



BinaxNOW™ COVID-19 Ag Card Training

Rapid Antigen Assay

Date 2020

Name

Abbott Technical Consultant



Emergency Use Authorization Granted by FDA

Intended Use

The BinaxNOW™ COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from **individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.** The BinaxNOW™ COVID-19 Ag Card does not differentiate between SARS-CoV and SARS-CoV-2.

Antigen is generally detectable in nasal swabs during the **acute phase of infection.** Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Emergency Use Authorization

The BinaxNOW™ COVID-19 Ag Card is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests. The BinaxNOW COVID-19 Ag Card is only for use under the Food and Drug Administration's Emergency Use Authorization.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.

BinaxNOW™ COVID-19 Ag

Emergency Use Authorization Responsibility

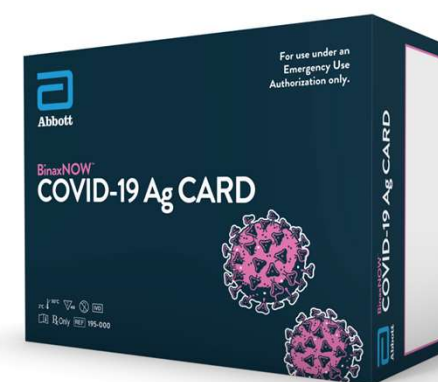
Test Site Obligations

- Notify relevant public health authorities on intent to run test
- Report all results to healthcare providers and include the Healthcare Provider Fact Sheet. Healthcare providers to include Patient Fact Sheet with results.
- Ensure all operators are trained to perform and interpret the test
- Per Product Insert: collect performance data and report via email to FDA/HHS and to Abbott Technical Support
- Retain all records associated with EUA until otherwise directed by FDA

BinaxNOW™ COVID-19 Ag Card

Product Overview

Test Summary	Rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2
Testing Environment	For use at the Point of Care in settings operating under CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation
Specimen Type	Direct nasal swab
Time to Result	Results visually read at 15 minutes Results should not be read after 30 minutes



Reagent and Materials

Materials Provided:

- 40 Test Cards
- Extraction Reagent
- Patient Collection Nasal Swabs
- Positive Control Swab
- Blank Nasal Swab for Negative Control
- Product Insert
- Procedure Card
- Healthcare Provider & Patient COVID-19 Fact Sheets

Materials Required but not Provided:

- Clock, timer or stopwatch

Optional Materials:

- Plastic Transport Tube

Storage & Stability:

- Store kit at 2-30°C
- Ensure all test components are at room temperature before use
- Stable until the expiration date marked on the outer packaging



Quality Control

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:

- In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position, which is an internal procedural control.
- 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.
- 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.



Note: 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.

Quality Control

External Positive & 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
- These swabs will monitor the entire assay

Required Frequency:

- New shipments received
- Untrained operators
- Conforming with local, state, and/or federal regulations, accrediting groups, or lab's standard QC procedures.

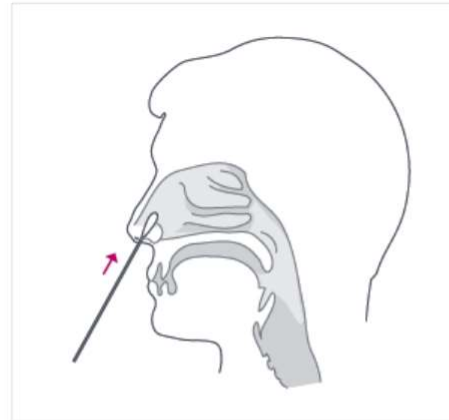


*If correct results are not obtained, contact
Technical Services before testing patient specimens.*

