

# UPDATE CORONAVIRUS (COVID-19)



Stay informed. Take precautions. Stay safe.

Dear Members,

Mass-ALA is pleased to share the announcement made by EOEA today that ALRs with CLIA (Clinical Laboratory Improvement Amendment) Waivers can apply to receive Point of Care Tests from the state supply. Mass-ALA has advocated for assisted living residences to have access to this supply of tests and we are grateful to EOEA and EOHHS for working with us and providing this access.

Today's EOEA guidance provides information to ALRs on how to request BinaxNOW test kits from DPH, updates and clarifications to the situations in which certain tests may be used, and the documentation and protocols that must be in place prior to requesting test kits. Some of the highlights related to the use of tests in ALRs are:

- ALRs may have access to POC rapid diagnostic tests purchased directly or distributed by U.S. Department of Health and Human Services, including BinaxNOW test kits. This guidance applies only to BinaxNOW test kits supplied by DPH and does **not** apply to POC rapid diagnostic tests obtained by LTC Facilities from the federal government.
- At this time, BinaxNOW test kits requested from DPH may only be used for testing symptomatic staff and residents at the ALR and for testing ALR staff and/or residents that came into close contact with an individual who is suspected of being COVID-19 positive or is COVID-19 positive.
- ***BinaxNOW test kits may not be used for routine surveillance testing of staff and residents.***
- Residents or staff who have symptoms of an illness consistent with COVID-19 may be tested using the BinaxNOW test.
- ALRs may request a prescribed number of BinaxNOW test kits from the Department of Public Health until January 31<sup>st</sup>, 2021
- See pages 3 and 4 for the formula of how many test kits you may request.

Please see the entire guidance below from the Executive Office of Elder Affairs regarding BinaxNOW Rapid Point of Care testing for assisted living residences and details related to acquiring tests from the state supply.

Mass-ALA is also pleased to announce confirmation of the CMS temporarily exercising enforcement discretion under CLIA for COVID-19 testing when a facility has submitted a CMS-116 application for a CLIA Certificate of Waiver, but has not yet been assigned a number. Facilities that have applied for a CLIA

waiver to perform POC testing can begin that testing and reporting results as soon as they have submitted their application to their state agency. If a facility has tests in hand, those tests may be used, but the facility must receive the CLIA Certificate of Waiver in order to request additional tests from the state.

Earlier this month, Mass-ALA sent out [this notice](#) to inform you of the availability of CLIA waivers and how to apply. Many ALRs have successfully applied for and received those waivers.

For facilities that do not yet have a CLIA certificate and would like to obtain one, the application (CMS Form 116) can be found [here](#).

- 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](mailto:clialab@mass.gov)

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

---

Good Afternoon,

Please see the attached guidance from the Executive Office of Elder Affairs regarding BinaxNOW Rapid Point of Care COVID-19 Testing for Assisted Living Residences.

Have a good afternoon and enjoy the rest of the week.

Thank you,

Patricia C. Marchetti  
Director, Assisted Living Certification & Compliance  
Executive Office of Elder Affairs - Room 517  
One Ashburton Place  
Boston, MA 02108

Direct Tel: (617)222-7503  
Main EOEATel: (617) 727-7750  
[patricia.marchetti@mass.gov](mailto:patricia.marchetti@mass.gov)

[View the EOEAGuidance  
Here](#)

***If you have questions, please contact, [MassALA@mass-ala.org](mailto: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.*

---

**MASS-ALA | [Website](#)**

