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**Memorandum**

**TO:** Assisted Living Executive Directors

**FROM:** Elizabeth Chen, Secretary of Executive Office of Elder Affairs

**SUBJECT:** BinaxNOW Rapid Point of Care COVID-19 Testing for Assisted Living Residences

**DATE:** August 9, 2021

**Background**

This memorandum replaces the memorandum issued in May 2021 and is effective immediately. Content changes are reflected in red text. This updated memorandum extends the ability of Assisted Living Residences (ALRs) to request BinaxNOW Rapid Point of Care COVID-19 test kits until October 31, 2021.

The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Defense (DOD) recently announced an initiative to deliver Abbott BinaxNOW COVID-19 Ag Card Point of Care (POC) SARS-CoV-2 rapid diagnostic tests (“BinaxNOW test kits”) to states. Massachusetts has been advised that it will receive tests for use in priority settings, including but not limited to long-term care Facilities (LTC Facilities) and schools. Massachusetts Department of Public Health (DPH) and the Executive Office of Elder Affairs (EOEA) is making BinaxNOW test kits available for use at Assisted Living Residences (ALR) for the purpose of testing staff who are not fully vaccinated prior to the beginning of each shift, staff who feel they are at increased risk of exposure, testing visitors, and symptomatic staff and residents as well as close contacts, at no cost to the ALR. ALRs may request a prescribed number of BinaxNOW test kits from the Department of Public Health until October 31<sup>st</sup>, 2021.

This guidance provides information to ALRs on how to request BinaxNOW test kits from DPH, updates and clarifications to the situations in which kits requested from DPH may be used, and what documentation and protocols must be in place prior to an LTC Facility requesting test kits.

**Use of BinaxNOW test kits in Massachusetts ALRs:**

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 should be used for the following purposes:

- for individuals entering the facility who are not regularly reporting staff (e.g. visitors);
- testing symptomatic staff and residents at the ALR;
- testing asymptomatic staff and residents at the ALR as part of outbreak testing;
- testing direct care staff prior to beginning a shift on a unit they are not assigned.
- testing staff who are not fully vaccinated prior to beginning each shift. If staff are working two consecutive shifts then they only need to be tested prior to beginning the first shift; and
- testing staff who feel they are at increased risk of exposure; and
- testing visitors.

BinaxNOW test kits should **not** be used for broad scale asymptomatic testing of staff and residents when there are no resident or staff cases in the facility.

Situations in which BinaxNOW test kits requested from DPH may be used are described below:

*Non-staff entering the building:* Individuals who come inside the ALR for the purpose of visiting a resident, performing work, etc. This does not include regularly reporting staff. (**NOTE:** This guidance does not affect indoor visitation requirements and does not impose a requirement for visitors to ALR facilities to be tested. The most current visitation guidance for ALRs may be found on the [DPH COVID-19 website.](#))

- Those who test positive should be treated as a positive COVID-19 case, be denied entry into the ALR, and encouraged to contact their healthcare provider.
- Those who test negative may be allowed to enter the ALR, provided, that they meet the screening criteria (e.g. are not exhibiting any COVID-19 like symptoms) and comply with other in-person visitation requirements such as wearing a mask and social distancing as described in the Visitation Guidance.

*Residents and staff with symptoms:* Residents or staff who have symptoms of an illness consistent with COVID-19 (see the box below) may be tested using the BinaxNOW test

<b><u>Symptoms consistent with COVID-19</u></b>
<ul style="list-style-type: none"><li>• Fever (100.0° Fahrenheit or higher), chills, or shaking chills</li></ul>

- Cough (not due to other known cause, such as chronic cough)
- Difficulty breathing or shortness of breath
- New loss of taste or smell
- Sore throat
- Headache
- Muscle aches or body aches
- Nausea, vomiting, or diarrhea
- Fatigue
- Nasal congestion or runny nose

*Residents and staff in close contact of the COVID positive or suspected COVID positive individual:* Residents or staff who do not have symptoms of an illness consistent with COVID-19 but came into close contact with a COVID positive or suspected COVID positive individual may be tested using the BinaxNOW test. BinaxNOW test kits may be used to meet the recommended all staff and resident testing every three days following the identification of a new resident or staff case.

