

**Project: ACE-IT**  
Assisting Childhood Education through Increased Testing

**Project ACE-IT Training Materials**

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4. BinaxNow™ Certification of Training	One (1) or two (2) copies
5. BinaxNow™ Job Aid	Several copies, posted for reference
6. BinaxNow™ Temperature Log	One (1) copy
7. BinaxNow™ External Quality Control Log	One (1) or two (2) copies
8. BinaxNow™ Internal Controls & Downtime Patient Log	One (1) or two (2) copies <b>per hour of event</b>

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**BinaxNOW™ COVID-19 Ag Card Training Checklist**

FACILITY/LABORATORY: \_\_\_\_\_

USER NAME: \_\_\_\_\_ USER ID: \_\_\_\_\_

<b>BinaxNOW™ COVID-19 Ag CARD - KIT OVERVIEW</b>	<b>USER'S INITIALS</b>	<b>DATE</b>
<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"> <li>• Kit Storage temperature</li> <li>• Lot number and expiration date</li> <li>• Package Insert including Precautions and Limitations</li> <li>• BinaxNOW™ COVID-19 Ag Card Procedure Card</li> <li>• Extraction Reagent</li> <li>• Swabs provided in the BinaxNOW™ COVID-19 kit</li> <li>• 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.</li> <li>• 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.</li> </ul>		
<b>SPECIMEN COLLECTION, STORAGE AND HANDLING</b>	<b>USER'S INITIALS</b>	<b>DATE</b>
<p>The user acknowledges being shown; sample collection and storage conditions in the package insert:</p> <ul style="list-style-type: none"> <li>• For use with direct nasal swab specimens with swabs provided in the kit ONLY</li> <li>• 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.</li> <li>• 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</li> </ul>		

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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"> <li>• Bring all materials and patient sample to room temperature</li> <li>• Label test card with appropriate QC or Patient Identification information.</li> </ul> <p style="text-align: center;"><b>For External QC</b></p> <ol style="list-style-type: none"> <li>1. <b>Follow instructions for external controls.</b> Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the <b>TOP HOLE</b>, slowly adds <b>8 DROPS</b> to the <b>TOP HOLE</b> of the swab well. DO NOT touch the card with the dropper tip while dispensing.</li> <li>2. Insert the (+) or (-) control swab into <b>BOTTOM HOLE</b> and firmly push upwards so that the swab tip is visible in the <b>TOP HOLE</b>.</li> <li>3. Rotate (twirl) swab shaft 3 times <b>CLOCKWISE</b> (to the right). Do not remove swab.</li> <li>4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card.</li> <li>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.</li> </ol> <p style="text-align: center;"><b>For Patient Testing</b></p> <ol style="list-style-type: none"> <li>1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the <b>TOP HOLE</b>, slowly add <b>6 DROPS</b> to the <b>TOP HOLE</b> of the swab well. DO NOT touch the card with the dropper tip while dispensing.</li> <li>2. Insert sample swab into <b>BOTTOM HOLE</b> and firmly push upwards so that the swab tip is visible in the <b>TOP HOLE</b>.</li> <li>3. Rotate (twirl) swab shaft 3 times <b>CLOCKWISE</b> (to the right). Do not remove swab.</li> <li>4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card.</li> <li>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.</li> </ol>		

USER'S SIGNATURE:

DATE:

TRAINER'S SIGNATURE:

DATE:

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**BinaxNow™ Training Attendance Log**

**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 Binax NOW 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.

Date Training Materials Reviewed	Tester Name (PRINT)	Tester Signature	QC Test (✓)	Patient Test (✓)	Observer Name (PRINT)	Observer Signature

Lab Director's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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**BinaxNOW™ COVID-19 Ag Card Quiz**

**Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Circle T (True) or F (False) for each Question:**

- |     |  |   |   |
|-----|--|---|---|
| 1.  | For testing patient direct nasal swabs, 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.                     | T | F |
| 2.  | The BinaxNOW™ COVID-19 Ag Card device should not be removed from the foil pouch until just before use.   | T | F |
| 3.  | A nasopharyngeal swab is an acceptable sample type for testing on the BinaxNOW™ COVID-19 Ag Card.  | T | F |
| 4.  | Direct nasal swab samples may be stored at room temperature for 24 hours.  | T | F |
| 5.  | It is acceptable to return the nasal swab after patient collection to its original packaging.  | T | F |
| 6.  | False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.  | T | F |
| 7.  | If no lines are seen, or if just the Sample Line is seen, the assay is negative.   | T | F |
| 8.  | Results should be read promptly at 15 minutes, and not before. Results should not be read after 30 minutes.  | T | F |
| 9.  | The appearance of a pink-to-purple Control Line and a pink-to-purple Sample Line below it is a positive result.  | T | F |
| 10. | Test using only with swabs provided in the kit, and collect direct nasal swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. | T | F |

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#### 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**

1120007069 v01 09/20 BinaxNOW™ COVID-19 Ag Card

**Source:** City of Philadelphia Public Health Department, 500 South Broad Street Philadelphia PA 19146

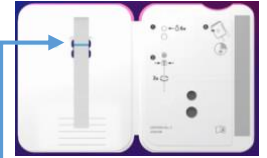
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Effective Date: 12/11/20

**Job Aid: BinaxNow™ COVID-19 Ag CARD Procedure**

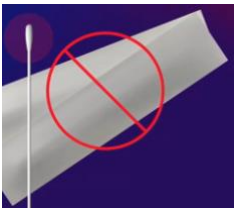


- Please confirm with site administrator/proctor that quality control (QC) has been performed on the lot of the box this test came from. If not, please wait until QC has been performed.
- When you first open the BinaxNow card (step #5), please check that the **blue Control Line** is present. If it is 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**

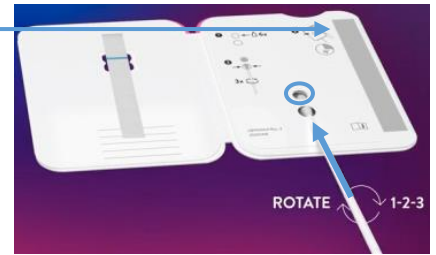
5. Open the test card just prior to use and **lay it flat.** **Do not perform testing with the card in any other position.**
  - a. Hold Extraction Reagent bottle vertically, hovering ½ inch about the **TOP HOLE.**
  - b. Slowly add **6 DROPS** to the **TOP HOLE.** While putting drops on the card, **hold 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.



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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.



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**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 1<sup>st</sup> 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:** 15° to 30° C / 59° to 77° 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@email.chop.edu](mailto:eisenm@email.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

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#### 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: \_\_\_\_\_

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**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.

DATE	PATIENT NAME	PATIENT ID NUMBER	PATIENT RESULTS	CONTROL LINE PRESENT?		INTERNAL CONTROL RESULTS		COMMENTS	TESTER'S INITIALS
				NO	YES	+	-		

**SUPERVISOR REVIEWED BY:** \_\_\_\_\_ **DATE:** \_\_\_\_\_

**Source:** City of Philadelphia Public Health Department, 2230 Cottman Avenue Philadelphia, PA 19149