Dear Members,

Clinical Laboratory Improvement Amendments (CLIA) Waivers are available to ALRs through the Department of Public Health. A CLIA Waiver enables onsite Point of Care COVID-19 testing and certifies that an ALR may legally test and will also put an ALR on the distribution list for future federal shipments of tests. Some ALRs who have acquired a CLIA Waiver have already received Abbot BinaxNOW tests from the U.S. Dept. of Health and Human Services. While EOEA does not endorse any specific testing platform, a CLIA Waiver will enable ALRs to consider different Point of Care platforms that are available and, also, to participate in federal programs. Argentum announced that they learned from HHS today that they have a plan to acquire and distribute another 30 million BinaxNOW rapid tests to communities with CLIA waivers through mid-March, which is approximately 6-8 weeks beyond the current supply.

For additional information on applying for a CLIA Waiver, please see below for instructions from EOEA.

Requirements for ALRs

1. Obtaining a CLIA certificate:

For facilities that do not yet have a CLIA certificate, the application for a CLIA Certificate (CMS Form 116) can be found here.

For your convenience, the below information may help you fill out your CLIA application if your facility does not already have one:

- In section I, please select “Other Changes (Specify)” and fill in “COVID 19” to alert our program that your application is a part of this distribution effort
- In section II, please select “Certificate of Waiver”.
- In section III, please select “ “4-Assisted Living Facility”
- In section V, please select “Yes” if you are applying as a company and have more than one ALR facility in your organization.
    - In #1 in section V, please select “Yes” as each ALR facility may act as a temporary testing location should there be a need to test residents or staff.
    - In #2 and #3 in section V, please select “No”.
- In section V, please select “No. If no, go to section V1” if you are applying as a single facility at a single site.

- In section VI, please enter "BinaxNOW™ COVID-19 Ag Card"
- Please completely fill out the other sections, as applicable.

Please also include information about other tests you may be performing at this location and provide specifics on the test systems.

If you are only performing COVID-19 testing pursuant to a CLIA certificate of waiver then you may not need to obtain a state clinical laboratory license, the state clinical laboratory program will follow up with you, as appropriate.

Please send the completed application to The Clinical Laboratory Program at clialab@mass.gov

Should you have any questions, please contact the Clinical Laboratory Program at (617) 660-5385.

2. Maintaining an adequate supply of PPE

All staff administering Abbott BinaxNOW test kits must wear appropriate personal protective equipment (PPE) when running each test and handling patient specimens. For healthcare personnel collecting specimens or within 6 feet of individuals suspected to have COVID-19, the following PPE is required:

- N95 mask or higher-level respirator (a surgical mask can be used only if an N95 is not available)
- Eye protection
- Gloves
- Gown, when collecting specimens

Staff administering tests must change gloves between handling of specimens suspected of COVID-19. Refer to DPH Comprehensive PPE Guidance or contact your local board of health for further information regarding the proper use of PPE.

3. Ensuring staff complete training requirements

All staff administering Abbott BinaxNOW test kits within a LTC facility must complete all Abbott BinaxNOW training modules. The training modules can be found here.

The Abbott BinaxNOW training modules include:
Module 1: Getting Started
Module 2: Quality Control
Module 3: Specimen Collection and Handling
Module 4: Patient (Individual) Test
Module 5: Navica Admin App

These modules provide a detailed step-by-step guide to the test process. All the modules should be completed in their entirety prior to staff performing test on individuals.

It is the responsibility of the LTC facility to ensure that all the staff administering tests have completed the necessary training requirements. Staff administering tests must watch the Abbott BinaxNOW video training modules as part of their attestation prior to ordering tests.

Additionally, further information about the proper use of the Abbott BinaxNOW

test kits can be found on the package insert and here. This includes information regarding specimen collection, handling, transportation, and storage.

Staff who have questions or concerns about the administration of the test can utilize these direct links to Abbott support: 800-257-9525, 8:00am – 8:00pm, Monday through Friday or ts.scr@abbott.com

4. Provider Order:
The Abbott BinaxNOW test must be ordered by a licensed independent provider such as a physician or nurse practitioner.

5. Reporting Test Results:
Massachusetts ALRs that receive any rapid POC antigen test equipment must report both positive and negative test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS).

Results of BinaxNOW tests should be reported to DPH using Casetivity, with "BinaxNOW COVID Antigen" in the "Test" field. If your facility does not have access to Casetivity, you will need to gain access by sending an email to ISIS-ImmediateDiseaseReporting@mass.gov and following the instructions you receive. There is an initial file validation process. Please include the name of your facility and contact information in the email.

DPH strongly encourages all facilities in Massachusetts to monitor the CDC website for up-to-date information and resources:

- CDC website: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html
- HHS website: https://www.hhs.gov/coronavirus/testing/rapid-test-distribution/index.html

If you have questions, please contact, MassALA@mass-ala.org

**The information provided in this COVID 19 update is solely for general informational purposes to assist in understanding the evolving guidance regarding the current COVID 19 public health threat. It is not intended to be a primary public health or medical resource, but is provided as a clearinghouse for or compilation of various guidance issued by official and related sources.*