- Those who test positive should be treated as a positive COVID-19 case, managed accordingly and have follow up with PCR testing for COVID-19.
- No further testing is required for those who test negative. If a staff member or residents develops symptoms consistent of an illness with COVID-19, then they should be retested.

*Testing staff who are not fully vaccinated prior to beginning to work a shift:* If a staff member is not fully vaccinated, meaning at least two weeks 2 weeks after their second dose in a 2-dose series, such as the Pfizer or Moderna vaccines, or 2 weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine, the ALR should perform BinaxNOW testing on the individual prior to beginning to work a shift. If the staff member is working two consecutive shifts, then they only need to have BinaxNOW testing performed on them before beginning the first shift.

*Testing for staff who feel they are at increased risk of exposure:* If a staff member feels they are at increased risk of exposure they may request that the facility perform BinaxNOW testing prior to beginning to work a shift, regardless of vaccination status.

If a resident has a positive BinaxNOW test result, the resident should be cared for using COVID-19 positive precautions while waiting for a PCR test confirmation.

If a staff member has a positive BinaxNOW test, they should isolate at home while waiting for the results of a PCR test confirmation.

*PCR test confirmation for staff and residents:* Given the superior accuracy of PCR testing, ALRs should arrange PCR testing for staff and recommend PCR testing for residents as soon as possible after staff and residents become symptomatic. A PCR test result (rather than a

BinaxNOW or any other antigen test result) should be used to determine the proper protocol for the resident or staff member when taken within 2 days of a BinaxNOW or any other antigen test result; the result of a PCR test taken within 2 days of a BinaxNOW or any other antigen test will “override” the result of the BinaxNOW or any other antigen test.

### **Temperature Controls for BinaxNOW test kits**

In accordance with the BinaxNOW test instructions for use (IFU), test kits must be stored at temperatures between 2 and 30°C (35.6 - 86°F). The IFU states to ensure that the test components (Antigen card and buffer) are at room temperature (59 and 86°F) during performance of the test. DPH requires the room temperature to be recorded upon test administration. Data obtained by DPH indicates that the test’s accuracy is significantly reduced when used outside of this temperature range.

### **Requirements for ALRs requesting BinaxNOW test kits:**

ALRs must meet the four following requirements in order to request Abbott BinaxNOW test kits from DPH:

1. Have an approved CLIA certificate of waiver;
2. Secure a signed provider order for testing;
3. Maintain an adequate supply of PPE;
4. Review consent forms;
5. Ensure all staff performing testing meet training requirements (see Appendix A (4)); and,
6. Report test results to DPH.

All ALRs must complete the above requirements and submit an attestation via the online survey [ALR BinaxNOW Test Kit Checklist](#) prior distribution of Abbott BinaxNOW test kit(s) attestations

Additional information about each requirement and how that requirement may be met is provided below in [Appendix A: Requirements for Assisted Living Residences](#)

### **Requesting BinaxNOW test kits**

ALRs that currently meet all requirements outlined above and submit the required attestation may request BinaxNOW test kits through the DPH resource request process until **October 31<sup>st</sup>, 2021**. Test kits supplied by DPH are intended to supplement allocations provided directly from the federal government. DPH shipment quantities may be modified if test kits are not used appropriately, and any unused tests may be subject to recollection.

The maximum number of BinaxNOW test kits an ALR may request is equal to the number of certified units of the ALR multiplied by four, per month. BinaxNOW test kits contain 40 tests. To determine the maximum number of BinaxNOW test kits to request, multiply the number of

certified units of the ALR by four then divide by 40, then round up to the nearest whole number. The ALR may request the number of BinaxNOW test kits necessary to satisfy that quantity. For example, an ALR with 100 certified units is eligible to receive 400 tests; therefore, this ALR may request 10 BinaxNOW test kits containing 40 tests each per month. The maximum number of BinaxNOW test kits each ALR may request per month based on the number of certified units, this is identified in *Appendix B: Assisted Living Residence Maximum Order Volumes*.

