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Standard Operating Procedure (SOP) for Wyoming antigen testing with BinaxNOW COVID-19 Ag CARD

Training Videos and Competency Quiz

Abbott Watch Modules 1-4

https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

Covid-19 Testing: Demonstration of Self Swabbing for Students - California

https://www.youtube.com/watch?v=DU_G-D_sL3I

Competency Quiz (an optional quiz to test knowledge of reading Binax Tests)

https://redcap.link/WYbinaxquiz

Consent

Parent or Guardian consent is required for testing individuals younger than 18 years old. Schools should obtain consent in writing from parents/guardians for students younger than 18 who will participate in school-based testing.

The Wyoming Department of Health (WDH) offers a consent form that schools can use. The consent form is available as a REDCap survey which can be filled in electronically or as a PDF which can be printed and filled in. The REDCap survey can be found here: https://redcap.link/wyschoolCOVIDconsent. If schools would like to use the REDCap survey, please email alexia.harrist1@wyo.gov with the name, phone number, email address and title for the individual(s) who will need to access the completed consent forms.

Schools may also develop and use their own consent forms.

CLIA Waivers

Schools must have a CLIA waiver authorizing them to conduct COVID-19 testing with BinaxNOW antigen cards. To obtain or update a CLIA waiver, or if you have questions about your CLIA waiver, please visit https://health.wyo.gov/aging/hls/clia-clinical-laboratory-improvement-amendments/.

General procedures

1. Students and staff will be checked in
2. Participants are directed to the test station
3. Ensure consent forms are complete.
4. If the participant is 15 years of age or older, the participant self-collects the nasal swab sample according to instructions given by the observer. If the participant is less than 15 years of age, the sample is collected by the observer.

5. The observer receives the swabs from the participant or collects the swab and hands it to the tester for immediate antigen testing
   a. NOTE: Swab **cannot** be put back in the package
6. Implement BinaxNOW Antigen Test protocol (below)
7. If the participant is asymptomatic and has a negative antigen test, they can leave and are advised to continue with mitigation strategies such as mask wearing, frequent washing of hands, and social distancing.
8. If a symptomatic participant has a negative antigen test or an asymptomatic participant has a positive antigen test, a school representative (ex. school nurse or school administrator) will contact the participant, obtain a sample for confirmatory PCR or refer the participant to a community testing site, and advise the participant (participant's parent) on the district's isolation policy. Please see the algorithm here for more details:
   https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/Antigen_Testing_Algorithm_2020-12-14_v03_NO_DRAFT_SPW_508.pdf

Testing Supplies

The person observing or collecting the test should wear the following PPE and follow CDC's recommended biosafety practices for the collection, handling, and testing of COVID-19 specimens.

1. Recommended PPE
   a. Gown
   b. N95 or face mask
   c. Face shield
   d. Gloves

2. Each box of BinaxNOW test kits contains:
   a. 40 test cards
   b. 42 swabs
      i. 40 specimen collection swabs
      ii. 1 positive control swab
      iii. 1 negative control swab
   c. 1 10ml dropper bottle extraction reagent
   d. 1 package insert
   e. 1 procedure card
3. Other materials needed but not included in kit
   a. Disinfectant
      i. A list of EPA approved disinfectants for SARS-CoV-2 can be found here
         https://www.epa.gov/pesticide-registration/list-n-disinfectants-coronavirus-covid-19
   b. Paper towels
   c. Timer (depending on test volume and pace may need more than 1 timer)
      i. Note: tests may be done in groups, but it is essential to ensure that every test is read within the 15-30 minutes window. If a test is not read before the 30 min deadline, the card should be discarded and the test repeated with a new sample swab. **Do not read the test after 30 minutes**.

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Nasal Swab Specimen Collection (Observed Self-Collection)

- For participants 15 years of age or older, a swab is freshly collected by the participant (self-collection) with observation by the observer. For participants less than 15 years of age, the observer collects the swab. The recommended procedures for collecting nasal swabs are provided below. Direct nasal swabs are tested by the BinaxNOW antigen test immediately after collection.
- The swab included in the BinaxNOW kit **MUST** be the swab used for the antigen testing.
- Instructions for collection of nasal swab specimens.
  - Using gentle rotation to push the swab into the **right nostril** until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab for 15 seconds against the nasal wall then slowly remove from the nostril.
  - Repeat with the same swab in the left nostril
  - NOTE: BinaxNOW swab **cannot** be put back in the package and should be immediately handed to the tester who will be performing BinaxNOW antigen testing.
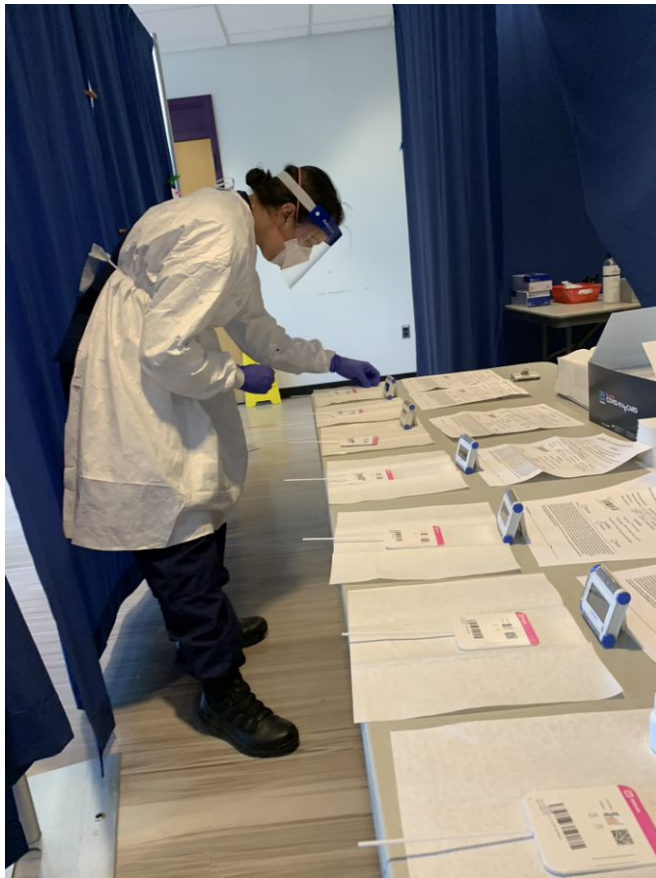
Testing protocol

