

Commonwealth of Massachusetts  
**DEPARTMENT OF HOUSING &  
COMMUNITY DEVELOPMENT**

Charles D. Baker, Governor ♦ Karyn E. Polito, Lt. Governor ♦ Jennifer D. Maddox, Undersecretary

**To:** EA, Individual Shelter, Youth Shelter, and Domestic Violence Shelter Providers  
**From:** Alvina Brevard, Director of Division of Housing and Stabilization at the Department of Housing and Community Development  
**Date:** January 11, 2022  
**Subject:** Guidance for Shelter regarding COVID-19, Testing (Including Accessing Abbott BinaxNOW Rapid Tests) and Positive Tests in Shelter (Updated)

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Summary: This document compiles COVID-related guidance to homeless shelters in one location. This document was drafted with consultation from the Massachusetts Department of Public Health (DPH) and is based on recommendations from the Center for Disease Control (CDC) and DPH. This document is subject to change based on further public health guidance.

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**I. DHCD Support Regarding Mask Compliance**

- a. The Governor has maintained a mask mandate in congregate care settings, such as congregate shelters. The Massachusetts Department of Housing and Community Development (DHCD) strongly recommends that masks be worn by all persons above the age of 2 in all common spaces of congregate shelter and that shelters follow practices and mandates issued by state and municipal governments and directives from the CDC and DPH.
- b. Within EA family shelters, DHCD is discouraging the use of the EA Non-Compliance system as a means to enforce mask wearing in family shelters, in favor of more effective and trauma-informed practices to support families who struggle with mask compliance. Interventions may include consultations with DHCD, referrals to DPH/FOR Families, and transfers. However, Non-Compliances shall be considered and may be expedited when the refusal to wear a mask is combined with other aggressive behavior that meets the criteria under serious incidents/health and safety and/or other rule violations.
  - i. [Printable flyers regarding mask wearing can be found here.](#)

- c. DHCD may be able to assist in securing additional PPE for staff and families if a shelter program is not able to obtain specific items. Please reach out to [Virginia.k.griffin@mass.gov](mailto:Virginia.k.griffin@mass.gov) for support.

## II. Offsite Testing

- a. Testing sites are located across the state, and in many cases, are free or covered by insurance. Find testing sites here: <https://www.mass.gov/info-details/find-a-covid-19-test>.
- b. Abbott BinaxNOW Rapid Tests

DHCD in collaboration with DPH can provide the Abbott BinaxNOW Rapid tests, and participating shelters can receive the test kits at no cost. In most cases, participating shelters will be able to administer the test using existing staff resources. Personnel performing, and shelter participants self-administering, the tests will need training; please see “Training Requirements” below.

This section of the memo provides participating shelter agencies with an overview of the use of Abbott BinaxNOW test kits and information regarding the documentation, reporting requirements, and protocols required prior to and after receiving test kits. The last part of this section includes a Readiness Review Checklist for completion by the participating shelter agency as a prerequisite to request for distribution of Abbott BinaxNOW test kits.

### **Use of Abbott BinaxNOW test in Shelters:**

The Abbott BinaxNOW test is a rapid antigen test. Rapid antigen tests perform best when the person tests in early stages of infection (when the person is within 7 days of the onset of symptoms) with SARS-CoV-2, which is when the viral load is generally highest.

### **Allowable uses for the Abbott BinaxNOW test:**

- Testing symptomatic shelter guests and staff
- Testing asymptomatic shelter guests and staff
- Testing new guests upon entry into shelter

When a shelter participant or staff member appears to have a medical need other than a clearly identifiable physical injury (e.g., broken finger), the shelter should respond using the following protocol:

1. Shelter participants or staff without symptoms of an illness consistent with COVID-19 may be considered for testing using the Abbott BinaxNOW tests upon entry into the shelter and for regular surveillance testing protocols.
2. Shelter participants and staff with severe or life-threatening symptoms: Call 911 immediately
3. Shelter participants and staff with the following symptoms of an illness consistent with COVID-19 should be tested using the Abbott BinaxNOW test:
  - Fever (100.0° Fahrenheit or higher) or chills
  - Cough
  - Difficulty breathing or shortness of breath

- New loss of taste or smell
  - Sore throat
  - Headache
  - Muscle aches or body aches
  - Nausea or vomiting
  - Diarrhea
  - Fatigue
  - Nasal congestion or runny nose
4. Those who test positive should follow the COVID-19 positive guidance in Sections VI and VII of this guidance and their primary care provider should be notified of the positive test.
  5. Those who test negative should be informed of the test results and follow up with their healthcare provider, as needed.
    - If there is strong clinical suspicion of COVID-19, best practice is to isolate the individual and follow up with a viral test (antigen or PCR) as soon as possible, including:
      - i. If a healthcare professional identifies significant COVID-19 symptoms, (i.e., fever, cough) and/or
      - ii. There was known **close contact (i.e., 15 minute or more of contact at less than 6 feet of distance or being coughed or sneezed upon by, or caring for a COVID-19-positive individual)**
    - If symptoms persist, individual should be re-tested after 1-3 days using the Abbott BinaxNOW test.

