



## COVID-19 GUIDANCE

# Guide to Abbott BinaxNOW Rapid Point-of-Care Antigen COVID-19 Tests

### Background

The federal government is distributing 150 million Abbott BinaxNOW COVID-19 tests to states free of charge. The tests are intended to enable schools to reopen in whatever capacity is deemed safe, to support vulnerable communities, and to allow frontline workers to continue working safely. With allotments based on population size, Colorado will be receiving approximately 1.73 million tests via the U.S. Department of Health and Human Services (HHS) program over the next few months. Since Colorado's first allotment of tests at the end of September, the State has received over 200,000 BinaxNOW tests.

The Abbott BinaxNOW test is a rapid antigen point-of-care (POC) test that can be used to diagnose an active COVID-19 infection. The Abbott BinaxNOW test tests for the presence of SARS-CoV-2 proteins and can provide results within minutes of administering the test. The BinaxNOW test uses a card and nasal swab to determine the presence of SARS-CoV-2. This means that no additional tools, machines, or resources are needed to use this rapid antigen test. The tests are stable until the expiration date on the packaging of the kit and should be stored at 2-30°C.

In addition to antigen POC tests for diagnosing active infections, the Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) to use Real-Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) tests and POC molecular tests to identify active SARS-CoV-2 infections. Rapid antigen POC and rapid molecular POC tests are not as sensitive as RT-PCR tests, which are considered to be the only way to get a definitive COVID-19 diagnosis and can take a few days to receive results. Since the Abbott BinaxNOW tests are not as sensitive as PCR tests and may miss an active COVID-19 infection, a follow-up PCR test may be warranted to confirm a negative test result if the individual is presenting symptoms or has a known exposure to COVID-19. Community-living individuals who test positive using a rapid antigen or rapid molecular POC test should be treated as a true positive case. However, positive results from rapid antigen POC tests should be confirmed prior to any cohorting decisions in congregate living settings.

In addition to rapid antigen POC tests, rapid molecular POC tests and RT-PCR tests, the FDA has approved serology tests to determine if an individual has been infected with SARS-CoV-2 in the past. The serology tests, also referred to as antibody tests, cannot be used to determine if an individual has an active infection.

## General Considerations for Performing POC Testing

Given that antigen tests are less sensitive than RT-PCR tests, the Abbott BinaxNOW tests and other antigen tests are most effective when administered early in the infection when the individual's viral load is the highest (generally within five days of symptom onset). If an individual has known exposure to the virus but no symptoms, the Abbott BinaxNOW test should be used seven days after the last known exposure. The State of Colorado is prioritizing the Abbott BinaxNOW tests for use in schools to identify infected students, staff, and teachers as well as to assist in identifying infections among individuals experiencing homelessness, especially in congregate settings.

The following circumstances have been identified as optimal uses for the Abbott BinaxNOW tests in the State of Colorado:

1. To test **symptomatic students, staff, and teachers** in schools open for in-person learning. Given that these tests are rapid, results can be known in a matter of minutes and can initiate a quicker public health response. BinaxNOW can also be offered to individuals experiencing symptoms at home, as long as the administration of the test does not put the community at-risk of exposure. Those who test negative should seek a PCR test to confirm their negative result.
2. To test **asymptomatic individuals who may have been exposed to COVID-19** when PCR testing is not available. Schools can arrange for students, staff, and teachers who may have been exposed to COVID-19 to get a BinaxNOW test. Schools may also consider utilizing BinaxNOW as part of a surveillance testing strategy in coordination with their LPHA.
3. To test **asymptomatic individuals experiencing homelessness**, especially those in congregate settings, who have no known exposure to COVID-19, and are not identified as members of a community experiencing an outbreak. If PCR testing is unavailable to symptomatic individuals or if antigen testing is being used as a public health response to an outbreak, then the Abbott BinaxNOW can be used for these individuals.

The Abbott BinaxNOW and other rapid antigen and molecular POC tests should not be used to rule out active infections in either symptomatic individuals or individuals who have known exposure to COVID-19. A negative test result from a BinaxNOW test, or any other test, cannot be used to release a person from quarantine.

## Regulatory Requirements for Performing POC Testing: Clinical Laboratory Improvement Amendment (CLIA) Waiver

Entities that intend to administer diagnostic COVID-19 testing, including administering the BinaxNOW tests, must obtain a Clinical Laboratory Improvement Amendment (CLIA) Waiver prior to offering testing to any individuals. In order to obtain a CLIA waiver, entities should complete the CMS-116 (<https://tinyurl.com/m53tenf>). Facilities with multiple sites, such as a school district, can receive a multiple site exemption and file one CMS-116 form to cover all testing locations. The address of all testing locations must be included on the multiple site certificate.