If an ALR's prior allotment of tests has not been used or results have not been properly reported to the department, a new request for test kits will not be fulfilled. Requests in excess of this amount will not be fulfilled by DPH.

In order to request BinaxNOW test kits, ALRs should complete [Appendix C: Resource Request Form](#) and email the completed form to [COVID19.Resource.Request@mass.gov](mailto:COVID19.Resource.Request@mass.gov). Delivery timelines may vary based on DPH delivery capacity. ALRs should expect to receive requested test kits within one (1) week of a request being submitted.

## *Appendix A: Requirements for Assisted Living Residences (ALR)*

### **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:

<https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>

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](mailto:clialab@mass.gov)

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

### **2. Securing a signed provider order:**

The Abbott BinaxNOW test must be ordered by a licensed independent provider such as a nurse practitioner or physician. The participating ALR must have a standing provider order in place prior to requesting test kits from DPH. ALRs may obtain a standing order from a local board of health medical director.

DPH has drafted a model standing order which can be used by ALRs to request a standing order a local board of health medical director. The model standing order can be found attached in Appendix D.

### **3. 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 any staff 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.

### **4. Review consent forms**

ALRs must review Appendix E: *Abbott BinaxNOW Antigen Testing - Registering Users and Reporting Results*. Use of the NAVICA app referenced in the BinaxNOW materials is not necessary. Reporting will be done through Project Beacon. Refer to Appendix E: *Abbott BinaxNOW Antigen Testing - Registering Users and Reporting Results* for more details.

### **5. Ensuring staff complete training requirement**

All staff administering Abbott BinaxNOW test kits within an ALR 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 8:00 am – 8:00 pm Monday through Friday or [ts.scr@abbott.com](mailto:ts.scr@abbott.com)

## **6. Reporting Test Results:**

Massachusetts ALRs that receive BinaxNOW or 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).

ALRs are required to use the Project Beacon system to collect consent for the administration of the Abbott BinaxNOW COVID-19 test and authorization to report the results to the Massachusetts Department of Public Health (DPH) and others. For more details refer to *Appendix E: Abbott BinaxNOW Antigen Testing - Registering Users and Reporting Results*.

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>



*Appendix B: Assisted Living Residence Maximum Order Volumes*

The maximum number of BinaxNOW test kits an ALR may request from DPH is equal to half the number of certified units of the ALR. BinaxNOW test kits contain 40 tests. To determine the maximum number of BinaxNOW test kits to request, divide half the number of certified units of the ALR by 40, then round up to the nearest whole number. The ALR may request the number of BinaxNOW test kits necessary to satisfy that quantity. For example, an ALR with 100 certified units is eligible to receive 50 tests; therefore, this ALR may request two (2) BinaxNOW test kits containing 40 tests each. The maximum number of BinaxNOW test kits each ALR may request based on the number of certified units as identified in spread sheet

ALRs may only request BinaxNOW test kits from the Department of Public Health until **October 31<sup>st</sup>, 2021**.

The document embedded below contains the maximum number of test kits permitted for each Facility to **request per month, by October 31<sup>st</sup>, 2021**:



ALR Max Order  
Volumes BinaxNOW €

*Appendix C: Resource Request Form*

<b>Date Submitted to DPH:</b>	OPEM 213TS – Resource Request Form – COVID19 <i>Abbott BinaxNOW Test Kits</i>	Page 1 of 1 Version 10-5-20
<b>I. REQUESTING AGENCY POINT OF CONTACT - Please Type ALL Answers</b>		
1. Requestor's Name (Please Print)	2. Title	3. Requestor's Phone No.
4. Requestor's Organization		5. Requestor's E-Mail Address
6. DELIVERY Address (include any special instructions; such as if there is a loading dock, of if the facility needs to be contacted prior to delivery).		7. DPH Facility ID number <b>NA for ALRs</b>
		8. <u>24/7</u> Contact Name and Phone number for delivery issues
		9. Hours of operations to receive delivery (for example 8:00 am – 3:00 pm M-F)
<b>II. REQUEST SPECIFICS - Please Type ALL Answers</b>		
10. Order (Please complete all fields)		
No. Requested	Items Available:	Date Need, pending availability
	<p align="center"><b>Abbott BinaxNOW COVID-19 Test Kit</b></p> <p align="center">[Each kit contains test cards and swabs to conduct 40 tests, therefore, please request the total number of <b>kits</b> needed based on this quantity]</p>	
<b>III. Submittal Process</b>		
11. To submit a request, please email completed form to: <p align="center"><a href="mailto:COVID19.Resource.Request@mass.gov">COVID19.Resource.Request@mass.gov</a></p>		