**Disposal of Used Tests:**

All staff and shelter participants self-administering the tests should follow the instructions provided on the Abbott BinaxNOW package insert regarding specimen collection, handling, transport and storage as is detailed here: <https://www.fda.gov/media/141570/download>.

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.

Nasal swabs from a test kit used to determine whether a person has an infection and that are disposed of in a shelter setting are not considered medical or biological waste since they would be exempt from the definition of pathological waste as defined in 105 CMR 480.010. Such waste can be included in regular solid waste trash provided it is not packaged or labeled as biohazard waste. As a reasonable precaution, used swabs should be sealed in zip lock bags.

**Requirements:**

All participating shelter agencies must complete all six of the following requirements in order to receive approval from DHCD for their distribution of Abbott BinaxNOW test kits.

- ✓ Obtain an approved CLIA certificate of waiver

- ✓ Secure a signed physician order or state standing order for testing
- ✓ Confirm ability to maintain an adequate supply of PPE
- ✓ Ensure all testing staff meet training requirements
- ✓ Review consent forms
- ✓ Verify ability to complete DPH reporting requirements

Shelter agencies should expect a supplementary memo with information on consent forms and DPH reporting requirements; use of the NAVICA app referenced in the BinaxNOW materials is not necessary. Reporting will be done through another system provided by DPH.

The testing should be performed at room temperature (59-86 deg F). This is important, as the performance of the test can deteriorate at lower or higher temperatures.

**Distribution process:**

**Each participating shelter agency must complete the Readiness Review Checklist available here which certifies that they have completed all the requirements.**

After the checklist is completed and submitted, DHCD will follow up with shelters directly. If all requirements are satisfied, the shelter agency will submit an order form directly to DPH to schedule a delivery of test kits.

**Obtaining a CLIA certificate of Waiver:**

Before receiving and administering tests, shelters must have a “Clinical Laboratory Improvement Amendments (“CLIA”) Certificate of Waiver.

Please find the application for a CLIA Certificate (CMS Form 116) here:

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

You need one CLIA Certificate of waiver for your shelter agency, regardless of how many shelter sites you operate, if CLIA multiple site criteria are met.

For your convenience, we are sharing some information that may help you fill out your CLIA application if your facility does not already have a CLIA Certificate of Waiver or other appropriate CLIA certificate:

- In section I, please select “Initial Application” and under “Other Changes (Specify)” fill in “COVID 19” to alert the Clinical Laboratory Program that your application is a part of this distribution effort. The Facility Address must be the physical address of a location that is performing testing even if you are applying for multiple site designation. DHCD suggests that the Director should be an individual who is positioned to ensure compliance with CLIA regulations, like your organization’s Executive Director.
- In section II, please select “Certificate of Waiver” if you will be performing only the Abbott BinaxNOW COVID-19 Ag Card test or other CLIA-waived tests.
- In section III, please select “29- Other, and specify Homeless Shelter”
- In section IV, select the appropriate hours the shelter is open.

- In section V, please select “No” if you have one single shelter location, please select “Yes” if you are applying as a shelter agency and have more than one shelter location.
  - In #1 in section V, please select “No”
  - In #2 in section V, please select “Yes” enter the number of shelter locations.
  - In #3 in section V, please select “No.”
  - Please note that only one of the multiple site criteria may be selected.
- In section VI, please enter “Abbott BinaxNOW COVID-19 Ag Card Test” and provide the Estimated Total Annual Test Volume (2 x the total number of shelter guests); however, DPH is still determining the number of tests available per shelter agency. If additional CLIA-waived tests will be performed, the test and specific test system information should be included in this section.
- In Section VII, please leave blank.
- In Section VIII, please leave blank.
- In Section IX, enter the type of organization you are.
- In Section X, enter information about additional laboratories, if any, and have the Executive Director, CEO, or equivalent sign the form. If no additional laboratories, please leave blank (most shelters will leave this section blank).

