



Conducting COVID-19 Testing in K-12 Schools using the Abbott BinaxNOW COVID-19 Point of Care Test

Advancements in testing for coronavirus disease 2019 (COVID-19) have resulted in a high performing test designed for use in multiple settings including schools. The federal government will soon be making the Abbott BinaxNOW COVID Antigen (Ag) Card available for distribution to South Dakota public and non-public schools. Through a coordinated effort between the South Dakota Departments of Health (SD DOH) and Education (SD DOE), a SD BinaxNOW testing program will begin the week of October 12, 2020. This document provides information on requirements of participation in the program and information regarding the use of the Abbott BinaxNOW COVID Antigen (Ag) Card testing kits.

Appropriate Use

The BinaxNOW COVID Ag Card is a point-of-care¹, rapid antigen test² 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, in a school setting, a positive result should trigger isolation of the patient and corresponding COVID-19 mitigation procedures.

The BinaxNOW should be used on students and staff that present with symptoms of COVID-19 while at school. 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

Testing should only occur after appropriate consent is received from the symptomatic individual, or if a minor, the parent or guardian (see **Appendix A**). COVID-19 testing in schools is meant to occur in

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>.

concert with established mitigation procedures, are not to replace any prevention measures, and results do not support modification of isolation or quarantine guidelines³. Individuals tested should also be provided a copy of the *Handout for Individuals Participating in Rapid COVID-19 Testing (Appendix B)*.

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://dohsd.sjc1.qualtrics.com/jfe/form/SV_3pD7PtahdDcUyPP.

Specimen Collection and Handling

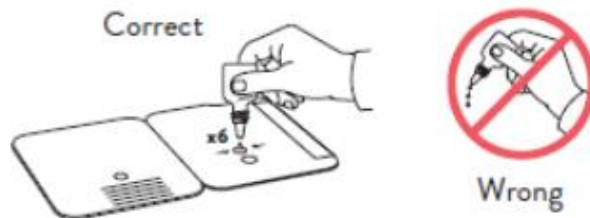
Specimens should be tested immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling may produce invalid results. Refer to the Centers for Disease Control and Prevention (CDC) *Interim Guidelines for Collecting, Handling, and Testing Clinical 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). Schools can request PPE from the SD DOH using the form provided in **Appendix C**. **Appendix C** also contains information on PPE that can be requested from the SD DOH.

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.

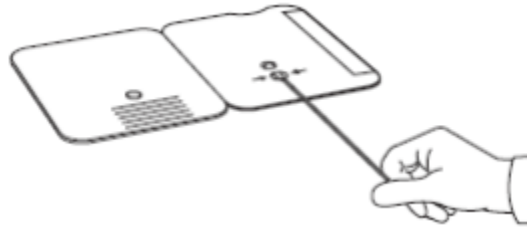
STEP 1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.



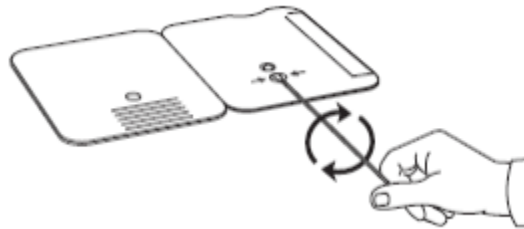
Within three minutes of adding extraction agent drop in Step 1, the swab must be inserted into the test card as shown in Step 2 below.

³ CDC does not recommend using antigen tests to make decisions about discontinuing isolation.

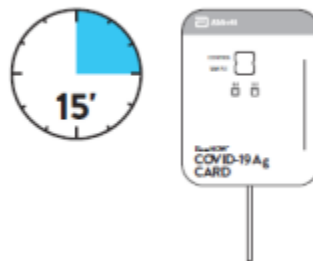
STEP 2. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.



STEP 3. Rotate (twirl) swab shaft 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:

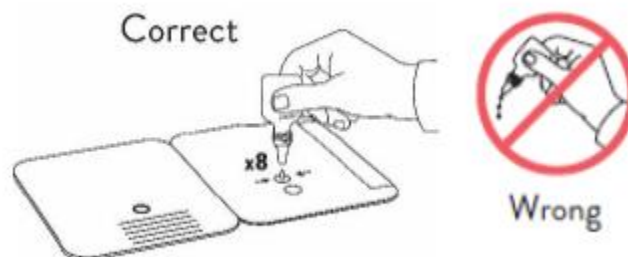
1. The pink-to-purple line at the “Control” position is an internal procedural control. If the test flows and the reagents work, this line will always appear.
2. The clearing of background color from the result window is a negative background control. The background color in the window should be light 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.⁴ 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.



