# COVID-19 Testing Using Abbott BinaxNOW, Emergency Use Authorization, Procedure

| **Location (includes Employee Health, Custody Health, hospital and all inpatient and outpatient locations and subacute facilities of the hospital, unless otherwise indicated)** | |
|---|---|
| Enterprise Wide, Includes Employee Health and Custody Health | X |
| O'Connor Hospital | |
| Santa Clara Valley Medical Center | |
| St. Louise Regional Hospital | |

| **Who May Perform This Procedure** | | | |
|---|---|---|---|
| RN | X | MUC | |
| LVN | X | HSR | |
| HSA | | Techs | |
| MA | | MD, APPs, Residents | X |
| Other (specify) Clinical Lab Scientist | X | | |

**REFERENCES:**

BinaxNow COVID-19 Ag Card, Abbott Diagnostics Scarborough, Inc., Accessed 12.21.2020 from: https://www.fda.gov/media/141570/download

BinaxNOW™ COVID-19 Ag Card, Abbott Diagnostics Scarborough, Inc. Fact Sheet for Healthcare Providers, Updated December 16, 2020. Accessed 12.21.2020 from: https://www.fda.gov/media/141568/download

BinaxNOW™ COVID-19 Ag Card, Abbott Diagnostics Scarborough, Inc. Fact Sheet for Patients, Updated December 16, 2020. Accessed 12.21.2020 from: https://www.fda.gov/media/141569/download

SARS-CoV-2 Testing Procedure for Asymptomatic and Symptomatic Patients and Healthcare Workers (HCWs). SARS-CoV-2 Testing Procedure

SARS-CoV-2 Nasal Swab Collection Procedure for Asymptomatic Healthcare Workers in the County of Santa Clara Health System. SARS-CoV-2 Nasal Swab Collection Procedure

**PURPOSE:** To outline the indication(s) and process for use of the BinaxNOW™ COVID-19 Ag Card.

**BACKGROUND:**

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus is the cause of the COVID-19 pandemic that has spread over 190 countries, across all continents.

BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal (nares) swabs with a 15-minutes turnaround time. The BinaxNOW COVID-19 Ag Card kit contains all components required to carry out an assay for SARS-CoV-2 (test cards, extraction reagent, nasal swabs, positive control swab, negative control swab, product insert and procedure card).

The BinaxNOW's Emergency Use Authorization (EUA) is for symptomatic individuals within 7 days of symptom onset and can be used as a point-of-care test in settings that operate under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Less is known about the use of BinaxNOW in asymptomatic people. However, preliminary data suggests that there is value to incorporating BinaxNOW into the testing algorithm of asymptomatic individuals as part of a cluster investigation or routine frequent screening.

**POLICY:**

A. All individuals will receive the Fact Sheet for Patients: Abbott Diagnostics Scarborough, Inc. – BinaxNOW COVID-19 Ag Card.

B. This test is to be performed on anterior nasal (nares) swab specimens of the following groups:

**Patients**

- Symptomatic individuals within 7 days of symptom onset.
- Asymptomatic individuals as part of a concern for possible outbreak, or cluster investigation.
- All patients presenting for care in EPS.
- Asymptomatic patients presenting to ENT clinic who may undergo an AGP.
- Asymptomatic patients presenting to oncology clinic for treatment.
- Asymptomatic patients presenting for dialysis.
- Inpatients with a persistent positive test (beyond 90 days) to assist in the assessment for new versus old infection.
- Asymptomatic patients presenting to pediatric short-stay
- Asymptomatic patients presenting to dental clinic

**Visitors**

- Asymptomatic visitors presenting to maternal child units or the ICU, or other locations approved by Hospital Command Center, if needed.

**Staff**

- Symptomatic individuals within 7 days of symptom onset.
- Asymptomatic individuals as part of a concern for a possible outbreak or a cluster investigation.
- Asymptomatic screening if consistent with current Employee Health policies.

C. Asymptomatic workers will be provided written and verbal instructions on how to perform self-swab specimen collection and will be observed by a staff member as the procedure is performed. The observer does not have to be a clinical staff person and observation staff may include volunteers. The observer will be trained on the self-collection procedure.

**PRINCIPLE:** The BinaxNOW COVID-19 Ag Card is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card. To perform the test, a nasal swab specimen is collected from the individual, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The test sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole (where the extraction reagent is). The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.

**SPECIMEN REQUIREMENTS:**

1. Accepted specimen types: Anterior nasal (nares)
2. Accepted swabs: swab provided with the test kit ONLY.
3. Stability: Swabs can be held at room temperature (15° to 30°C / 59° to 86° F) for up to one (1) hour prior to testing.

**REAGENTS AND EQUIPMENT:**

1. Test Cards: A cardboard, book-shaped hinged test card containing the test strip
2. Extraction Reagent: Bottle containing 10 mL of extraction reagent

3. Store kit at 2° to 30° C (35.6° to 86° F). The BinaxNOW COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

4. Nasal Swabs: Sterile swabs for use with BinaxNOW COVID-19 Ag Card test

5. Positive Control Swab: Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab

6. Negative Control Swab: The use of a sterile patient swab ensures appropriate negative results are obtained

7. Clock, timer, or stopwatch

8. Cleaning Agents

    A. 70% ethanol - available in commercial wipes or on a damp, lint free cloth or
    B. 70% isopropanol - available in commercial wipes or on a damp, lint free cloth or
    C. 10% bleach - on a damp, lint free cloth only

9. Personal Protective Equipment
    - Gloves
    - Eye protection (goggles or face shield)
    - Surgical mask (if testing asymptomatic individual), N95 (if testing symptomatic individual or in mass testing setting)

**ADDITIONAL SUPPLIES:**

1. Surgical mask or N95 mask if symptomatic individual or mask testing setting (for staff/observer)
2. Gloves
3. Face shield/goggles for staff/observer
4. Hand sanitizer or hand washing station
5. Red biohazard bags and trash can

## 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:**

1. 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.