Please send the completed applications to The Clinical Laboratory Program at [CLIALab@mass.gov](mailto:CLIALab@mass.gov). If you have any questions, you may contact the Clinical Laboratory Program at (617) 660-5385.

A resource you may find helpful is this Quick Start Guide from CMS:  
<https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf>

**Securing a signed physician order:**

The Abbott BinaxNOW test must be ordered by a physician. The participating shelter agency must have a standing physician order in place prior to requesting test kits from DPH. Shelter agencies may obtain a standing order from a local board of health medical director.

If the participating shelter agency has a Medical Director on staff, that Medical Director (or other licensed doctor or certified nurse practitioner) may sign the standing order

DPH has drafted a model standing order which can be used by shelters to request a standing order a local board of health medical director. The model standing order can be found attached in Appendix 1.

If the participating shelter agency does not have a Medical Director on staff, and is also unable to obtain a signed standing order from a local health care provider with a National Provider Identifier (NPI) number, then the participating shelter agency may utilize the following information on the standing order:

**Dr. Larry Madoff, NPI number 1720044050, MD, 15 Coolidge Street, Brookline, MA, 02446.**

**Maintaining an adequate supply of PPE:**

There are additional personal protective equipment (PPE) requirements for administration of COVID tests by shelter staff. Shelter Agencies should acquire their own PPE, and alert DHCD if unable to obtain specific items.

All staff administering Abbott BinaxNOW test kits must wear appropriate PPE when running each test and handling patient specimens.

Staff administering tests, and shelter guests self-administering, must change gloves and perform hand hygiene between handling of specimens suspected of COVID-19.

Refer to [PPE, testing and vaccine supply resources during COVID-19 | Mass.gov](#) or contact your local board of health for further information regarding the proper use of PPE.

Shelter Agencies must be able to maintain an adequate supply of PPE as is required to administer tests as needed.

### **Ensuring all staff complete training requirements:**

All staff and shelter participants self-administering Abbott BinaxNOW test kits within a sheltering agency must complete the Abbott BinaxNOW training modules below. The Abbott BinaxNOW training modules 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

These modules provide a detailed step-by-step guide to the test process. Modules 1-4 must be completed in their entirety prior to performing tests.

It is the responsibility of the participating shelter agency to ensure that the necessary training requirements are completed. Staff and shelter participants 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.

General questions or concerns about the administration of the test can be directed to the Abbott support line: 800-257-9525 8:00 am – 8:00 pm Monday through Friday or [ts.scr@abbott.com](mailto:ts.scr@abbott.com).

### **Obtaining consent:**

DHCD and DPH will provide further information on the consent and authorization for the administration of Abbott BinaxNOW test kits. Any individual receiving a BinaxNOW test must consent to the administration of the test as well as the information sharing required to report results to the Massachusetts DPH.

This consent process, which will include options for electronic or paper consent forms, will include obtaining signature from shelter participants prior to administering the tests.

### **Verifying ability to complete all reporting requirements:**

Shelter agencies participating in this initiative must report all test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences (BIDLS) AND continue to report ALL positive test results to DHCD weekly by 5:00pm on Fridays.

- EA shelter reports sent to: [Virginia.K.Griffin@mass.gov](mailto:Virginia.K.Griffin@mass.gov) by 5 pm every Friday
- Individual shelter reports sent to: [Amber.Noyes@mass.gov](mailto:Amber.Noyes@mass.gov) by 5 pm every Friday

Additional information about how participating shelter agencies will report test results to the Department of Public Health's Bureau of Infectious Diseases and Laboratory Sciences to be provided in a supplementary memo prior to the distribution of test kits.

### **Create a Project Beacon Account:**

Once you have completed the training modules for test administration, please complete [this form](#).

For "Location Name," put the name of the Shelter Agency where you will be conducting tests.  
For "CLIA Certificate of Waiver Number," please insert your CLIA Certificate of Waiver Number.  
For ordering provider information, please use: Dr. Larry Madoff, NPI number 1720044050, MD, 15 Coolidge Street, Brookline, MA, 02446.

Under Account 1, use your name and email address. If you are creating accounts for coworkers who are also going to be administering accounts, you can put in their information below. Otherwise, simply agree to the affirmation on page 5, and you have completed the process.

You and anyone else whose information you included will receive an email confirming your account soon.