## Designating Personnel to Perform POC Testing

The FDA's EUA allows for any individual who obtains training and can accurately interpret the results of the BinaxNOW to administer BinaxNOW tests. Abbott has provided online resources (<https://tinyurl.com/yyjdkbcc>) to train those who will be administering the BinaxNOW tests. The State requires that these individuals complete training and have demonstrated ability to accurately interpret results of the BinaxNOW test cards prior to administering the test to patients. This includes, at minimum, one positive control and one negative control test swab.

## Obtaining an Order for a POC Test

A healthcare provider must issue an order for a POC test. CDPHE is revising our standing order for COVID testing to include point-of care tests (such as BinaxNOW).

## Training and Personal Protective Equipment

Under CLIA requirements, those who administer POC tests must adhere to the Center for Disease Control and Prevention's (CDC) guidance on using personal protective equipment (PPE). This includes utilizing N95 equivalent or higher-level respirator (or facemask if respirators are not available), facemasks, gloves, gowns, eye protection (goggles or disposable face shields that cover the front and sides of the face), and physical barriers (e.g., plexiglass). The CDC's training for those who will be administering COVID-19 tests can be found at <https://www.cdc.gov/labtraining/training-courses/ready-set-test.html>.

## Ordering BinaxNOW Tests and Quality Control

Entities that obtain CLIA waivers and meet any of the three criteria for testing listed above can request BinaxNOW tests from the State of Colorado using the order form found at <https://tinyurl.com/y2ucznw3>.

Upon receiving a shipment of BinaxNOW tests from the state, the receiving entity must perform and document quality control measures to ensure the integrity of the shipment. Quality control for the BinaxNOW tests consists of running one positive control and one negative control test swab. There is no requirement to report the quality control tests, only patient results. Facilities should document their quality control test for each shipment and lot number on site in preparation for potential future CLIA audit inspection.

## Disposal Requirements

All testing sites are required to establish biohazard waste streams and have protocol in place to ensure proper disposal of tests and PPE. To avoid cross contamination of tests and potential false test results, sites must decontaminate testing surfaces and change gloves between tests.

## Considerations for Performing COVID-19 POC Testing and Interpreting Results

Multiple factors should be considered when deciding to use a POC COVID-19 test including symptoms, possible exposure, outbreak response, and test availability.

For **symptomatic individuals**, rapid antigen tests like the Abbott BinaxNOW should be used as soon as symptoms begin. The maximum allowable time from symptom onset to specimen collection for rapid antigen tests is between five and seven days. For the Abbott BinaxNOW it is five days, but earlier collection is preferable. These tests are intended to quickly identify individuals with active SARS-CoV-2 infections to initiate isolation and contact those who may have been exposed to the individual to quarantine. A positive test result from a symptomatic individual using a rapid POC test is reported and investigated as a probable case and the individual will need to isolate for ten days. Contacts of the individual will need to quarantine for 14 days from their last contact with the individual who tested positive. A negative result from a symptomatic individual should be followed up with a PCR test to confirm a negative result, and the individual should quarantine while awaiting results from the confirmatory PCR test.

For individuals living in congregate settings, positive results should be confirmed by a PCR test prior to any cohorting decisions. This will avoid placing an uninfected individual with a false-positive Abbott BinaxNOW test in a cohort with individuals with COVID-19.

For **asymptomatic individuals**, if PCR testing is unavailable, rapid POC tests can be used to identify active infections in those who may have been exposed to COVID-19. Asymptomatic individuals who test positive should immediately isolate for ten days, and those who test negative should quarantine themselves for 14 days from their last contact with a known COVID-19 case.

**Surveillance or serial testing** of individuals experiencing homelessness using rapid POC testing is appropriate to identify individuals who may have active SARS-CoV-2 infections in congregate settings. Those who test positive should immediately isolate for ten days. Those who are contacts of a case or experiencing symptoms should follow the guidelines listed above.

## Guidance for Interpreting Viral Test Results for SARS-CoV-2

Test Modality	Symptomatic		Asymptomatic - Known exposure		Asymptomatic - No known exposure	
	Positive	Negative	Positive	Negative	Positive	Negative
RT-PCR	Positive - Isolation	Negative	Positive - Isolation	Negative - Quarantine	Positive - Isolation	Negative
POC - Molecular	Positive - Isolation	Negative	Positive - Isolation	Negative - Quarantine	Positive - Isolation	Negative
POC - Antigen	Positive* - Isolation	Follow up with RT-PCR	Positive* - Isolation	Negative - Quarantine	Positive* - Isolation	Negative

\*Confirm positive antigen test results with PCR before making cohorting decisions in congregate care settings.

