



Project ACE-IT Training Materials

Table of Contents

1. Training Checklist	One (1) for each trainee
2. Training Attendance Log	One (1) or two (2) copies
3. BinaxNOW™ Quiz	One (1) for each trainee
4. BinaxNOW™ Answers to Quiz	One (1) for each trainee
5. Certification of Training	One (1) or two (2) copies
6. BinaxNOW™ Job Aid	Several copies, posted for reference
7. Temperature Log	One (1) copy
8. External Quality Control Log	One (1) or two (2) copies
9. Internal Controls & Downtime Patient Log	One (1) or two (2) copies per hour of event
10. PA Rapid Test Reporting App. Onboarding Tip Sheet	One (1) for each trainee
11. QR Code Set-Up How-To	One (1) for each trainee
12. Referral sheet for confirmatory PCR testing	One (1) for each trainee



BinaxNOW™ COVID-19 Ag Card Training Checklist

FACILITY/LABORATORY: _____

USER NAME: _____ USER ID: _____

BinaxNOW™ COVID-19 Ag CARD - KIT OVERVIEW	USER'S INITIALS	DATE
<p>The user acknowledges being shown and understands the following kit components and precautions in the package insert:</p> <ul style="list-style-type: none"> • Kit Storage temperature • Lot number and expiration date • Package Insert including Precautions and Limitations • BinaxNOW™ COVID-19 Ag Card Procedure Card • Extraction Reagent • Swabs provided in the BinaxNOW™ COVID-19 kit • Patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal. • Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19. 		
SPECIMEN COLLECTION, STORAGE AND HANDLING	USER'S INITIALS	DATE
<p>The user acknowledges being shown; sample collection and storage conditions in the package insert:</p> <ul style="list-style-type: none"> • For use with direct nasal swab specimens with swabs provided in the kit ONLY • To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinate (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril. • 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 the 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 (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1-hour delay occurs, dispose of sample. A new sample must be collected for testing. DO NOT RETURN THE SWAB TO ITS ORIGINAL PACKAGING 		

SAMPLE PREPARATION TEST PROCEDURE FOR QUALITY CONTROL & PATIENT TESTING	USER'S INITIALS	DATE
<p>The User follows instructions for QC and Patient Testing of BinaxNOW™ COVID-19 Ag Card.</p> <p>The User follows instructions for Patient testing as outlined in the package insert and BinaxNOW™ COVID-19 Ag Card Procedure Card:</p> <ul style="list-style-type: none"> • Bring all materials and patient sample to room temperature • Label test card with appropriate QC or Patient Identification information. <p style="text-align: center;">For External QC</p> <ol style="list-style-type: none"> 1. Follow instructions for external controls. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly adds 8 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing. 2. Insert the (+) or (-) control swab 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 swab. 4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. 5. Read result in the window 15 minutes after closing the card. It is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes. <p style="text-align: center;">For Patient Testing</p> <ol style="list-style-type: none"> 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 swab 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 swab. 4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. 5. Read result in the window 15 minutes after closing the card. It is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes. 		

USER'S SIGNATURE:
DATE:

TRAINER'S SIGNATURE:
DATE:

BinaxNOW™ Training Attendance Log



Project: ACE-IT
Opening Schools
Safely, Together

Location: _____

The lab director's signature on the bottom indicates that training on QC and patient tests as well as any quality assurance documentation has been performed as required. All testers have reviewed and understand all steps outlined in the BinaxNOW job-aid, including specimen collection, QC and patient testing. The tester's signature indicates that they have reviewed all training videos and resources on [BinaxNOW COVID-19 Ag Card | Abbott Point of Care Testing \(globalpointofcare.abbott\)](#) and is confident in the performance of this test. The observer's signature indicates (s)he has observed a control test as well as a patient test being done.

Skill Validation Date	Tester Name (PRINT)	Tester Signature	School/Org.