### **III. Positive Tests in EA**

If an EA family member or onsite staff member tests positive, immediately:

- a. If the individual has difficulty breathing or other life-threatening symptoms, call 911.
- b. Positive individuals should isolate from other household members to the extent possible, for example in a separate room and separate bathroom. When not possible to fully separate, household members should wear masks and enhance hand and surface hygiene.
- c. If in congregate/shared shelter setting, Isolate the person or household in a location away from others or send the staff person home.
- d. If in a scattered site shelter setting, the household should remain in their scattered site unit and facilitate food and other deliveries as needed. The shelter staff should contact the family daily, if not more regularly, to inquire about their status and needs.
- e. Contact Virginia Griffin, Barbara Duffy and your contract manager, and identify whether the family can safely isolate in their current placement or should be moved to another unit with the same provider or, if needed, a nearby EA provider.

To access Isolation and Recovery sites, providers must reach out to Barbara Duffy prior to contacting the Isolation and Recovery intake line.

- f. Individuals with confirmed COVID-19 need to be isolated from others for 5 days and continue to wear a mask around others for 5 additional days. Prior to releasing the individual from isolation, it is strongly recommended that a COVID-19 viral antigen test (i.e. Abbott BinaxNOW test) be performed and has resulted as negative. If the test is positive, then the individual should remain on isolation precautions until after day 10.
- g. An employee or resident who has had close contact (within 6 feet of someone for a cumulative total of 15 minutes or more over a 24-hour period) with an individual who has tested positive for COVID-19 must follow the [COVID-19 Isolation and Quarantine Guidance](#) for the General Public. If Abbott BinaxNOW rapid tests are not available and there is evidence of virus spread within the congregate site (i.e., 2 or more cases in a facility within 2 weeks), please call the MA Department of Public Health at 617-983-6800 to be screened by the on-call epidemiologist at DPH. DPH will deploy mobile units as necessary.

#### IV. Positive Tests in Individual Shelters

If a shelter resident/staff tests positive, immediately:

- a. Isolate the person in a room or location away from others. If it is necessary for the individual who tested positive to be around other persons for any length of time, require them to wear a mask.
- b. If the individual has difficulty breathing or other life-threatening symptoms, call 911.
- c. If the individual does not appear to have life-threatening symptoms or require hospital-level of care, they can be referred to the State's COVID-19 Isolation and Recovery (I&R) sites. In order to access the I&Rs, the individual must have a positive COVID-19 test result and be able to safely isolate without intensive medical supervision. This site is NOT available for individuals who:
  - i. Require assistance with Activities of Daily Living from on-site staff; or
  - ii. Require medication administration (except for methadone); or
  - iii. Require the level of care provided at a Skilled Nursing Facility.
- d. If the criteria in "C" above are met, shelters, medical providers, outreach staff, etc. can refer the person by calling 617-367-5150 Monday through Friday between 9am and 5pm or Saturdays between 10am and 2pm.
- e. For any questions, concerns or issues accessing the State's I&R site, please contact Josh Cuddy ([josh.cuddy@mass.gov](mailto:josh.cuddy@mass.gov)) at the Executive Office of Health and Human Services.
- h. Individuals with confirmed COVID-19 need to be isolated from others for 5 days and continue to wear a mask around others for 5 additional days. Prior to releasing the individual from isolation, it is strongly recommended that a COVID-19 viral test (i.e. Abbott BinaxNOW test) be performed



and has resulted as negative. If the test is positive, then the individual should remain on isolation precautions until after day 10.

## V. COVID-19 Exposures (EA and individual shelters)

- a. An employee or resident who has had close contact (within 6 feet of someone for a cumulative total of 15 minutes or more over a 24-hour period) with someone who has tested positive for COVID-19 must follow the [COVID-19 Isolation and Quarantine Guidance](#) for the General Public including the below updated guidance:
- b. Fully vaccinated residents who are less than six months out from their second Pfizer or Moderna doses or less than two months out from their J&J vaccine, or have received a booster dose are not required to [quarantine](#) following a COVID-19 exposure but should wear a mask around others for 10 days.
- c. Residents who are not fully vaccinated or are more than six months out from their second Pfizer or Moderna dose (or more than 2 months after the J&J vaccine) and not yet boosted, are required to quarantine for 5 days and continue to wear a mask around others for an additional 5 days. They may be released from quarantine according to DPH [guidance](#).
- d. If guests or staff of a congregate shelter have had close contact (within 6 feet of someone for a cumulative total of 15 minutes or more over a 24-hour period), the shelter should follow the below testing protocol:
  - i. If Abbott BinaxNOW tests are available and the shelter is approved for Abbott BinaxNOW use, test all individuals who may have been in contact with the person who tested positive or any member of their household using Abbott BinaxNOW tests.
  - ii. If Abbott BinaxNOW Tests are not available *and* there is evidence of virus spread within the congregate site (i.e., 2 or more cases in a facility within 2 weeks), please call the MA Department of Public Health at 617-983-6800 to be screened by the on-call epidemiologist at DPH. DPH will deploy mobile units as necessary