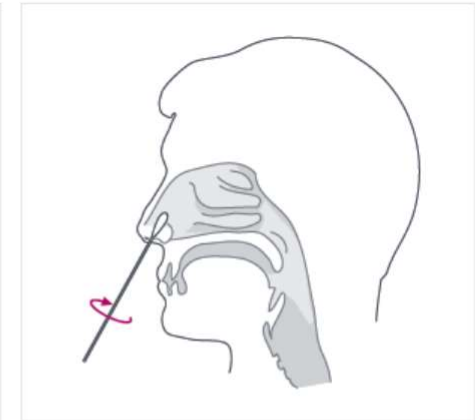
Nasal Swab Sample Collection

Test specimens immediately after collection for optimal performance

- Insert the nasal swab into the nostril exhibiting the most drainage or congestion
- Using gentle rotation, push the swab until resistance is met
 - At the level of the nasal turbinates
 - Less than one inch into nostril
- Rotate the swab 5 times or more against the nasal wall
- Slowly remove the swab
- Using the same swab, repeat sample collection in the other nostril



1 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.



2 Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall and then slowly remove from the nostril.

3 Using the same swab, repeat sample collection in the other nostril.

Only the swab provided in the kit is to be used for nasal swab collection.

Specimen Transport & Storage


For best performance, direct nasal swabs should be tested as soon as possible after collection.

If immediate testing is not possible:


- **Do not return the nasal swab to the original paper packaging**
- To avoid contamination and preserve sample integrity, place the nasal swab in a clean, unused, tightly capped plastic tube & label with the patient information
- The sample is stable in the plastic tube at room temperature (15-30°C) for up to one (1) hour prior to testing
- If greater than one (1) hour delay occurs, dispose of sample & collect new sample

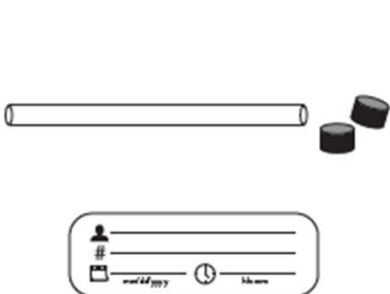


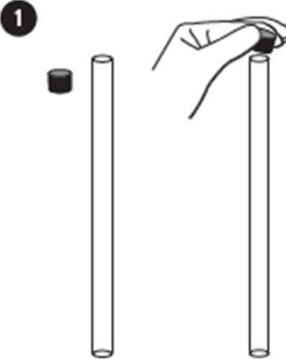
Specimen Transport & Storage

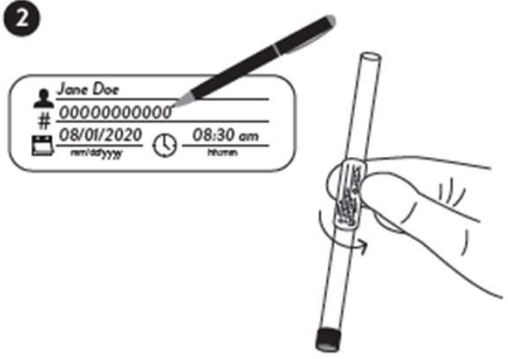


Swab Transport Tube Accessory Pack




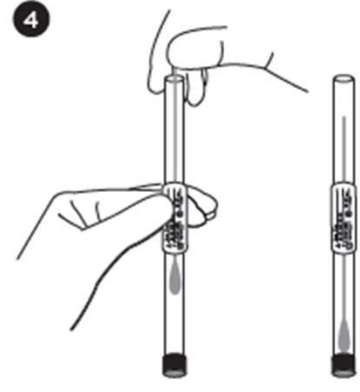


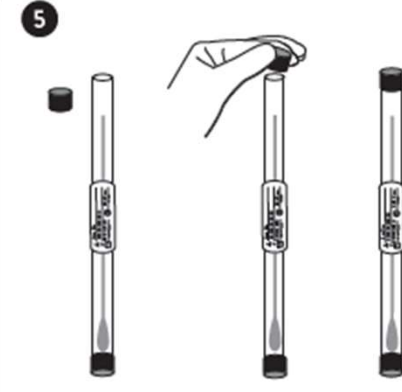
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2

Jane Doe
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08/01/2020 08:30 am
nm/02/yyyy Room