Lab Director's Signature: _____ Date: _____

Source: Infectious Disease Diagnostics Lab, Children's Hospital of Philadelphia – Rev. 12/7/20



Project: ACE-IT
Opening Schools
Safely, Together

BinaxNOW™ COVID-19 Ag Card Quiz

Name: _____

Date: _____

Check box under True or False for each question:

Question	True	False
Prior to inserting the nasal swab in the BinaxNOW COVID-19 Ag card, add 8 drops of reagent to the top hole of the swab well.		
Once the drops have been placed in the well, the swab should be placed in the BinaxNOW COVID-19 Ag Card immediately.		
A nasopharyngeal swab is an acceptable swab for use with the BinaxNOW COVID-19 Ag Card.		
Direct nasal swab samples may be stored at room temperature for 24 hours.		
It is acceptable to return the nasal swab to its original packaging after specimen collection.		
False negative results can occur if the sample swab is not rotated (twirled) after placement into the card prior to closing the card.		
After 15 minutes, if no lines are seen; or, if just the Sample Line is seen, the assay is negative.		
Results should be read promptly at 15 minutes and not before. Results should not be read after 30 minutes.		
The appearance of a pinkish-purple Control Line and a pinkish-purple Sample Line below it is a positive result.		
A result must be recorded in the PA Rapid Test App only when the test result is positive.		



BinaxNOW™ COVID-19 Ag Card Quiz Answers

Answer	Explanation
False	Six (6) drops of reagent are used when performing a test. Eight (8) drops of reagent are used when running a positive control test with a positive or negative control swab.
True	The BinaxNOW COVID-19 Ag Card should remain in the foil pouch until just before use. Do not open pouch until you are ready to perform the test. Once you've opened the pouch, be sure to wait until just before you've collected the nasal specimen to drop the reagent into the top hole/well. If you drop the reagent into the top hole/well and wait too long before placing the swab in the card with the reagent, some of the reagent could evaporate, resulting in invalid results.
False	A nasal swab is used to obtain a sample from the anterior nares (aka, nostrils). Do not use a nasopharyngeal swab or a saliva sample for this test. Do not attempt to collect the specimen from anywhere beyond the anterior nare, about 1 inch inside the nostril. The swab must be inserted into the 1st nostril until the foam tip is not visible. Rotate it around the walls of the nostril with more drainage or that is more congested for 10-15 seconds. Repeat this process in the 2nd nostril using the same swab.
False	Once the nasal swab has been obtained, the BinaxNOW test must be performed immediately. The sample cannot be stored at any temperature for later testing. If the test cannot be completed within 15 minutes of obtaining the sample, discard the swab and obtain another sample and re-initiate the testing process from the beginning with card and swab.
False	Once the nasal swab has been obtained, it must be used immediately to perform the test. The swab should not be placed back into its paper/plastic pouch.
True	Once the swab has been placed into the card, it must be twirled three times before the card is closed and the reaction begins. At this point, you should set your timer for 15 minutes. This process allows the nasal secretions to mix with the reagent, which is necessary to get an accurate test result. If the swab is not twirled and the card is not sealed shut, a false negative test result may occur.
False	If after 15 minutes either no lines are visible or just a line next to the word "sample" is visible, the test is INVALID. There must be a pinkish-purple line at the top of the window next to the word "control" for the test to be valid.
True	The test must be read no earlier than 15 minutes and no later than 30 minutes after the card is closed and sealed. If you read the card before 15 minutes or after 30 minutes your result may be incorrect.
True	A positive test occurs when there are two pinkish-purple lines in the window at 15 minutes.
False	All test results, including those that are positive, negative, and invalid, must be reported in the PA Rapid Test app. Once you have scanned the unique bar code on the BinaxNOW COVID-19 Ag card and bonded it to the subject's demographic info. by scanning their unique QR code, you must remember to enter their result after the reaction has occurred (15 minutes later). You can easily call up a given subject's testing encounter in the PA Rapid Test App once you have their result by scanning the bar code on the BinaxNOW card, to enter their result. Best practice is to record the result in the PA Rapid Test app IMMEDIATELY, once the result has appeared on the card. It is risky to wait until the end of the day or the next day to enter results into the PA Rapid Test app.



Certification of Training

This is to verify that personnel responsible for running the BinaxNOW™ COVID-19 Ag Card at _____ have been thoroughly in-serviced on the test and the test procedure. This has included:

- **Review of the package insert**
- **Demonstration of the product assay**
- **Successful performance of the BinaxNOW™ COVID-19 Ag Card and interpretation of results**

Names of the personnel who have been trained with the BinaxNOW™ COVID-19 Ag Card and are responsible for reporting patient results:

PRINT NAME	SIGNATURE	DATE

Signature of Laboratory Director(s) responsible for personnel and testing:

SIGNATURE

DATE

MEDICAL DIRECTOR SIGNATURE

DATE

TRAINER

DATE



Job Aid: BinaxNOW™ COVID-19 Ag CARD Procedure

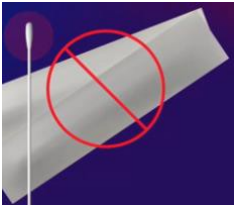


- Please confirm with site administrator/proctor that quality control (QC) has been performed on the lot of the box this test came from. If not, please wait until QC has been performed.
- When you first open the BinaxNow card (step #5), please check that the **blue Control Line** is present. If it is not, discard the test and start over with a new one.
- Make sure you are both registered and familiar with the registration and results reporting app if you have any data entry responsibilities.