## **Appendix D: Model Standing Order**

### ***Massachusetts Department of Public Health Sample Standing Order***

#### **Abbott BinaxNOW Rapid Point of Care COVID-19**

These sample standing orders are current as of December 2020. They should be reviewed carefully against the most current recommendations from the Executive Office of Elder Affairs (EOEA) and the Department of Public Health (DPH).

**Purpose:** To facilitate the rapid identification SARS-CoV-2 using the rapid point of care Abbott COVID-19 Ag Card test, this standing order is issued pursuant to my authority as a licensed physician in Massachusetts to order the examination of any specimen derived from the human body, pursuant to G.L. c. 112D, section 8(7). This standing order allows individuals to undergo testing for SARS-CoV-2, the virus that causes COVID-19, subject to the terms and requirements outlined below:

#### **1. Ensure the test is administered in a qualified point-of-care setting by trained personnel**

The EUA for the Abbott BinaxNOW COVID-19 Ag card test allows for use in point-of-care settings that are qualified to have the test performed and are operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Personnel must have completed training to perform the sample collection and testing.

#### **2. Temperature requirements for BinaxNOW COVID-19 Ag Card tests**

In accordance with the BinaxNOW COVID-19 Ag Card test's instructions for use (IFU), test kits must be stored at temperatures between 2 and 30°C (35.6 - 86°F). The IFU states to ensure that the test components (Antigen card and buffer) are at room temperature (59 and 86°F) during performance of the test. DPH requires the room temperature to be recorded upon test administration. Data obtained by DPH indicates that the test's accuracy is significantly reduced when used outside of this temperature range.

#### **3. Instruct staff collecting the test to follow infection control precautions when handling clinical specimens.**

Precautions when caring for or obtaining samples from an individual suspected to be COVID-19 positive include contact and droplet precautions with hand hygiene and the use of PPE that includes gown, gloves, N95 filtering facepiece respirator or higher (use a facemask if a respirator is not available), and eye protection such as goggles or faceshield. Guidance for prioritizing and optimizing use of Personal Protective Equipment can be found [here](#).

**4. Assess individuals for their eligibility to be tested and the protocol to be followed upon completion of the test.**

Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest.

At this time, BinaxNOW test kits requested from DPH may only be used for:

- testing symptomatic staff and residents at the ALR;
- 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 and staff with symptoms:* Residents or staff who have symptoms of an illness consistent with COVID-19 (see the box below) may be tested using the BinaxNOW test.

<b><u>Symptoms consistent with COVID-19</u></b>
<ul style="list-style-type: none"><li>• Fever (100.0° Fahrenheit or higher), chills, or shaking chills</li><li>• Cough (not due to other known cause, such as chronic cough)</li><li>• Difficulty breathing or shortness of breath</li><li>• New loss of taste or smell</li><li>• Sore throat</li><li>• Headache</li><li>• Muscle aches or body aches</li><li>• Nausea, vomiting, or diarrhea</li><li>• Fatigue</li><li>• Nasal congestion or runny nose</li></ul>

*Residents and staff in close contact of the COVID positive or suspected COVID positive individual:* Residents or staff who do not have symptoms of an illness consistent with COVID-19 but came into close contact with a COVID positive or suspected COVID positive individual may be tested using the BinaxNOW test. BinaxNOW test kits may be used to meet the recommended all staff and resident testing every three days following the identification of a new resident or staff case.

- Those who test positive should be treated as a positive COVID-19 case, managed accordingly and have follow up with PCR testing for COVID-19.
- No further testing is required for those who test negative. If a staff member or residents develops symptoms consistent of an illness with COVID-19, then they should be retested.