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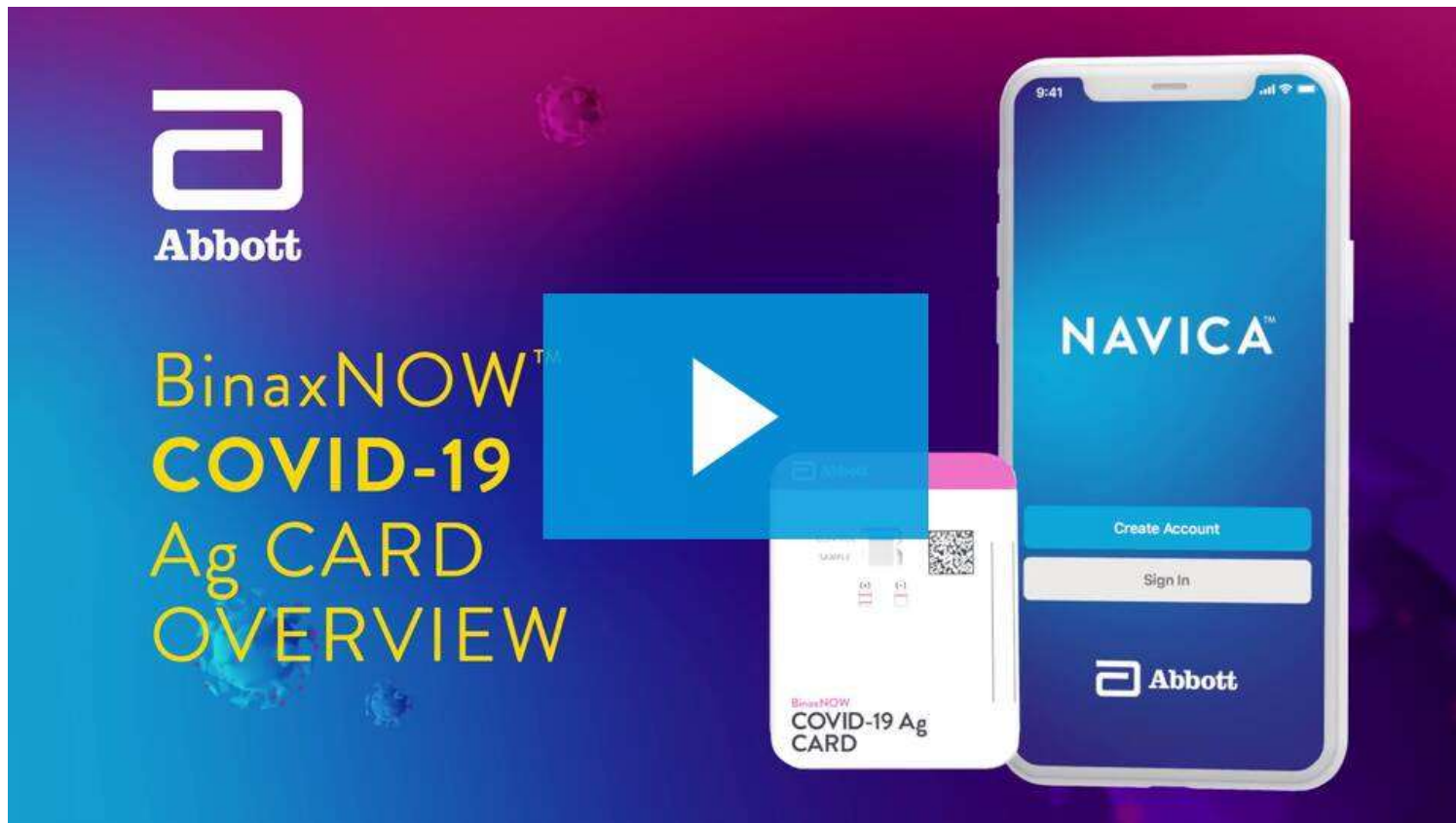
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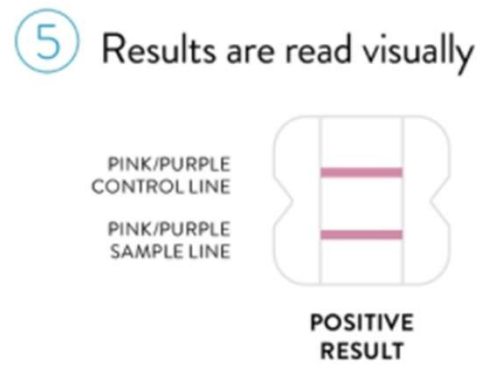