Collecting Anterior Nares Specimen

1. **Make sure you are wearing PPE as directed.** Perform hand hygiene and put on new gloves.
2. Gently insert swab at least 1 cm inside the nostril with more drainage, or that is more congested.



3. Rotate swab > 5 times gently against nasal membrane for 10-15 seconds; then gently remove the swab. **Repeat with same swab in other nostril.**
4. Test swab with specimen **immediately after collection** and **do not return the swab to its original packaging.**

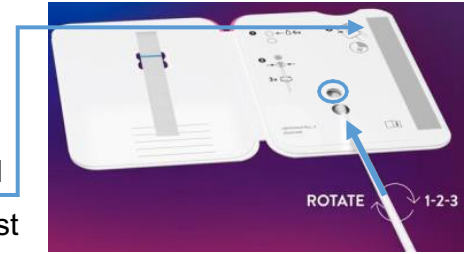


Running the Test

5. Open the test card just prior to use and **lay it flat. Do not perform testing with the card in any other position.**
 - a. Hold Extraction Reagent bottle vertically, hovering ½ inch about the **TOP HOLE**.
 - b. Slowly add **6 DROPS** to the **TOP HOLE**. While putting drops on the card, **hold the swab with specimen in the other hand**, taking care not to have it touch anything.
 - c. **DO NOT** touch the card with the dropper tip while dispensing.



6. Insert sample into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.
7. Twirl swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.
8. Peel off **adhesive liner** from the right edge of the test card. Close and securely seal the card and **set a timer for 15 minutes**. The card must lay flat during the entire 15 minutes of the test—not just when dropping in the reagent.



Reading the Results

9. **Read result in the window promptly at 15 minutes after closing the card.** Reading before 15 minutes or after 30 minutes reduces assurance of proper test performance. 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.

Negative Result: 1 pink-to-purple (or, pinkish-purple) line

Positive Result: 2 pink-to-purple (or, pinkish-purple) lines



Valid Results



No lines

Sample line only

Blue Control Line still blue after testing



Invalid Results



Invalid Results



10. If result is invalid, please repeat specimen collection and test with new BinaxNOW card.
11. Dispose of all items used in biohazard bag provided.
12. Report results as directed.



BinaxNOW™ COVID-19 Ag Card – Temperature Log

SITE LOCATION: _____ MONTH/YEAR: _____

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Initials of Recorder																
Room Temperature																
Min-Max (High/low) Temperatures																

Day of Month	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Initials of Recorder															
Room Temperature															
Min-Max (High/low) Temperatures															

Temperature Ranges: Please reset the thermometer's high-low temperatures the day before a weekend or holiday. On the 1st day back after the office/school has been closed for one or more days, the high/low display (actual number range) is written in the space (or spaces) for the closed day or dates. The large single number display is written for the daily temperature on days the office/school is open and the temperature is read.

Room Temperature Acceptable Range: 2° to 30° C / 35.6° to 86° F

Corrective action for room temperatures that deviate from the acceptable temperature range:

- Contact departments responsible to get repair or adjustment information or to determine the service representative to call. Contact Maggie Eisen: eisenm@chop.edu for unacceptable temperatures.
- Call product manufacturer for consultation regarding impact of temperature on lab supplies.
- Document all corrective action directly on the temperature log. Save copies of any service call paperwork.

Source: Infectious Disease Diagnostics Laboratory, Children's Hospital of Philadelphia, Rev. 12/7/20; updated 8/3/21



BinaxNOW™ COVID-19 Ag Card External Quality Control Log

Abbott recommends that external positive and negative controls be run:

- ◆ Once with each new shipment received
- ◆ Once for each untrained operator
- ◆ When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures

If the expected external control results are not obtained, do not report patient results. Contact Technical Service at 800-257-9525.

