# Massachusetts Department of Public Health

***SAMPLE STANDING ORDER***

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

These sample standing orders are current as of May 2022. They should be reviewed carefully against the most current recommendations from the Executive Office of Health and Human Services (EOHHS) 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 independent provider 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:

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

The EUA for the Abbott BinaxNOWCOVID-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.

# **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 signficiantly reduced when used outside of this temperature range.

# **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, and eye protection such as goggles or faceshield. Guidance for prioritizing and optimizing use of Personal Protective Equipment can be found [here](https://www.mass.gov/info-details/personal-protective-equipment-ppe-during-covid-19).

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

Inidviduals may be tested with the BinaxNOW COVID-19 Ag Card test’s in the following situations, as is in accordance with the [EOHHS Congregate Care Surveillance Testing Guidance](https://www.mass.gov/doc/eohhs-congregate-care-surveillance-testing-guidance/download).

1. *Asymptomatic individuals, testing in accordance with the Surveillance Testing Guidance:*
* Those who test positive should be treated as a positive COVID-19 case; these individuals should be managed accordingly.

Those who test negative should be informed of their test result. Negative tests in asymptomatic individuals do not need to be confirmed by a PCR test. However, individuals should be counseled that if they develop **any** symptoms of COVID-19 within several days, should be retested.

1. *Individuals with symptoms testing in accordance with the Surveillance Testing Guidance:* staff and residents who have symptoms of an illness consistent with COVID-19 may be tested using the BinaxNOW test:

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| Symptoms consistent with COVID-19 |
| * Fever (100.0° Fahrenheit or higher), chills, or shaking chills
* 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, when in combination with other symptoms
* Muscle aches or body aches
* Nausea, vomiting, or diarrhea
* Fatigue, when in combination with other symptoms
* Nasal congestion or runny nose (not due to other known causes, such as allergies) when in combination with other symptoms
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* Those who test positive should be treated as a positive COVID-19 case;
* Those who test negative should be informed of the test result. Those who test negative should be informed that the negative test is presumptive and the facility should follow up with the individual’s provider and order a repeat test for COVID-19[[1]](#footnote-2)
* Limited data on the ability of a negative BinaxNOW test to exclude COVID-19 in children 18 and under are available. Clinicians may choose to follow-up negative BinaxNOW tests in symptomatic children with a PCR.

*PCR test confirmation for patients and community members: Unless there are extenuating clinical circumstances (i.e. a resident has a negative antigen test but is symptomatic), a molecular or PCR test is not needed.* The result of a PCR test taken within 2 days of an antigen test will “override” the result of the antigen test in situations where the test results are different. Antigen positive individuals should not routinely try to get a PCR test in the hope of testing negative.

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

For tests administered for individuals who are legally unable to provide consent (e.g., minors), organizations must obtain the appropriate consent from the individual's guardian prior to administering the test.

# **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) during normal business hours before testing patient specimens.

# **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.*

1. **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.

1. **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.

1. **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.

 

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



1. 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.*

1. 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.*

# **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.

Organizations participating in this initiative must report positive test results to the Department of Public Health’s Bureau of Infectious Diseases and Laboratory Sciences (BIDLS) through the Project Beacon system.

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| **Standing Orders Authorization**This policy and procedure shall remain in effect for all residnets and staff of the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ name of organizationuntil rescinded or until \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. dateHealthcare Provider’s signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature date \_\_\_\_\_\_\_\_\_\_ Effective date\_\_\_\_\_\_\_\_\_\_Print Healthcare Provider’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#:~:text=A%20negative%20antigen%20test%20result,alternative%20to%20confirmatory%20NAAT%20testing. [↑](#footnote-ref-2)