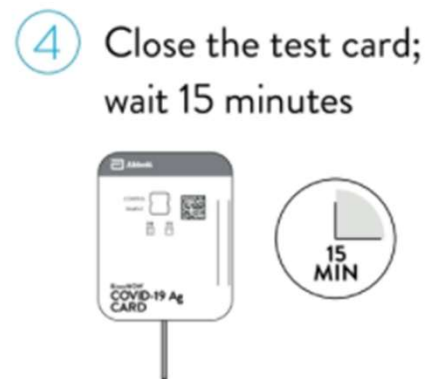
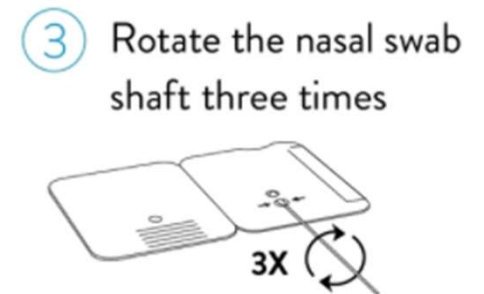
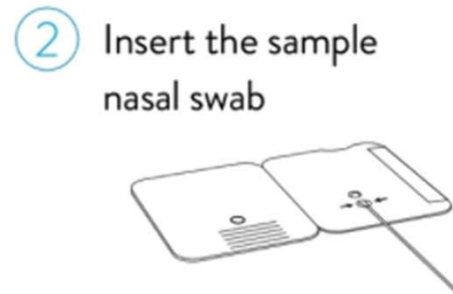
Binax Test Demonstration Video



