Policy and Procedure

Title: Abbott BinaxNOW™ COVID-19 Tests

Policy

Facility will conduct COVID-19 antigen testing with the Abbott BinaxNOW™ COVID-19 Tests as outlined by the manufacture, CMS, CDC and FDA.

Procedure

Specimen Collector Competencies

Specimen Collectors are required to complete the following competencies to ensure they have a basic understating of the Abbott Binax Now™ COVID-19 test:

1. Go to https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html and complete the following
    A. Watch modules 1-4
    B. Review the 'Helpful Documents'
    C. Review the FAQ's
2. Complete attached competencies 'Abbott Testing Procedure Competency'

Quality Control

Built-in procedural controls

1. 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.
2. 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.
3. 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.
4. Background color should not hinder reading of the test.

Performing External Quality Control Test

Control testing should be performed when:

1. New shipments are received
2. New employee starts conducting tests
3. Conforming to local, state, and/or federal regulations, accrediting groups, or lab's standard QC procedures.

BinaxNOW™ COVID-19 Ag Card kits contain a positive control swab and sterile swabs that can be used as a negative control.

1. Ensure all test components are at room temperature before use
2. Open test card just prior to use and lay it flat
    a. If the blue line is not present at the Control Line prior to running the test do not use and discard the test card.
3. Hold extraction reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the top hole
    a. **DO NOT** touch the card with the dropper tip while dispensing
4. Insert **POSITIVE CONTROL SWAB** into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**
5. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). **Do not remove swab**
    a. False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card
6. Peel off adhesive liner from the right edge of the test card.
7. Close and securely seal the card.
8. Read results in the window 15 minutes after closing the card
9. Record results
10. Repeat control testing procedure with a sterile swab to receive a negative result
11. **If correct results are not obtained, contact Technical Services before testing patient specimens.**

Sample Collection

1. Ensure swab is at room temperature
2. Insert the nasal swab into the nostril exhibiting the most drainage or congestion
3. Using gentle rotation, push the swab until resistance is met
    A. At the level of the nasal turbinates
    B. Less than one inch into nostril
4. Rotate the swab 5 times or more against the nasal wall
5. Slowly remove the swab
6. Using the same swab, repeat sample collection in the other nostril

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

Specimen Processing

Specimen samples must be processed immediately as the transport tubes are not included in the testing kits provided.

1. Ensure all test components are at room temperature before use
2. Open test card just prior to use and lay it flat
    A. If the blue line is not present at the Control Line prior to running the test do not use and discard the test card.
3. Hold extraction reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **6 DROPS** to the top hole
    A. **DO NOT** touch the card with the dropper tip while dispensing
4. Insert swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**
5. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). **Do not remove swab**

   A. False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card
6. Peel off adhesive liner from the right edge of the test card.
7. Close and securely seal the card.
8. Read results in the window 15 minutes after closing the card
9. Record results

Result Interpretation

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**

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.

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.

Please see the attached 'Procedure Card' for a visual representation of each result

Disposal

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

Attachments: Procedure Card
Collection of a Nasal Swab for the Binaxnow™ Covid-19 Ag Card
Abbott Testing Procedure Competency

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BinaxNOW™ COVID-19 Ag CARD

Technical Support Advice Line
Further information can be obtained from your distributor, or by contacting Technical Support on:
US +1 800 257 9525 ts.scr@abbott.com

PROCEDURE CARD

For Use Under an Emergency Use Authorization (EUA) Only.

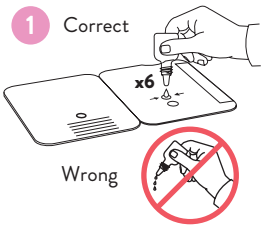
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms.

IMPORTANT: See Product Insert, including QC section, for complete use instructions, warnings, precautions and limitations. **False negative results may occur if specimens are tested past 1 hour of collection. Specimens should be tested as quickly as possible after specimen collection.** Open the test card just prior to use, lay it flat, and perform assay as follows.

Part 1 - Sample Test Procedure

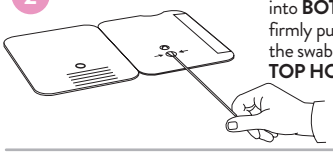
Patient Samples require 6 drops of Extraction Reagent.

1 Correct



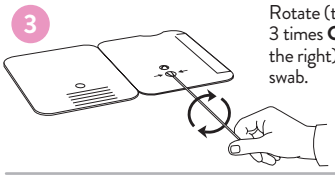
Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2



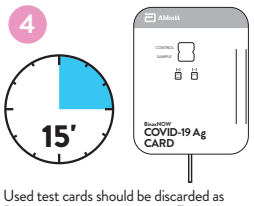
Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

3



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

4



Used test cards should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

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.

Part 2 - Result Interpretation

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.

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.

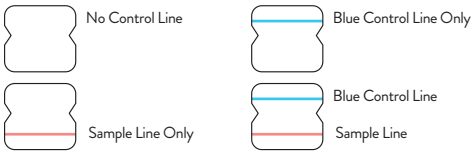
Negative Result

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 line is positive.

Positive Result

If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated.

Invalid Result



Procedure for External Quality Control Testing

External Controls require 8 drops of Extraction Reagent

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 shown.