## VI. Prevention

Staff and guests can help stop COVID spread. Specifically:

- a. **Get Vaccinated and Get a Booster Shot. Vaccination is the single most important thing we can all do to protect ourselves and our communities. It is safe and effective and easily available.**

[To find a MA vaccination location click here](#)

For assistance with connecting to a vaccinating partner for on-site clinics, please reach out to: [Virginia.k.griffin@mass.gov](mailto:Virginia.k.griffin@mass.gov)

- b. **Wear a mask**, any time you are interacting with people outside of your household.

- c. **Wash your hands often** with soap and warm water for at least 20 seconds, and/or sanitize hands with sanitizing solutions that are at least 60% alcohol.
- d. **Cover your mouth when you cough or sneeze. Use a tissue or your inner elbow, not your hands.**
- e. **Avoid touching** your eyes, nose and mouth.
- f. **Increased housekeeping practices**, please refer to the Center on Disease Control’s Effective Cleaning and Disinfecting Recommendations for shelter facilities: [Interim Guidance for Homeless Service Providers to Plan and Respond to Coronavirus Disease 2019 \(COVID-19\) | CDC](#) (most recently updated as of 11/3/2021).
- g. **Reduce sharing** of dishes, drinking glasses, cups, eating utensils, towels, bedding, or other items with other people. Wash items thoroughly with soap and hot water. Consider disposable paper and plastic products.
- h. **Increase social distancing** as much as is feasible – consider staggering meals or asking residents to eat in their rooms; shifting the structure of house meetings to smaller gatherings; increase use of flyers, bulletin boards, email, texting, and phone calls to communicate instead of face to face contact.
- i. **Isolate if you are sick** and avoid close contact with others.
- j. **COVID-19 Guidance for Individual Homeless Shelters** – please visit this link: [for additional guidance around Public Health recommendations to mitigate the risk of transmission in shelter.](#)

Please post the following notice in a conspicuous location in all shelter facilities (EA and individual)

- a. Required: <https://www.mass.gov/doc/wear-a-mask-or-face-covering/download>; additional languages are available here: <https://www.mass.gov/info-details/covid-19-printable-fact-sheets#wear-a-mask->
- b. Optional Posters: <https://www.mass.gov/info-details/covid-19-printable-fact-sheets>

## VII. Covid Testing as a barrier to accessing Emergency Shelter and Mitigation of Spread Within shelters

- i. If Abbott BinaxNOW Tests are not available *and* there is evidence of virus spread within the congregate site (i.e., 2 or more cases in a facility within 2 weeks), please call the MA Department of Public Health at 617-983-6800 to be screened by the on-call epidemiologist at DPH. DPH will deploy mobile units as necessary

Shelters that receive FEMA, ESG-CV, or state appropriation (7004-0102) funding through DHCD are not allowed to require a negative Covid-19 test in order to access a bed in their programs.

Federal regulations require the elimination of all possible barriers to accessing shelter utilizing these funds and the CDC states that it is unknown whether entry testing effectively mitigates COVID spread.

Instead of requiring a negative test prior to entry, providers may:

1. Create space within their facilities that can be used for general quarantine. Providers with access to hotel / motel shelter resources are welcome to structure those resources in a manner that allows them to be used for quarantine.
2. Complete the application process for access to the [Abbott BinaxNOW COVID test](#) (limiting need for long-term quarantine)
3. Test individuals upon entry and place them in a safe quarantine location while they await test results. Use of the Abbot BinaxNOW tests for this purpose is acceptable and recommended.
4. Participate in DHCD's surveillance testing option for asymptomatic persons

These steps do not, however, negate the need for continued prevention measures.

Even when social distance spacing has been achieved in sleeping areas, congregate settings are encouraged to **create barriers between beds**. This often takes the form of curtains hanging from above. Some shelters have had success in creating socially distant dining in their facilities by creating **dining shifts** – and thus reducing the number of people in the dining area at any given time.

As always, encourage **hand washing** and requiring mask wearing when in the facility are strongly encouraged, as is symptom screening as people enter the building.

