COVID-19 TESTING GUIDANCE IN SCHOOL SETTINGS
ABBOTT BINAXNOW – POINT OF CARE TEST

Background:

In schools across Nevada, COVID-19 mitigation strategies have been implemented to reduce and prevent the spread of COVID-19. In addition to the current prevention measures already in place, testing to screen and diagnose COVID-19 should be included into school's comprehensive mitigation plans. In the coming weeks, the federal government is expected to provide Nevada with the Abbott BinaxNOW COVID Antigen (Ag) Card testing kits. These test kits will be distributed to school districts through a coordinated effort between the Nevada Division of Emergency Management (DEM), the Nevada Department of Health and Human Services (DHHS), and the Nevada Department of Education (NDE).

The BinaxNOW COVID Ag Card is a point of care, rapid antigen test that provides results in as little as 15 minutes. The BinaxNOW is intended for the qualitative detection of antigen from COVID-19 in direct nasal swabs from individuals suspected of COVID-19 by their health care provider within the first seven (7) days of symptom onset. Use of these tests should be reserved for instances where a positive result would direct immediate clinical decisions or infection control measures. For example, in a school setting, a positive result should trigger isolation of the patient and corresponding COVID-19 mitigation procedures. Both positive and negative results in this scenario should be considered presumptive. In order to confirm a positive BinaxNOW antigen test result, an additional specimen should be collected from the patient and sent to a laboratory for molecular testing. A negative BinaxNOW antigen test result should also be confirmed in the same manner, if a patient has clinical signs and symptoms of COVID-19 and/or has a known exposure to COVID-19.

Abbott BinaxNOW Ag Card Usage

The BinaxNOW should be used on students and staff that present with symptoms of COVID-19 while at school and within the first seven (7) days of symptom onset. Individuals with COVID-19 have reported 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

The BinaxNOW antigen test should be administered by a health care provider, who usually is the school nurse in the school setting. Testing should only occur after appropriate consent is received. Adult staff members must provide consent prior to a test being administered on them. Students must have consent provided by a parent or legal guardian prior to the test being administered.

Prior to conducting testing, each school district is required to have a State of Nevada laboratory license and a Federal CLIA certificate. The process for fulling this requirement can be found here: http://dpbh.nv.gov/Reg/MedicalLabs/dta/Forms/Medical_Laboratories_-_Forms/.

Application of Results in the School Setting

The BinaxNOW Ag Card can be used as a screening tool within the school setting. It is important that both positive and negative results be followed by a confirmatory molecular test, such as a Reverse-Transcriptase Polymerase Chain Reaction test (RT-PCR) as soon as possible, but no later than two days from the antigen result. Ideally, it would be best practice for the school nurse to collect the RT-PCR sample at the time the antigen test is performed. The samples should be sent to either Nevada State Public Health Laboratory or Southern Nevada Public Health Laboratory for processing.

Immediate application of school's COVID-19 mitigation plans should follow positive BinaxNow antigen test results. This includes immediate isolation of all cases and quarantine of all identified contacts.

A negative result for a symptomatic staff and/or student does not negate the need to follow the school's COVID-19 illness management guidance that was created in partnership with the Local Health Authority.

COVID-19 testing in schools is meant to occur in concert with established mitigation procedures and not to replace any prevention measures.

Reporting of Results

All COVID-19 laboratory results must be reported to the DHHS, which include both positive and negative results. **Daily** reporting of all results using the established format from the DHHS must occur with no exceptions. The report must be sent daily via secure email to the following address COVIDepi@health.nv.gov.

Storage and Stability

Test kits must be stored at 2-30°C. The BinaxNOW COVID-19 Ag Card Kit is stable until the expiration date marked on the outer packaging and containers. All test components must be prepared at room temperature before use.

Specimen Collection and Handling

Specimens should be tested immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous 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) 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, the swab must be pushed until resistance is met at the level of the nasal turbinates (less than one inch into 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.

Specimen Transport and Storage

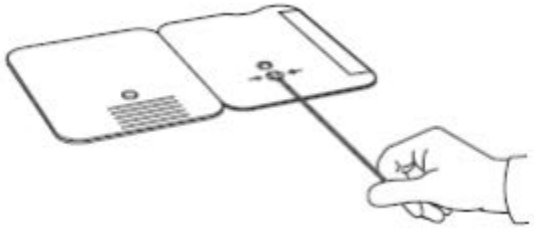
It is important not to return the nasal swab to the original paper packaging. For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended that 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 one (1) hour prior to testing. It is important to ensure the swab fits securely within the tube and the cap is tightly closed. If a delay longer than one hour occurs, the sample must be disposed of and a new sample must be collected for testing.

Test Procedure for Patient Specimens

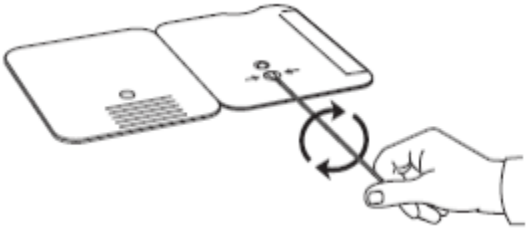
To perform the assay test the card must be opened and laid flat just prior to use. The test card must be flat when performing the testing. Do not perform testing with the test card in any other position.

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.

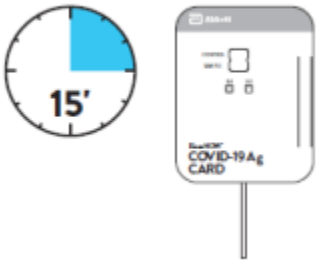
STEP 2. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.



STEP 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.



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:

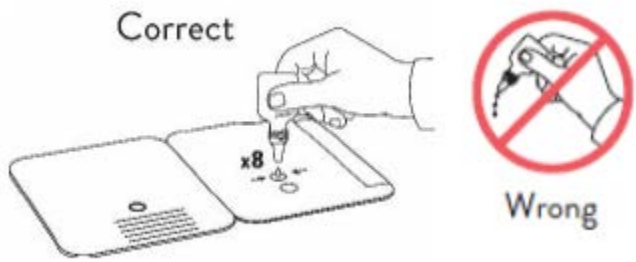
1. The pink-to-purple line at the “Control” position is an internal procedural control. If the test flows and the reagents work, this line will always appear.
2. The clearing of background color from the result window is a negative background control. The background color in the window should be light 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. 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 lab’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.

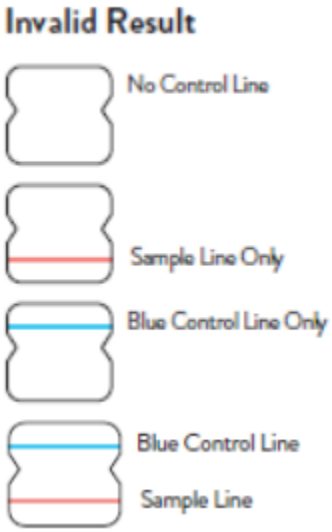
1. Hold Extraction Reagent bottle vertically Hovering 1/2 inch above the TOP HOLE, slowly add 8 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.



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.

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.	
Invalid If no 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 here: https://www.fda.gov/media/141570/download.