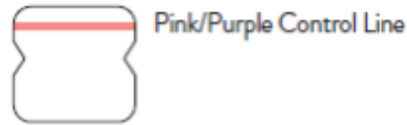
2. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.

Result Interpretation:

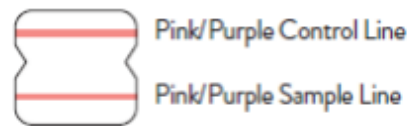
In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position. In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working. *If the blue line is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

⁴ Assay is an analysis conducted to determine the presence and amount of a substance.

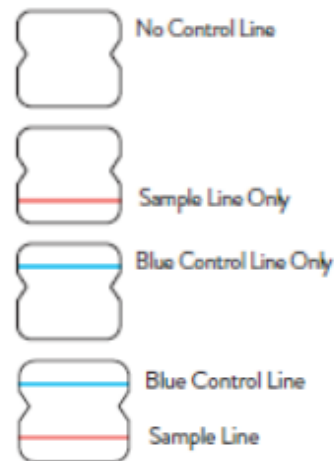
- **Negative Result:** A negative specimen will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.



- **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>

APPENDIX A – RELEASE OF INFORMATION AND INFORMED CONSENT



**SOUTH DAKOTA DEPARTMENT OF HEALTH
RELEASE OF INFORMATION AND INFORMED CONSENT TO COVID-19 TESTING**

Name: _____ DOB: _____

Address: _____ Phone Number: _____

City: _____ State: _____ Zip Code: _____

Please carefully read and sign the following Informed Consent:

1. I authorize this COVID-19 testing unit to conduct specimen collection and laboratory testing for COVID-19 through nasal swab, as ordered by an authorized medical provider or public health official.
2. I authorize my test results to be disclosed to the South Dakota Department of Health and School District Contact.
3. I acknowledge that a positive test result is an indication that I must self-isolate and/or wear a mask or face covering as directed to avoid infecting others.
4. I understand the South Dakota Department of Health is not acting as my medical provider, this testing does not replace treatment by my medical provider, and I assume complete and full responsibility to take appropriate action with regard to my test results. I agree I will seek medical advice, care and treatment from my medical provider if I have questions or concerns, or if my condition worsens.
5. I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result.
6. I, the undersigned, have been informed about the test purpose, procedures, possible benefits and risks. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask additional questions at any time. I voluntarily agree to this testing for COVID-19.

Signature: _____ Date: _____

Person to be tested (If minor, parent or guardian signature)

This form must be signed prior to specimen collection



Handout for Individuals Participating in Rapid COVID-19 Testing

The BinaxNOW COVID Ag Card is a point-of-care, rapid antigen test 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.

GETTING YOUR TEST RESULTS

Individuals will receive test results within 15 minutes. Individuals testing positive for COVID-19 will be called by a SD DOH Disease Investigation staff member and provided guidance on isolation requirements.

If you test positive

- ❖ **If you have symptoms**, follow the instructions under the “Separate yourself from others” section below until all three of these things are true – fever-free for 24 hours without the use of medication AND improvement in respiratory symptoms AND at least 10 days have passed since symptoms began.
 - Drink plenty of fluids and eat when you can.
 - You may take medicine for pain or fever if you need to.
 - Rest as much as you can.
- ❖ **If you do not have symptoms**, stay home for 10 days after your test date. If you develop symptoms during those 10 days, stay home until all three of these things are true – fever-free for 24 hours without the use of medication AND improvement in respiratory symptoms AND at least 10 days have passed since symptoms began.
- ❖ Staff with the South Dakota Department of Health will call to follow up with you and give you more information about what to do and how long you should stay home.

If you test negative

- ❖ A negative COVID-19 test at one point in time does not mean you will stay negative. You could become ill with COVID-19 and/or test positive at any time.
- ❖ If you develop symptoms of COVID-19, talk to your doctor or other health care provider about getting tested again.
- ❖ Remember to wash your hands often, avoid touching your face, stay 6 feet from people you do not live with, and wear a cloth facemask when you go out.

WHAT TO DO IF YOU DEVELOP SYMPTOMS?

Separate yourself from others

- ❖ **Stay home.** Do not go to work, school, or any other place outside the home.
- ❖ **Stay away from other people in your home.** As much as possible, stay in a separate room and use a separate bathroom, if available.
- ❖ **Wear a facemask** if you need to be around other people, and cover your mouth and nose with a tissue when you cough or sneeze.
- ❖ **Avoid sharing personal household items.** Do not share food, dishes, drinking glasses, eating utensils, towels, or bedding with other people in your home. After using these items, wash them with soap and water. Clean all frequently touched surfaces in your home daily, including doorknobs, light switches, and faucets.
- ❖ **Wash your hands** often with soap and water for at least 20 seconds, or use an alcohol-based hand sanitizer containing 60% to 95% alcohol. Avoid touching your face with unwashed hands.