Any person without a home who has tested positive should be referred to an isolation and recovery site by calling (617) 367-5150 between the hours of 7 a.m. and 7 p.m. Transportation to and from the site is provided.

### **More information and Guidance:**

Questions about accessing the Abbot BinaxNOW testing can be directed to [Virginia.K.Griffin@mass.gov](mailto:Virginia.K.Griffin@mass.gov).

More guidance and resources, as well as a frequently asked questions document specifically about emergency shelters and Covid-19 can be found on the [CDC website](#).

Detailed guidance and eligibility criteria for Isolation and Recovery sites for COVID positive persons without homes can be found at <https://www.mass.gov/info-details/covid-19-isolation-and-recovery-sites>

Consideration for Shelter Staff and Volunteers:

DHCD recommends that shelter providers adhere to the CDC Interim Guidance for Homeless Service Providers (most recent update 11/3/2021).

## VIII. Appendix 1: Model Standing Order

Massachusetts Department of Public Health

***SAMPLE STANDING ORDER***  
***for shelters with medical directors or that are otherwise able obtain the necessary signature***  
**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 Department of Housing and Community Development (DHCD) 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 and shelter participants 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 and shelter participants 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 appropriate PPE. 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.

When a shelter participant or staff member appears to have a medical need other than a clearly identifiable physical injury (e.g., broken finger), the shelter should respond using the following protocol:

- A. Shelter participants and staff with severe or life-threatening symptoms: Call 911 immediately
- B. Shelter participants and staff **with the following symptoms of an illness consistent with COVID-19** should be considered for testing using the Abbott BinaxNOW test:

<u>Symptoms consistent with COVID-19</u>
<ul style="list-style-type: none"> <li>• Fever (100.0° Fahrenheit or higher) or chills</li> <li>• 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 or vomiting</li> <li>• Diarrhea</li> <li>• Fatigue</li> <li>• Nasal congestion or runny nose</li> </ul>

Those who test positive should follow the COVID positive guidance in Sections VI and VII of the memo guidance provided by DHCD to shelters.

Those who test negative should be informed of the test results and follow up with their healthcare provider; if there is strong clinical suspicion of COVID-19, best practice is to follow up with a viral (PCR or antigen) test as soon as possible. If a healthcare professional identifies significant COVID-19 symptoms, (i.e., fever, cough), or if there was close contact (i.e., 15 minute or more of contact at less than 6 feet of distance or being coughed or sneezed upon by, or caring for a COVID-positive individual), a viral test is recommended to rule out COVID-19.

If symptoms persist, individual should be re-tested after 1-3 days using the Abbott BinaxNOW test.

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

Ensure consent has been granted prior to administering a test. Consent must be given by a parent/guardian if appropriate. DHCD 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. Abbott 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.

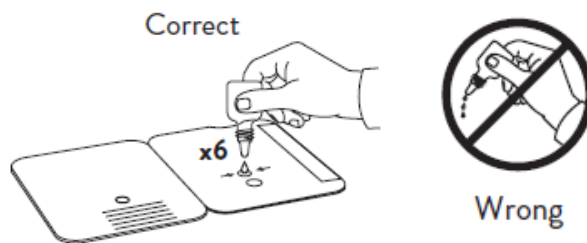
If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for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

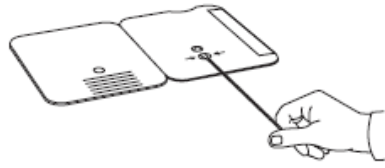
### C. TEST PROCEDURE: Procedure for Patient Specimens

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.

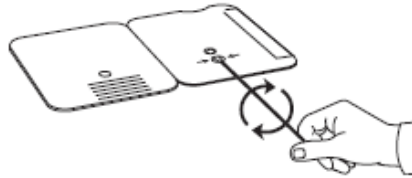
1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.



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

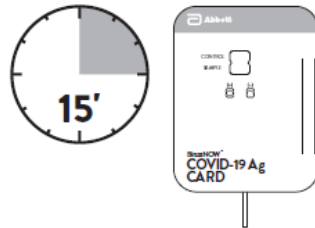


3. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.



*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. Shelters 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.

<b>Standing Orders Authorization</b>	
This policy and procedure shall remain in effect for all residents and staff of _____	_____ name of shelter
until rescinded or until _____	_____ date
Healthcare Provider’s signature _____	Signature date _____ Effective date _____

Print Healthcare Provider's Name:

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