BinaxNOW COVID-19 Tests - Proper Use and Required Reporting

Recommendations For Use

The following recommendations have been established to help guide the use of Abbott BinaxNOW COVID-19 antigen tests provided by the SDDOH:

1. HHS has granted authority for Abbott BinaxNOW use in both traditional and non-traditional testing environments if testing is performed under a CLIA Certificate of Waiver. Facilities or institutions may apply to the Centers for Medicare and Medicaid Services (CMS) for their own waiver, or they can be covered under an existing waiver at the discretion of the holder of the waiver. For CLIA needs please contact Denise Broadbent at (605)394-6173 or denise.broadbent@state.sd.us.

2. Only individuals with symptoms of COVID-19 should be tested using the Abbott BinaxNOW test. Currently, there is no data from the manufacturer, federal government, or in scientific literature to support BinaxNOW testing of asymptomatic individuals. Once performance characteristics of the BinaxNOW antigen test is established for asymptomatic testing, the test may be officially emergency use authorized by the FDA to be performed for asymptomatic individuals.

3. All Abbott BinaxNOW test results, both negative and positive, must be reported to the SDDOH within 24 hours to ensure accurate daily reporting of COVID-19 testing in South Dakota.

*Recommendation 2 (above) does not apply to long-term care facilities that have received Abbott BinaxNOW tests from federal allocation and must meet testing requirements issued by CMS based on county-level COVID-positivity rate.

Appropriate Use

The BinaxNOW COVID Ag Card is a point-of-care[1], rapid antigen test[2] that provides results in as little as 15 minutes. This test is designed for use in patients during the acute phase of infection, or during the first seven days of symptom onset. Use of these tests should be reserved for instances where a positive result would direct immediate decisions or infection control measures. For example, a positive result should trigger isolation of the patient and corresponding COVID-19 mitigation procedures.

[1] Point-of-care testing (POCT) is a medical diagnostic testing approach conducted at the time and in the place of patient care.

[2] Rapid antigen tests are commonly used in the diagnosis of respiratory pathogens, including influenza viruses and respiratory syncytial virus (RSV). The FDA has granted emergency use authorization (EUA) for antigen tests that can identify SARS-CoV-2. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html.

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The BinaxNOW should be used on individuals that present with symptoms of COVID-19. Individuals with COVID-19 typically report a variety of symptoms, which range from mild to severe. Symptoms may appear 2-14 days after exposure to the virus and may include:

- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

Required Results Reporting

All Abbott BinaxNOW COVID-19 results, both positive and negative, must be reported ***DAILY*** to the SD DOH using the South Dakota Confidential Disease Reporting website at https://apps.sd.gov/ph93morbidity/secure/index.aspx.

Future BinaxNOW Availability

Federal allocation of Abbott BinaxNOW COVID-19 antigen tests to SDDOH will end in December 2020. Facilities that depend on BinaxNOW resources should establish an account with Abbott or a vendor to purchase these test supplies when they become available on the open-market in early 2021. Facilities or institutions that need to establish an account with Abbott or purchase BinaxNOW COVID-19 antigen tests should contact the following:

Amy Kilburg
Account Executive
Abbott Rapid Diagnostics
CO, NE, SD
amy.kilburg@abbott.com

Specimen Collection and Handling

Specimens should be tested immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling may produce invalid results. Refer to the Centers for Disease Control and Prevention (CDC) Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) at https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.

The swab provided in the kit is to be used for nasal specimen/sample collection. To collect a nasal sample, swab must be carefully inserted into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, rotate the swab just inside – less than 1 inch – the nostril. Nasal swab must be rotated five (5) times or more against the nasal wall then slowly remove from the nostril. Using the same swab, sample collection must be repeated in the

other nostril. Staff performing specimen collection will need to use personal protective equipment (PPE).

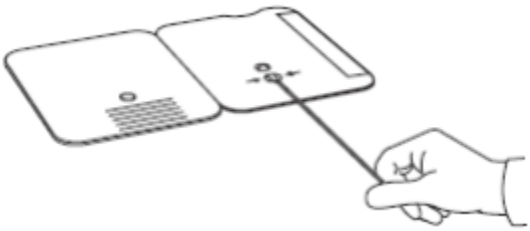
Test Procedure for Patient Specimens

The test card must be flat when performing the testing. Do not perform testing with the test card in any other position.