If a resident has a positive BinaxNOW test result, the resident should be cared for using COVID-19 positive precautions while waiting for a PCR test confirmation. ALRs should consult with their Local Board of Health for situation-specific considerations.

If a staff member has a positive BinaxNOW test, they should isolate at home while waiting for the results of a PCR test confirmation.

*PCR test confirmation for staff and residents:* Given the superior accuracy of PCR testing, LTC Facilities should arrange for PCR testing as soon as possible after staff and residents become symptomatic. A PCR test result (rather than a BinaxNOW or any antigen test result) should be used to determine the proper protocol for the resident or staff member when taken within 2 days of a BinaxNOW or any antigen test result; the result of a PCR test taken within 2 days of a BinaxNOW or any antigen test will “override” the result of the BinaxNOW or any antigen .

#### **5. Check for appropriate authorizations to perform testing.**

Ensure consent has been granted prior to administering a test. Consent must be given by a guardian if appropriate. EOE and DPH will release consent and reporting guidance that must be utilized when administering Abbott BinaxNOW COVID-19 Ag Card test kits.

#### **6. Perform positive and negative control tests for each new box opened**

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. BinaxNOW COVID-19 Ag Card kits contain a Positive Control Swab (i.e., a swab which will trigger a positive result, but does not contain any infectious virus) and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new box received, and once for each untrained operator.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support (1-800-257-9525 or [ts.scr@abbott.com](mailto:ts.scr@abbott.com)) during normal business hours before testing patient specimens.

#### **7. Prepare and administer Abbott BinaxNOW test.**

*Prepare and administer the Abbott BinaxNOW test according to the package insert. If instructions in the package insert contradict the instructions below, the instructions on the package insert should be followed.*

##### **A. NASAL SWAB**

Only the swab provided in the kit is to be used for nasal swab collection.

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible.

Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril).

Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

## B. SPECIMEN TRANSPORT and STORAGE

Do not return the nasal swab to the original paper packaging. For best performance, direct nasal swabs should be tested as soon as possible after collection.

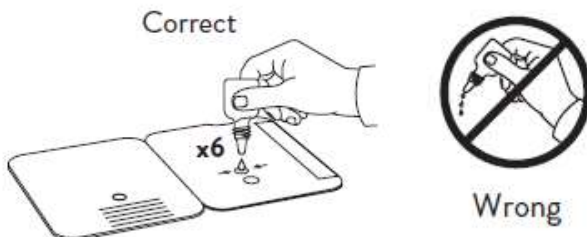
If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed.

If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

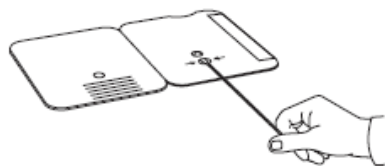
## C. TEST PROCEDURE: Procedure for Patient Specimens

Open the test card just prior to use, lay it flat, and perform assay as follows. The test card must be flat when performing testing, do not perform testing with the test card in any other position.

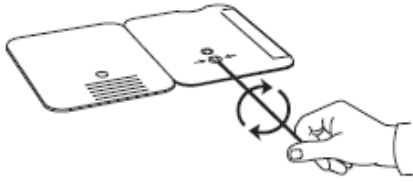
1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.



2. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.

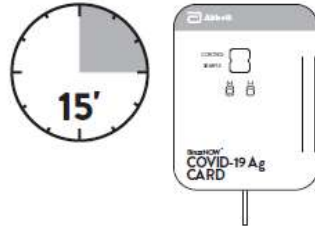


3. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.



*Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.*

4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.



*Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.*

**8. Document test administration and provide appropriate notice**

Every effort should be made to inform the individual’s primary care provider of the result of the test.

ALRs must report test results to the Department of Public Health’s Bureau of Infectious Diseases and Laboratory Sciences (BIDLS) through the Project Beacon system established by DPH.