### **Positive**

- Your test result indicates that the virus which causes COVID-19 was detected, and that you have a current COVID-19 infection.
- You should isolate for 10 days, starting either on the day symptoms started or the day this test was collected, whichever is earlier.
- Your close contacts, including household contacts and those you interacted within and outside of school, should quarantine.
- Instructions for isolation and quarantine are available here: <https://covid19.colorado.gov/are-you-sick/isolation-and-quarantine>

### **Negative**

- Your test result indicates that the virus which causes COVID-19 was not detected.
- If you have symptoms of COVID-19, you should seek a confirmatory PCR test from a healthcare provider, and isolate until that confirmatory test result is available. Your

close contacts, including household contacts and those you interacted within and outside of school, should continue to quarantine.

- If you have recently been exposed to someone with COVID-19, you should continue to quarantine for the full quarantine period (14 days from last exposure). You should not shorten your quarantine period based on the results of this test.
- All individuals should continue to self-monitor for new symptoms of COVID-19, and obtain repeat testing if symptoms develop. A list of symptoms are available here: <https://covid19.colorado.gov/covid19-symptoms>

### ***Inconclusive***

- Your test result was inconclusive.
- If you have symptoms of COVID-19, you should seek a PCR test from a healthcare provider, and isolate until that test result is available. Your close contacts, including household contacts and those you interacted within and outside of school, should continue to quarantine.
- If you have recently been exposed to someone with COVID-19, you should continue to quarantine for the full quarantine period (14 days from last exposure).

All individuals should continue to self-monitor for new symptoms of COVID-19, and obtain repeat testing if symptoms develop. A list of symptoms are available here:

<https://covid19.colorado.gov/covid19-symptoms>

## **How to use the Abbott BinaxNOW**

The Abbott BinaxNOW tests come in boxes of 40 test kits. A kit is an Abbott BinaxNOW test card in a sealed package. Each BinaxNOW shipment includes the test kits, instructions on how to use the tests and to report results, a data collection sheet, and labels. Each box of Abbott BinaxNOW tests come with two identical labels for each test kit, for a total of 80 labels per pack. These labels include a unique identification number and website where data is to be reported.

### ***Procedure for Reporting Data to the Colorado Department of Public Health and Environment (CDPHE)***

1. From the box of test kits, remove one sealed test kit, open the kit, remove the Abbott BinaxNOW test card, and affix one of the labels to the card.
2. Affix the matching label to an “Abbott BinaxNOW COVID-19 Test Information” data collection form.
  - a. The English form can be found at <https://tinyurl.com/y5g9wy3m>
  - b. The Spanish form can be found at <https://tinyurl.com/y4zstfus>
3. Give the Abbott BinaxNOW test card and data collection sheet to the patient and ask them to record their information.
4. Collect the data collection form and help the patient perform the test.

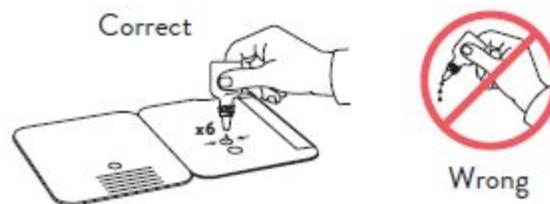
5. Wait 5 - 15 minutes for test results.
6. Disclose the results to only the patient. We recommend doing this in a private setting, if possible, in order to respect the person's privacy.
  - a. Follow the "Guidance for Interpreting Viral Test Results for SARS-CoV-2" section, above, with instructions on isolation/quarantine/contacts based on the result.
7. Record test results on the corresponding data collection sheet.
8. Report the information on each data collection sheet to CDPHE at <https://covidbinax.colorado.gov>. This is required per state statute and public health order.
9. Follow the "Disposal Requirements" instructions, above, and throw the test away as biohazard waste.
10. Schools may use the "Abbott BinaxNOW COVID-19 Ag Card Test Result Letter for Schools" form located within the Appendix of this toolkit, below, to communicate results to students, staff, and teachers.

### ***Procedure for Patient Specimens***

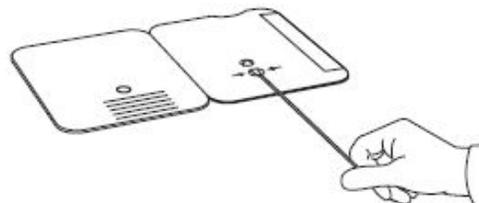
Test operators should use the following procedural guidance for performing and interpreting test card results from the Abbott BinaxNOW Emergency Use Authorization (EUA).