BinaxNOW Kit Storage and Stability

Store kit at 2-30°C. The BinaxNOW™ COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers (see attached guidance from Abbott and FDA about extension of shelf life). **Ensure all test components are at room temperature before use.**

Prepare Station for testing:

1. Clean off table area with disinfectant and paper towel
2. Place an unopened test kit on top of paper towel
3. For large-volume testing, set-up multiple stations for testing on the table (lined up across table) at once to prior to starting

Procedure for Testing Specimens:

1. Remove the BinaxNOW card from its packaging just prior to use and visually inspect the card to ensure it does not have any defects and that the blue control line is visible.
2. Write name of participant on BinaxNOW card.
3. The test card must be flat when performing testing; do not perform testing with the test card in any other position
4. 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.
   a. Do not touch the card with the dropper tip while dispensing.
5. Insert swab into the bottom hole and push upwards so that swab is visible in the top hole
6. Rotate swab three times clockwise
   a. Note: False Negatives can occur if sample swab is not rotated prior to closing the card.
7. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card
8. Set timer for 15 minutes
9. Read results at 15 minutes. Results should not be read after 30 minutes
   a. Reference results sheet show what positive, negative, and invalid test results look like on card
10. Either change gloves or spray gloves with disinfectant between samples and touching test cards to read results
11. Record test result on result log

12. Result Interpretation

    Note: 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
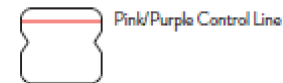
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has flowed through the test strip and the reagents are working. If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.

Negative

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.

Note: Invalid results are still reported; individual is given the option to repeat the test if desired.

13. Throw away BinaxNOW test card and swab in the biohazard bin, along with the paper towel on which it was laying
14. Clean off table area with disinfectant and paper towel
15. Set-up area again for next BinaxNOW antigen test

Confirmatory Testing

Negative BinaxNOW results among symptomatic individuals and positive results among asymptomatic individuals should be confirmed with a PCR test. See the attached CDC Antigen testing algorithm (https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html). You can use Curative test kits or state testing kits can be used and sent to the Wyoming Public Health Laboratory (**Do not use the BinaxNOW swab for PCR testing, another swab must be collected**). Please use the appropriate specimen

collection kits, ordering portal and shipping methods for confirmatory testing. Alternatively, the participant can be referred to a community testing site for PCR testing.

Managing and Reporting BinaxNOW test results using SimpleReport

Reporting of all COVID-19 test results is mandated by state and federal law. Results must be reported to the Wyoming Department of Health (WDH) and those results are reported to the Centers for Disease Control and Prevention (CDC). SimpleReport (https://simplereport.gov/) is a system created by the CDC which is HIPAA-compliant and automatically sends results to WDH, fulfilling reporting requirements. SimpleReport also allows schools to maintain and manage their testing records and automatically send results to participants or parents via text. Schools can use SimpleReport to ask parents to register their students for participation in the testing program.

The following steps can be used to sign up with SimpleReport:

1. Go to SimpleReport.gov/sign-up
2. The person you designate as your SimpleReport administrator will go through a process to verify their identity. Sometimes the verification process can happen automatically, other times a 15 minute video call may be needed. The video call can be completed within one business day.
3. After verification the account will be created and SimpleReport can be used.

The SimpleReport user guide is located here: https://simplereport.gov/assets/resources/SimpleReport_User_Guide.pdf. SimpleReport has a demonstration site available at https://training.simplereport.gov/app/ where schools can learn the features including how to submit a report and set up a patient record. Training videos about each step of the process are available on YouTube here: https://www.youtube.com/watch?v=qVkeizogmeQ&list=PL3U3nqqPGhab0sys3ombZmwOplRYlBOBF. There is also a K-12 start-up guide that can be found here: https://simplereport.gov/assets/resources/k12-guide.pdf. WDH can provide additional training if necessary. Questions can be addressed to the Simple Report team directly at support@simplereport.gov. This inbox is monitored 7 days a week.

If schools would like to use a reporting mechanism other than SimpleReport, please email alexia.harrist1@wyo.gov.

BinaxNOW Antigen Test Quality Control Procedures

BinaxNOW kit shipment inventory and lot documentation:

1) After receipt of BinaxNOW kits, ensure that each kit contains all necessary components and write on box whether complete or missing components
2) Document kit inventory and associated lot numbers

Procedural Controls:

BinaxNOW™ COVID-19 Ag Card has built-in procedural controls

A. 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.

B. 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 contain 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 the negative and positive control swabs once with each new shipment received and each lot of kits
2) Test positive and negative controls once for each untrained operator
3) If the correct control results are not obtained, do not perform patient tests or report patient results
4) Document External Positive and Negative Control testing and training