**Standing Orders Authorization**

This policy and procedure shall remain in effect for all residents and staff of

\_\_\_\_\_ name of Assisted Living Residence  
 until rescinded or until \_\_\_\_\_ date

Healthcare Provider’s signature \_\_\_\_\_ Signature date \_\_\_\_\_ Effective date \_\_\_\_\_

Print Healthcare Provider's Name:

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## **Appendix E: Abbott BinaxNOW Antigen Testing - Registering Users and Reporting Results**

Your organization is required to use the Project Beacon system to collect consent for the administration of the Abbott BinaxNOW COVID-19 test and authorization to report the results to the Massachusetts Department of Public Health (DPH) and others. To accomplish this, Project Beacon has created a responsive web application (which works equally well on desktop or mobile devices) to compile authorized consent and to automatically communicate results to DPH. Please note that reporting information in Project Beacon must take place in addition to continuing to report ALL positive test results to DHCD weekly by 5:00pm on Fridays.

### **The NAVICA App**

You do not need to use the NAVICA app that is referenced in the Abbott BinaxNOW materials. Currently the NAVICA app does not report results to Massachusetts DPH. Your organization must ensure that all test results are reported to Massachusetts DPH by entering all test results into the Project Beacon system described below.

### **Creating a Project Beacon Administrator Account**

Staff register for administrator accounts by completing an online [Account Registration Form](#). Staff will receive a message from Project Beacon when their account has been created. Please note that Project Beacon accounts function at a site/location level. Organizations with multiple locations will need to fill out this form for each individual site that will be conducting BinaxNOW tests.

Staff that create a Project Beacon administrator account and the people using the Project Beacon account may only do so for the purposes and in accordance with the contract between DPH and Project Beacon. The instructions in this document are consistent with that contract.

### **Consent to Testing**

Consent to administer the Abbott BinaxNOW COVID-19 test and to report results to DPH via Project Beacon are pre-requisites to test administration. Individuals must agree to all terms to be tested. Consent should be gathered using the forms attached to this guidance.

### **Creating Profiles in Project Beacon for People Receiving Tests**

If the person being tested has already been entered into Project Beacon at your location (i.e., if they had a previous test in the system at your location), it is not necessary to create a new profile for that person and you can go to the “Recording Test Results in Project Beacon” step.

Additional information can be found here: [How to conduct a test for a patient who has already received a results](#)

If the person being tested is not already in Project Beacon, you will have to set up a profile for them by going to “Personnel,” then “Add Personnel,” and then “Create Single Record.” You will be prompted to fill in necessary information about the person receiving the test, including:

- Contact Information

- First and last name
- Address
- Race
- Ethnicity
- Sex

After the profile has been created, you can reflect the consent given by the person about to receive the test by opening their profile and checking the box that says “Consent has been granted.”

Additional information can be found here: [How to collect consent](#)

### **Recording Test Results in Project Beacon**

Once the person receiving the test has been entered into the Project Beacon system, the person giving the test can search for them in the system and click “Check In.” The system will then begin the testing process, during which you will need to provide the Lot Number (located on the BinaxNOW box) and record the test result.

All test results should be input into Project Beacon as they are performed; it is crucial that there is no delay between test administration and test reporting.

Additional information can be found here: [How to enter results](#)

### **Uploading a Roster in Project Beacon**

It is strongly suggested to ALRs that they ensure staff are entering all information (consent and demographic information) about the person to be tested all at once right before they receive the test, in the method described above.

However, the Project Beacon system can also be used to allow the person receiving the test, if they have internet access and a working email address or phone number, to give consent and input their information ahead of time. To enable this, staff have two options: (a) they add users one at a time by following the directions in “Creating Profiles in Project Beacon for People Receiving Tests” above; or (b) they can add multiple users at once by uploading a “roster” to Project Beacon with the name and phone number/email of people who may need to be tested; after those people fill out their own information, if a test is necessary at a later date staff only need to input the lot number and test result.

Additional information can be found here: [How to create a roster](#)

*Project Beacon support can be accessed by emailing [help@beacontesting.com](mailto:help@beacontesting.com) or calling (617) 741-7310.*

*Abbott BinaxNOW Antigen Test – Sample authorization*

By completing and submitting this form, I authorize the administration of a COVID-19 antigen test on me. I understand that such testing is optional, and I can refuse to give this authorization, in which case, I will not be tested.