Monitor your symptoms

Most people have mild symptoms that get better in a week or two. Some people do not have any symptoms. People age 65 and older or people who have other underlying medical conditions may get very sick from COVID-19. If your symptoms get worse or you need medical care:

- ❖ **Contact your medical provider or local clinic.** Call ahead before going in.
- ❖ **Do not use public transportation** if you need to go to a clinic or hospital.

If you need emergency medical attention, call 911 and let them know that you have been tested for COVID-19 and your results are pending.

MORE INFORMATION

Learn more about COVID-19 at covid.sd.gov.

APPENDIX C – PPE Supply Requests

South Dakota Department of Health

PPE Supply Request Form

COVID-19 Response Activities Only



Name: _____

Facility/Agency: _____

Shipping Address: _____

Email Address: _____

Direct Phone Number to the person requesting? _____

Are you following CDC Guidance for PPE? Yes No

Items requested for Students/Staff:

Quantity	Item

Items requested for School-Based Nurse or other Medical Provider working in District:

Quantity	Item

Have you contacted multiple Vendors who were unable to fill/ partial fill/ cancel/ deny order supplies and/equipment? Yes No

Anticipated date of Critical Need? _____ / _____ / _____

Email to: COVIDResourceRequests@state.sd.us
If you have questions please call: 605.773.3048



PPE Supply Request Form.
Revised Date: March 17, 2020
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COVID-19 PPE for K-12 School Districts

(as of 31 Jul 2020)

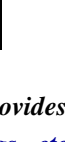


Please Note:

- Submit one order per school district rather than a request from each school in the district.
- Please complete the form, including a contact name and phone number of the individual making the request.
- Cloth masks and disposable face masks are *not intended to supply the entire student population and staff*, but rather to ensure the district has a supply on hand for students and staff when masks are forgotten, lost, soiled, broken, etc.





N-95 Respirators

Brand/Model Description	Picture
3M 1860	
3M 1860-S (small)	
Kimberly Clark, 46727-17 "Ducky" style	
3M 9501 Ear-loop design	
3M 1870	
3M 8000	





KN-90/95 KN-95 provides 95% protection for .3 micron particles.... KN90 provides 90% protection. KN-90s - for "non-medical" environments (infrastructure, businesses, schools, public gatherings, etc.)

Brand/Model Description	Picture
3M 9002/9001 (KN-90) Packs of 50	
3M 9502 (KN-95) Boxes of 50 Difference between 9502 & 9502+ ... is box vs bag of 50.	
3M 9502+ (KN-95) Packs of 50	



Surgical Masks

Brand/Model Description	Picture
KC-4712727 Surgical Masks Child size, Foldable	
Hanes - Cloth Face-Masks <i>ear loop design</i>	
FEMA – Miniso <i>ear loop design</i>	
AramSCO <i>ear loop design</i>	
V-Shine <i>ear loop design</i>	
Kimberly Clark – 47117-17	






Face-shields

Brand/Model Description	Picture
Medline NONF S300 Shield, Face, Full, Foam Top, Elastic	
Apple LTL	
Face Shield Shield, Face, Full, Foam Top, Elastic, FEMA	
Hardwire – Shield, Face, Full, Foam Top, Elastic	

Gloves

Brand/Model Description	Picture	Size
Vinyl Examination Gloves un-sterile with textured surface, seamless and without powder		Small
		Med
		Lg
		X-Lg
Nitrile Gloves un-sterile non-powdered 4 mil thick with rolled cuff		Small
		Med
		Lg
		X-Lg


Gowns Exam/Isolation

Brand/Model Description	Picture	Size
Reusable Gowns- smoothie green		M/Lg
Reusable Gowns- yellow		
Reusable Polyester Gowns		L/XL
Disposable Polyester Gowns		L/XL
		2XL/3XL
Disposable Gowns- blue		M/Lg

Goggles

Brand/Model Description	Picture
Safety Goggles	

Other PPE to Augment Suits

Brand/Model Description	Picture
Shoe/boot covers	

Non-Contact Infrared Thermometers

Brand/Model Description	Picture
Infrared Thermometers	

Hand Sanitizer

Brand/Model Description	Picture
Hand Sanitizer <i>Gallons or 8 oz. bottles</i>	Picture not available