



## Abbott BinaxNOW Ag Test Card Guidance October 29, 2020 Version

### Introduction:

The federal government is distributing rapid point-of-care (POC) antigen (Ag) tests, Abbott BinaxNOW COVID-19 Ag Card ("Ag Cards"), directly to states, including Maine, and directly to certain facilities. This guidance describes the conditions for receiving and using the State-distributed Ag Cards and is effective as of October 29, 2020. It may be updated as circumstances and science evolve.

### BinaxNOW COVID-19 Ag Card - Background:

- The BinaxNOW COVID-19 Ag Card is approved by the Food and Drug Administration (FDA) for use in the detection of COVID-19 in individuals who are suspected of COVID-19 because of the acute presentation of [symptoms consistent with COVID-19](#) and who are within the first seven days of onset of symptoms.
- Less is known about the efficacy of its use in asymptomatic individuals. Of note, the current FDA Emergency Use Authorization (EUA) for the BinaxNOW COVID-19 Ag Card was granted based on testing of 102 adults with acute COVID-19 symptoms; given that, there is insufficient evidence to date to recommend the routine use of the BinaxNOW COVID-19 Ag Card in individuals without acute symptoms. However, there are settings where antigen testing in asymptomatic individuals may help control the spread of COVID-19, specifically in an outbreak/exposure response when testing is conducted in a serial manner.
- The Maine Department of Health and Human Services (DHHS) is distributing 400,000 Ag Cards, as they are received, in periodic installments through December in two ways. First, it is working with Walgreens to make up to 300,000 Ag Cards accessible to residents across the State of Maine at its 65 drive-through sites. Second, it will distribute Ag Cards to facilities not directly receiving them from the Federal government that agree to the terms described in this guidance. Since demand may exceed the remaining 100,000 Ag Cards, DHHS will prioritize facilities that will use them for high-risk populations, in high-risk settings, or where access to COVID-19 testing is otherwise limited.

### Requirements to Use BinaxNOW for a Requesting Facility:

There are six core requirements that a facility will need to meet in order to receive BinaxNOW COVID-19 Ag Cards:

1. The facility is not currently receiving BinaxNOW Ag Cards from the federal government and will let DHHS know if it starts to receive them from the federal government.

2. The facility agrees to use the tests in accordance with Maine DHHS Guidance, which may be updated based on evolving science.
3. The facility has either a valid CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. A CLIA Certificate of Waiver requires an application (CLIA Waiver Application Form) and a \$180 fee. [More Information on Clinical Laboratory Improvement Amendments \(CLIA\)](#).
4. The facility must complete the BinaxNOW online training modules to ensure the test is used in a manner consistent with the manufacturer's instructions. That training is available at: [Abbott BinaxNOW Online Training](#).
5. The facility must immediately report all positive results to the Maine Center for Disease Control and Prevention (CDC). Furthermore, the facility must enroll in and use the electronic reporting portal, Research Data Capture (REDCap), once it is available to report all negative and positive test results.
6. The facility must be prepared to direct individuals to a testing site and/or identify a health care provider to order a confirmatory PCR test, when indicated.

### **Guidance for Using BinaxNOW Rapid COVID-19 Ag Card Testing:**

- Facilities can use the BinaxNOW COVID-19 Ag Card rapid test for individuals who exhibit [symptoms suggestive of COVID-19 infection](#).
  - A negative BinaxNOW test result is strongly suggestive that the individual does not have COVID-19. However, an individual in a high-risk setting, who has a known COVID-19 exposure, and/or who continues to have symptoms suggestive of COVID-19 should be further evaluated. A confirmatory PCR test should be considered.
  - A positive Ag Card test result indicates that the individual is a probable case. It is recommended that any positive be confirmed with a PCR test within 24 hours, but no longer than 48 hours after the initial positive.
    - The individual should be isolated at home and monitored by a medical provider in the community pending a confirmatory PCR test result.
- Facilities can use the BinaxNOW COVID-19 Ag Card for serial testing of asymptomatic close contacts of confirmed COVID-19 cases where the asymptomatic close contact works in a critical infrastructure setting (See Appendix A). At this time, the Maine CDC recommends that the BinaxNOW COVID-19 Ag Card could be used to conduct serial testing of asymptomatic individuals working in critical infrastructure settings who have been identified as a close contact of a confirmed COVID-19 case. Under this approach, asymptomatic close contacts of confirmed cases who work in certain critical infrastructure roles could, via serial BinaxNOW testing, potentially resume their core duties associated with their role. A decision to use BinaxNOW Ag Cards to conduct serial testing of these individuals must be made in partnership with and with advance approval of the Maine CDC.
  - A negative BinaxNOW Ag Card test result is suggestive that the individual does not have COVID-19. However, because these individuals by definition have a known COVID-19 exposure, those who have symptoms suggestive of

COVID-19 should be further evaluated, and a confirmatory PCR test should be considered.

- A positive BinaxNOW test result indicates that the individual is a probable case. It is recommended that any positive be confirmed with a PCR test within 24 hours, but testing should be done no more than 48 hours after the initial positive result.
  - The individual should be isolated at home and monitored by a medical provider in the community pending a confirmatory test result.

### **Supply and Distribution of BinaxNOW Ag Cards:**

Facilities can apply using this form. Given limited supply, the Department cannot fulfill all requests and will prioritize those facilities offering testing to high-risk populations, in high-risk settings, or who serve populations otherwise lacking access to testing. Facilities are encouraged to work with their respective associations to support logistics coordination and distribution.

### **Procedure for BinaxNOW Specimen Collection and Testing:**

- The BinaxNOW COVID-19 Ag Card can be used to test nasal swab samples directly using a dual nostril collection. Collection requires inserting the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. The individual collecting the sample uses gentle rotation, pushing the swab until resistance is met at the level of the turbinates (less than one inch into the nostril) and then rotates the swab 5 times or more against the nasal wall and then slowly removes from the nostril. Using the same swab, the individual repeats sample collection in the other nostril.
- To perform the test, following specimen collection from the patient, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes. [More information on BinaxNOW](#)

### **Storage and Stability:**

Each BinaxNOW Ag Test kit comes with 40 individually wrapped cardboard, book-shaped hinged test cards containing the test strip, as well as 40 collection swabs and one 10mL bottle of extraction reagent. Kits must be stored at 2-30°C. The test is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

## **Appendix A: Critical Infrastructure**

The Department of Homeland Security published a list of “Essential Critical Infrastructure Workforce” version 4.0 on August 18, 2020: [CISA Guidance on Critical Infrastructure](#). For purpose of serial testing of asymptomatic close contacts, Maine DHHS is starting with the first three categories of workers in the following sectors:

1. Healthcare
2. Law enforcement, public safety, and other first responders
3. Education

Please note that this list will continue to be updated once we have additional data on the BinaxNOW Ag Test Card, including its uses and efficacy, and as requests are approved