[BinaxNOW Covid19 Antigen Test Demonstration Video - \(R10\) EN/US - Abbott](#)

BinaxNOW™ COVID-19 Ag Card

Procedure Overview

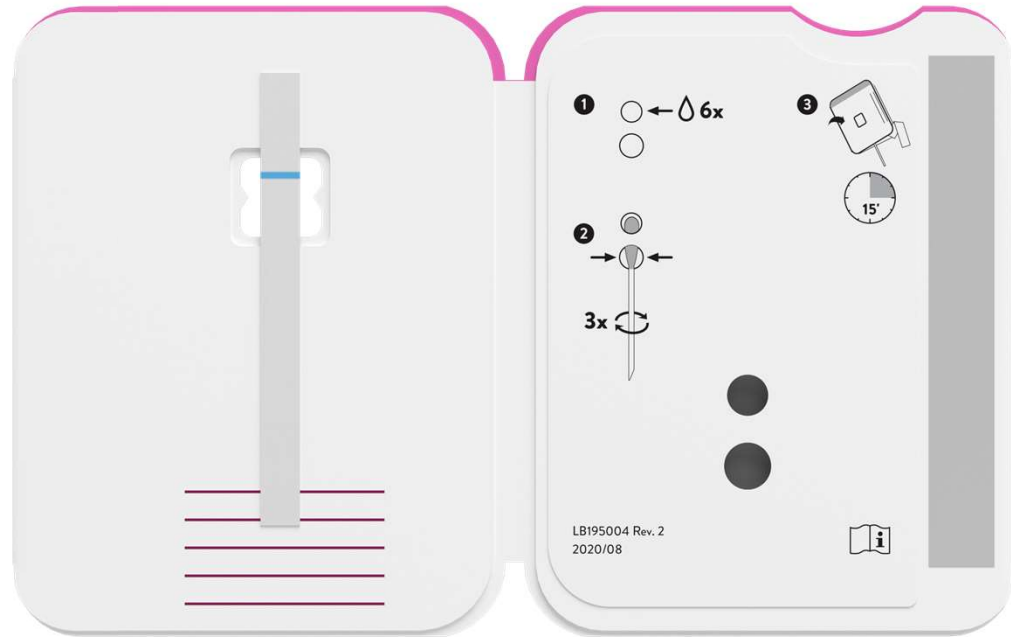


BinaxNOW™ COVID-19 Ag Card

Card Overview



Exterior View



Interior View

BinaxNOW™ COVID-19 Ag Card

Procedure for Patient & QC Tests

*Ensure all test components are at room temperature before use

Open test card just prior to use, **lay it flat and perform assay as follows

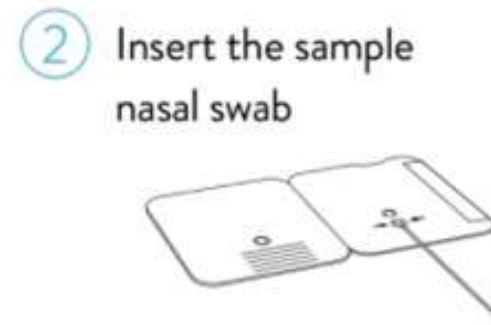
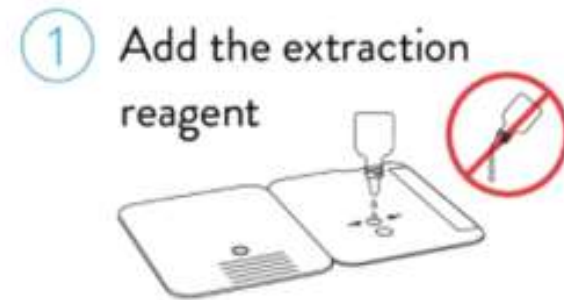
***If the blue line is not present at the Control Line prior to running the test, do not use and discard the test card.

Step 1: Hold extraction reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add:

- **6 DROPS** to the top hole if performing a patient test
- **8 DROPS** to the top hole if performing positive and negative control tests

DO NOT touch the card with the dropper tip while dispensing

Step 2: Insert patient or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**



BinaxNOW™ COVID-19 Ag Card

Procedure for Patient & QC Tests

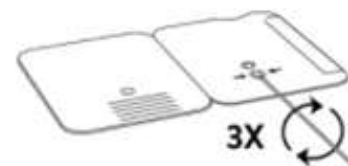
Step 3: Rotate (twirl) swab shaft 3 times
CLOCKWISE (to the right). Do not remove swab

Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card

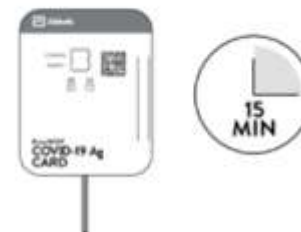
Step 4: Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read results in the window **15 minutes** after closing the card

*Note: 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*

③ Rotate the nasal swab shaft three times



④ Close the test card; wait 15 minutes



Result Interpretation

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.

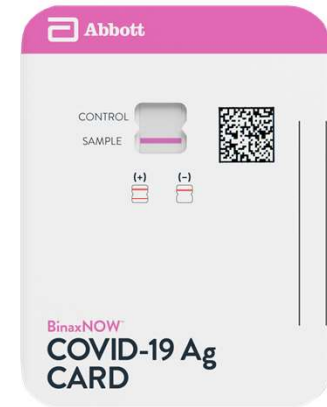


Positive: A positive specimen will give two **pink/purple** colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible **pink/purple** line is positive.



Result Interpretation

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.



Disposal

- All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements

Near-Patient Workflow: No Swab Transport*

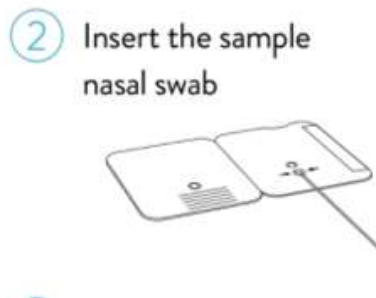
Option A (Collect Patient Swab First, Prior to Test Procedure)