KIT LOT NUMBER: _____

DATE	BINAXNOW™ COVID-19 Ag CARD KIT LOT/EXP	POSITIVE CTRL LOT/EXP	NEGATIVE CTRL LOT/EXP	POSITIVE RESULT	NEGATIVE RESULT	CONTROL LINE PRESENT: Y/N	TESTER'S INITIALS	CORRECTIVE ACTION / COMMENTS

SUPERVISOR REVIEWED BY: _____ **DATE:** _____



Project: ACE-IT
Opening Schools
Safely, Together

BinaxNOW™ COVID-19 Ag Card Internal Controls and Downtime Patient Log

LOT NUMBER _____ EXP. DATE _____ NAME OF FACILITY/SITE: _____

Record the Date, Patient's Name, Patient Test Result, Internal Control Results and the tester's initials.

Positive Internal Control = The pink-to-purple line at the “Control” position can be considered an internal positive procedural control.

Negative Internal Control = The background color in the window should be light pink to white within 15 minutes.

[illegible]

SUPERVISOR REVIEWED BY: _____ **DATE:** _____

Eff. 8/4/21

Doc. #10



Our new account/site registration page is currently down so please respond to the questions on this e-form to set up an account for each new proctor and/or new testing site: <https://forms.gle/Dn3gpZ7nJm4H8FHQ9>.

- Use this form for new proctor/test administrator account set up-up AND/OR to add a new site to the app.
- If your site is already in the app, please skip the “Add a new site to the app” section (sec. #3) and submit.

Here is the Penn Rapid Test site: <https://app.pennrapidtest.org/login> - you can use the generic log-on below to familiarize yourself and practice results reporting:

Username: onboarding_account@pennrapidtest.org

Password: P@testing2021!

BinaxNOW Bar Codes for Practice



QR Code for Practice



Remember not to click “submit” at the end of your practice session or the demo bar codes will not be reusable by others. Best practice here is to click “clear form” and then “save and exit” after each practice session.



Want to speed up the process?
Make a QR Test Code for yourself or your child before coming to a testing event

How to:

1. Click <https://register.pennrapidtest.org/> or enter this url into your web browser (the app is not compatible with Internet Explorer but should work on most other web browsers).
2. Follow instructions on your screen, which include answering questions about your (child's) demographic info. to create a personalized QR code.

Screen #1:

Screen #2:

Screen #3:

Screen #4:

1. Take a screengrab (photo) of the QR code and store it in your device in your photos app; or, cut/paste the screengrab onto a Word .doc, and print it out.
2. You may create as many personalized QR codes as you wish – each time you create a new one, you'll enter your demographic data; but each time you use that QR code in the PA Rapid Test app at a testing event, your demographic data will pre-populate.



Confirmatory Testing

For confirmatory testing, the CHOP Project: ACE-IT Team is developing a partnership with the CHOP Infectious Disease Diagnostics Laboratory and a vendor to collect and transport specimens to CHOP for a PCR test. Until that partnership is live, we recommend referring subjects needing confirmatory tests to their pediatrician or general practitioner, or to a free CHOP testing site.

COVID-19 Testing for Kids at Children's Hospital of Philadelphia

Children's Hospital of Philadelphia (CHOP) has partnered with the Philadelphia Department of Public Health (PDPH) to offer families online screening to determine if a child meets COVID-19 testing criteria and simple access to testing.

If children meet criteria, the screening tool will provide options to schedule an appointment at one of CHOP's testing sites located across the Greater Philadelphia region. Children do not need to be current CHOP patients to schedule an appointment at a [CHOP testing site](https://www.chop.edu/covid-19-testing-kids) (<https://www.chop.edu/covid-19-testing-kids>). **Testing is available by appointment only.** There is no copay or out-of-pocket costs associated with COVID-19 testing at CHOP, and uninsured patients can access testing with no cost to their families.

All CHOP testing sites use PCR testing and obtain the specimen using [less invasive anterior nares testing swabs](https://www.chop.edu/news/chop-pediatric-covid-19-test-sites-transitioning-less-invasive-swab) (<https://www.chop.edu/news/chop-pediatric-covid-19-test-sites-transitioning-less-invasive-swab>). Results of PCR tests are generally available within 24 to 48 hours.

[Access CHOP's COVID-19 Screening Tool](https://mychop.chop.edu/MyChart/covid19/#/) (<https://mychop.chop.edu/MyChart/covid19/#/>) or call CHOP's COVID-19 Helpline at 800-722-7112.