to have a CLIA Waiver. If not, please refer to the instructions above.