Collect Nasal Swab

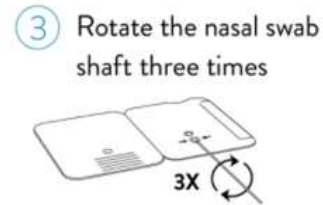
Step 1: Add the Extraction Reagent



Step 2: Insert sample into bottom hole and push firmly upwards so tip is visible in top hole



Step 3: Rotate (twirl) swab shaft 3 times clockwise (to the right)



Step 4: Peel off adhesive liner, close and securely seal card. Read results in the window 15 minutes after closing the card



*Swab will not be moved from immediate testing area where sample collection is performed

Near-Patient Workflow: No Swab Transport*

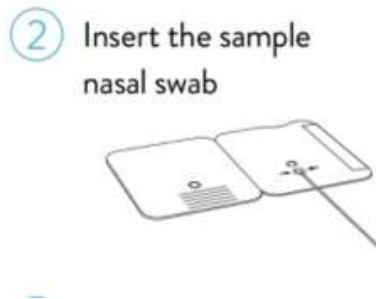
Option B (Begin Test Procedure, *Then* Collect Patient Swab)

Step 1: Add the Extraction Reagent



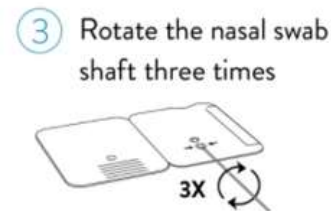
Collect Nasal Swab

Step 2: Insert sample into bottom hole and push firmly upwards so tip is visible in top hole



Within 3 minutes of adding extraction reagent drops, insert swab into test card

Step 3: Rotate (twirl) swab shaft 3 times clockwise (to the right)



Step 4: Peel off adhesive liner, close and securely seal card. Read results in the window 15 minutes after closing the card



*Swab will not be moved from immediate testing area where sample collection is performed

Additional Resources

Ordering Information

- 195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)
- 195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit
- 190-010: Optional COVID-19 Swab Transport Tube Accessory Pack (24 tubes)

Technical Support Line:

- US +1 800 257 9525, 8am-8pm EST M-F
- ts.scr@abbott.com

Additional Resources

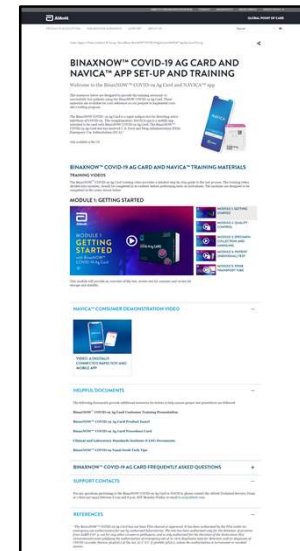
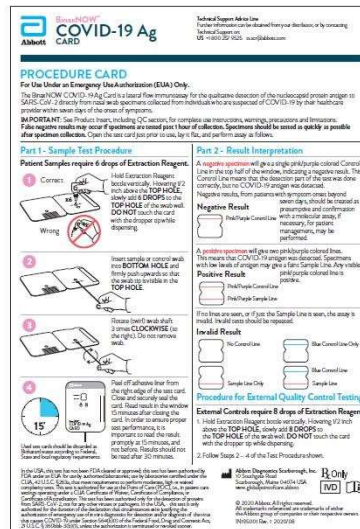
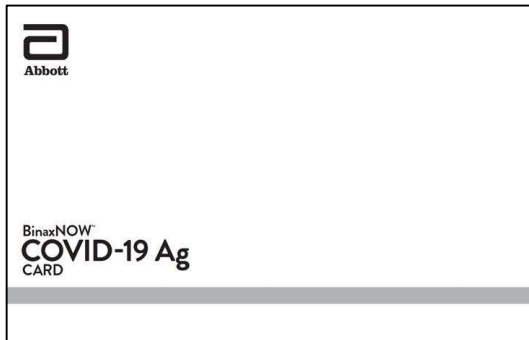
BinaxNOW™ COVID-19 Ag Card Demo Video:

- binaxnow-navica.abbott

BinaxNOW™ COVID-19 Ag Card Training Video Modules:

- globalpointofcare.abbott/navica-binax-training

Helpful Documents:



Questions?





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