**Demographic Information:**

First Name: \_\_\_\_\_

Last Name: \_\_\_\_\_

Middle Name: \_\_\_\_\_

Address (street, city, zip code): \_\_\_\_\_

\_\_\_\_\_

What is your date of birth? \_\_\_\_\_

What is your race? (Select all that apply):

American Indian/Alaskan Native

Asian

Black/African American

Native Hawaiian/Pacific Islander

White

Other

Are you of Hispanic origin? (Select one):

Yes

No

What is your sex? (Select one):

Male

Female

Do you have a disability? (Select one):

Yes

No

What is your primary language? \_\_\_\_\_

**Consent and Data Sharing (please initial):**

\_\_\_\_\_ I authorize an administration professional to administer the Abbott BinaxNOW COVID-19 antigen test on me. I understand that my test results will be loaded to Project Beacon, which will share them with the Massachusetts Department of Public Health in accordance with state law.

\_\_\_\_\_ I authorize the disclosure of my contact information to Project Beacon (a third party organization contracted to compile consent for testing and to share test results). I understand that along with test results Project Beacon will share my contact information with DPH. I also understand that I can create a user profile in Project Beacon that will notify me about test administration and test results I agree that if I create such a user profile, I will only use the Project Beacon system for the purpose of accessing information, including test results, that I am legally allowed to access.

I understand that I can change my mind and cancel this permission at any time, but that such cancellation is forward-looking only, and will not affect information I already permitted to be released. To cancel this permission for COVID-19 testing, I need to contact Project Beacon directly at (617) 741-7310.

\_\_\_\_\_  
Name (Print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

*Abbott BinaxNOW Antigen Test – Sample Parent/Guardian Authorization for Child*

By completing and submitting this form, I confirm that I am the appropriate parent / guardian to provide consent, and that I authorize the administration of a COVID-19 antigen test. I understand that authorizing a COVID-19 test is optional and that I can refuse to give this authorization, in which case a test will not be administered.

**Child’s Demographic Information:**

Child’s First Name: \_\_\_\_\_

Child’s Last Name: \_\_\_\_\_

Child’s Middle Name: \_\_\_\_\_

Child’s address (street, city, zip code): \_\_\_\_\_

\_\_\_\_\_

What is the child’s date of birth? \_\_\_\_\_

What is the child’s race? (Select all that apply):

- American Indian/Alaskan Native
- Asian
- Black/African American
- Native Hawaiian/Pacific Islander
- White
- Other

Is the child of Hispanic origin? (Select one):

- Yes
- No

What is the child’s sex? (Select one):

- Male
- Female

Does the child have a disability? (Select one):

- Yes
- No

What is the child’s primary language? \_\_\_\_\_

**Parent/Guardian Information:**

Parent/Guardian First Name: \_\_\_\_\_

Parent/Guardian Last Name: \_\_\_\_\_

Parent/Guardian Address (if different than above): \_\_\_\_\_

\_\_\_\_\_

Parent/Guardian Phone Number: \_\_\_\_\_

Parent/Guardian Email Address: \_\_\_\_\_

**Consent and Data Sharing (please initial):**

\_\_\_\_\_ I authorize an administration professional to administer the Abbott BinaxNOW COVID-19 antigen test on my child. I understand that my child’s test results will be loaded to Project Beacon, which will share them with the Massachusetts Department of Public Health in accordance with state law.

\_\_\_\_\_ I authorize the disclosure of my contact information to Project Beacon (a third party organization contracted to compile consent for testing and to share test results). I understand that along with test results Project Beacon will share my contact information with DPH. I also understand that I can create a user profile in Project Beacon that will notify me about test administration and test results. I agree that if I create such a user profile, I will only use the Project Beacon system for the purpose of accessing information, including test results, that I am legally allowed to access.

**Authorized Signatory:**

I understand that I can change my mind and cancel this permission at any time, but that such cancellation is forward-looking only, and will not affect information I already permitted to be released. To cancel this permission for COVID-19 testing, I need to contact Project Beacon directly at (617) 741-7310.

\_\_\_\_\_  
Parent/Guardian Name (Print)

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date