In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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Scarborough, Maine 04074 USA
www.globalpointofcare.abbott

℞ Only
IVD

IN195001 Rev. 1 2020/08

Abbott
BinaxNOW
COVID-19 Ag

ProCard

Size:
5.5" x 8.0"

Printed Colors

CMYK

Incoming Inspection Colors (For Reference Only)
Colors below are not used for printing

- PMS 2995 U Primary Blue
- PMS 2995 U Primary Blue 70%
- PMS 224 U Magenta Pink
- PMS 303 U Dark Blue
- PMS 185 U Red
- PMS 185 U Red 70%

PN: IN195001
Rev: 1

Date of Last Revision:
1.7 2020/08/25

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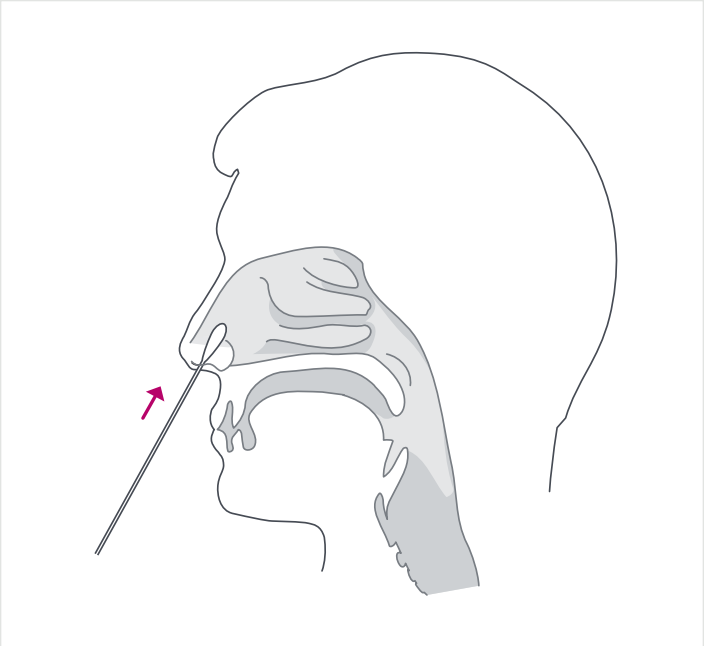
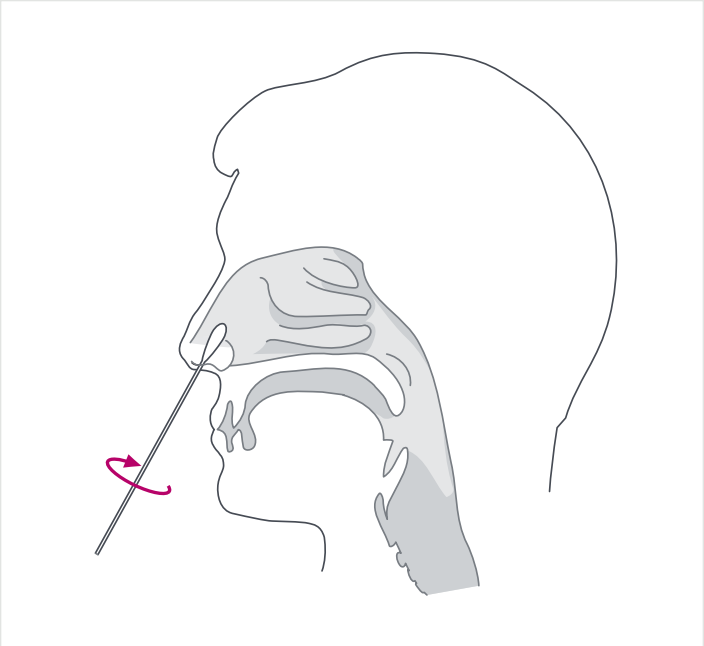
TECH TIPS

COLLECTION OF A NASAL SWAB FOR THE **BINAXNOW™ COVID-19 AG CARD** (ANTIGEN TEST)





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.

IMPORTANT REMINDERS

- Please refer to the BinaxNOW COVID-19 Ag Card product insert for full details.
- Use only the swabs provided in the test kit.

Abbott BinaxNOW™ Testing Procedure Competency

Team Member Name: _____ Date: _____

Evaluator Name: _____

Date team member watched the Abbott BinaxNOW™ Training Modules: _____

Procedure Step	Done Correctly	Not Done Correctly
1. Gather test materials and label test card with patient info.		
2. Open card and lay it flat		
3. Inspect card for blue control line		
4. Perform Hand Hygiene and don gloves, N-95/KN-95, gown, and face shield. Explain procedure of Nasal Swab Sample to the Resident/Team member		
5. Insert the nasal swab less than1 inch into the nostril of the exhibiting the most drainage or congestion. Rotate the swab 5 times or more against the nasal wall		
6. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.		
7. Withdraw the swab from the nasal cavity. The sample is now ready for processing.		
8. Swabs should be tested as soon as possible after collection. Use only swabs provided with the kit.		
9. Hold extraction reagent bottle vertically. Hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the top hole		
10. DO NOT touch the card with the dropper tip while dispensing		
11. Insert swab into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE		
12. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). **Do not remove swab**		
13. Peel off adhesive liner from the right edge of the test card		
14. Close and securely seal the card		
15. Allow test to process for 15 minutes. ***Incorrect results may occur if development time is less than 15 minutes.**		
16. When test is ready, read and record results		
17. At the completion of testing cycle, remove gloves and perform Hand Hygiene.		
18. Clean bench/work surfaces with spray or disinfecting wipe		