**Once the labels are affixed to the test card and data collection sheet, 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.**

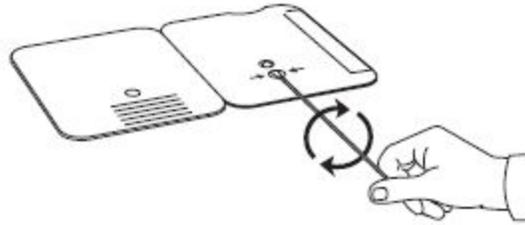
1. Hold extraction reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



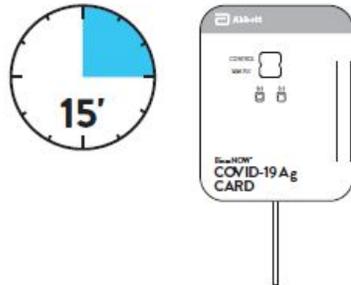
2. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.



3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove the swab.  
Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.



4. Peel off the adhesive liner from the right edge of the test card. Close and securely seal the card. Read the 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.

### ***Interpreting Abbott BinaxNOW Test Card***

- **Negative:** A negative specimen will give a single pink/purple colored control line in the top half of the window, indicating a negative result. This control line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

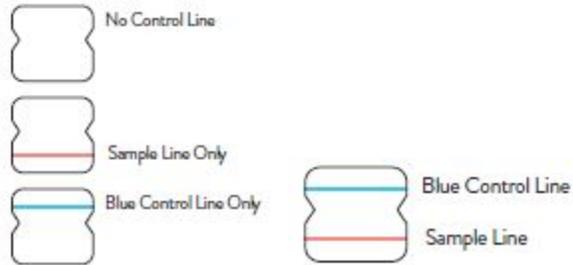


- **Positive:** A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint sample line. Any visible pink/purple colored line is positive.



- **Inconclusive:** If no lines are seen, or if just the sample line is seen, or if the blue control line remains blue, the assay is invalid. Invalid tests should be repeated.

**Invalid Result**



# Abbott BinaxNOW COVID-19 Ag Card Test Result Letter for Schools

Note: results should be conveyed to parents/guardians, with the exception of emancipated minors and individuals over age 18. Deliver results in a way that protects confidentiality and privacy of individuals receiving both negative and positive results.

You have recently been tested for SARS-CoV-2, the virus which causes COVID-19, using the Abbot BinaxNOW COVID-19 Ag Card. The results of your test are below, along with instructions about what actions you should take.

Tested individual: \_\_\_\_\_ DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_

Individual performing test: \_\_\_\_\_

Test performed on: \_\_\_\_/\_\_\_\_/\_\_\_\_ at \_\_\_\_:\_\_\_\_ am/pm

Testing location: \_\_\_\_\_

## TEST RESULT

### **[ ] POSITIVE**

Your test result indicates that the virus which causes COVID-19 was detected in this sample, and that you have a current COVID-19 infection.

- You should isolate for 10 days, starting either on the day symptoms started or the day this test was collected, whichever is earlier.
- Your close contacts, including household contacts and those you interacted within and outside of school, should quarantine themselves.

Instructions for isolation and quarantine are available here:

<https://covid19.colorado.gov/are-you-sick/isolation-and-quarantine>

### **[ ] NEGATIVE**

Your test result indicates that the virus which causes COVID-19 was not detected in this sample.

- If you have symptoms of COVID-19, you should seek a confirmatory PCR test from a healthcare provider and isolate until that confirmatory test result is available. Your close contacts, including household contacts and those you interacted within and outside of school, should continue to quarantine themselves.
- If you have recently been exposed to someone with COVID-19, you should continue to quarantine yourself for the full quarantine period (14 days from last exposure). You should not shorten your quarantine period based on the results of this test as you may still develop COVID-19.

All individuals should continue to self-monitor for new symptoms of COVID-19 and should obtain repeat testing if symptoms develop. A list of symptoms are available here: <https://covid19.colorado.gov/covid19-symptoms>

### **[ ] INCONCLUSIVE**

Your test result was inconclusive.

- If you have symptoms of COVID-19, you should seek a PCR test from a healthcare provider and isolate until that test result is available. Your close contacts, including household contacts and those you interacted within and outside of school, should continue to quarantine themselves.
- If you have recently been exposed to someone with COVID-19, you should continue to quarantine yourself for the full quarantine period (14 days from last exposure). You should not shorten your quarantine period based on the results of this test as you may still develop COVID-19.

All individuals should continue to self-monitor for new symptoms of COVID-19 and obtain repeat testing if symptoms develop. A list of symptoms are available here: <https://covid19.colorado.gov/covid19-symptoms>

## **Reporting**

All test results will be securely communicated to public health authorities by the person or institution which performed your test, as is required by law. You do not need to report your test result.