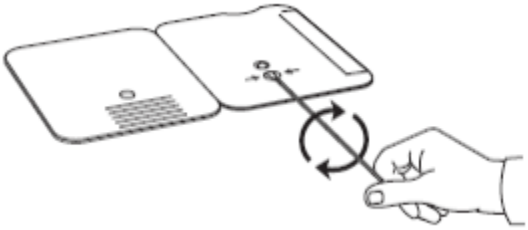
STEP 1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.

Within three minutes of adding extraction agent drop in Step 1, the swab must be inserted into the test card as shown in Step 2 below.

STEP 2. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE. **This step must be completed within three minutes of adding the extraction reagent drop completing Step 1**

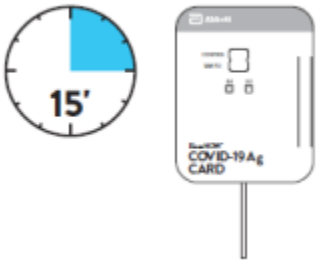


STEP 3. Rotate (twirl) swab shaft three (3) times CLOCKWISE (to the right). Do not remove swab. Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.



STEP 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.

Test Procedure for Controls

The BinaxNOW COVID-19 Ag Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run.

Procedural Controls:

1. The pink-to-purple line at the "Control" position is an internal procedural control. If the test flows and the reagents work, this line will always appear.
2. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

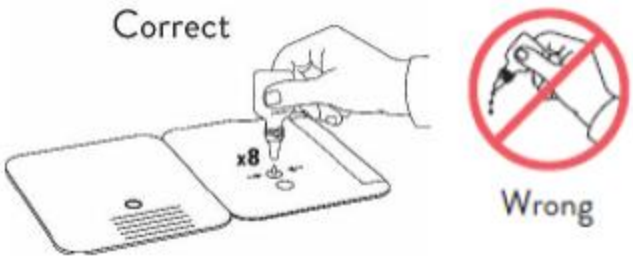
External Positive and Negative Controls:

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 contains a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay.[1] Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your laboratory's Standard Quality Control Procedures. If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

Open the test card just prior to use, lay it flat, and perform assay as follows.

1. Hold Extraction Reagent bottle vertically Hovering 1/2 inch above the TOP HOLE, slowly add 8 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.

[1] Assay is an analysis conducted to determine the presence and amount of a substance.



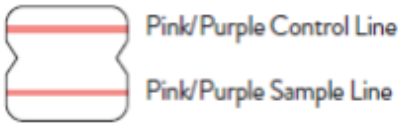
2. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.

Result Interpretation:

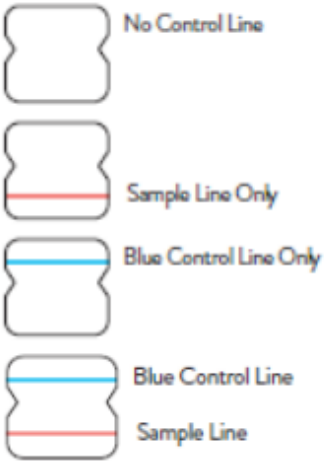
In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position. In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working. *If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.*

- **Negative Result:** 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 Result:** 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 sample line designates a positive result.



- **Invalid:** If no control and no sample lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.



The full FDA guidance and instruction can be found at https://www.fda.gov/media/141570/download. Additional information, including the Abbott BinaxNOW Package Insert and Procedure Card, can be found at the following Abbott website at https://www.globalpointofcare.abbott/en/product-details/navica-binaxnow-covid-19-us.html. Patient and healthcare provider fact sheets are available at:

- Abbott BinaxNOW Patient Fact Sheet – https://www.fda.gov/media/141569/download

Abbott BinaxNOW Healthcare Provider Fact Sheet – https://www.fda.gov/media/141568/download