2. 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:**

BinaxNOW COVID-19 Ag Card kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab.

Test these swabs once:

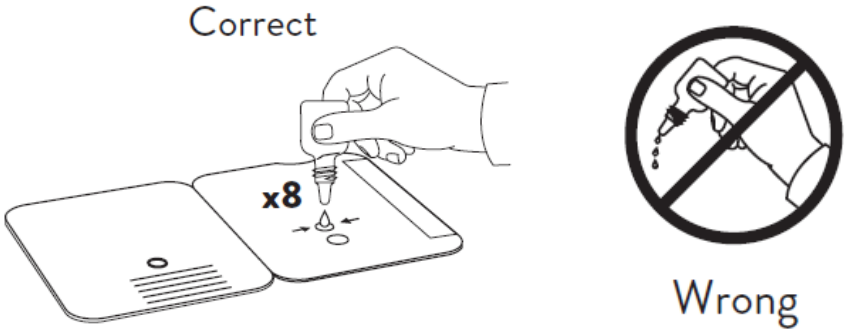
1. With each new shipment received.
2. For each untrained operator.
3. With annual competency.
4. When kit performance is questionable.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Point of Care Testing (see *Contacts*) during normal business hours before testing patient specimens.

**Quality Control protocol:**

Wash hands and don PPE. Open the test card just prior to use, lay it flat, and perform assay as follows.

1. Hold Extraction Reagent bottle vertically hovering ½ 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 Patient Testing Procedure for the positive and negative control swabs.

3. Document the external control result and Control Line on the Quality Control Log (see Attachment 1).

| | **SPECIMEN COLLECTION (Staff-Collected) AND TESTING PROCEDURE** | | |
|---|---|---|---|
| 1. | Done PPE (face mask, face shield/goggles, gloves) | 1.1 | If already wearing PPE, change gloves |

2. Provide individual with the COVID-19 Testing Consent Form and obtain signature.

3. Identify individual using two (2) patient identifiers.

4. Instruct individual to continue to wear face mask.

5. Explain procedure to individual

6. Open the swab package and remove the swab. Avoid contact with swab tip.

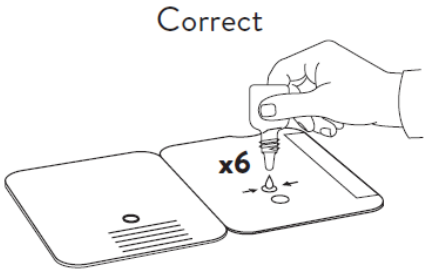
6.1 DO NOT use other swabs

7. Instruct individual to move mask down so that the nose is exposed but covering the mouth.

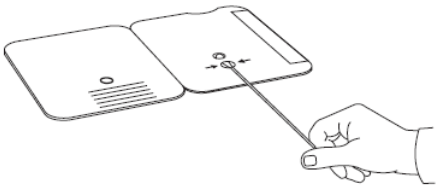
8. Ask the individual to tilt head back slightly to straighten the nasal passage.

9. Insert the entire absorbent tip of the swab (about 1-1.5 cm) into the nostril. Rotate the swab in a circular path against the nasal wall 5 times or more for 15 seconds.
Using the same swab, repeat the procedure in the other nostril

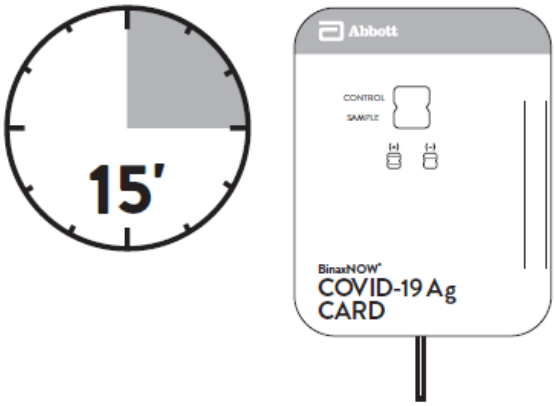
10. Slowly adds 6 drops of extraction reagent to the top hole of the swab well. Do not touch the card with the dropper tip.


11. Insert sample 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. | 12.1 False negative can occur if the sample swab is not rotated. |
| 13. | Peel off the adhesive liner from the right edge of the test card. Close and securely seal the card. Leave the card flat and undisturbed. | |




| | | |
|---|---|---|
| 14. | Read the result (see below for interpretation) 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. | |
| 15. | Document result and control line on the Quality Control Log (Attachment 1) and in medical or Health record. | |
| 16. | Clean work area after each test. | |

**SPECIMEN COLLECTION (Self – Collected) AND TESTING PROCEDURE**

| | | |
|---|---|---|
| 1. | Done PPE (face mask, face shield/goggles, gloves) | 1.1 If already wearing PPE, change gloves |

2. Provide individual with the COVID-19 Testing Consent Form and obtain signature.

3. Identify individual using two (2) patient identifiers.

4. Instruct individual to continue to wear face mask. Maintain 6 feet distance.

5. Observer opens the test card and lay it flat.

5.1 The test card must be flat when performing test.

6. Observer explains procedure to individual. Instruct individual to open the swab package and remove the swab. Avoid contact with swab tip.

6.1 DO NOT use another swab

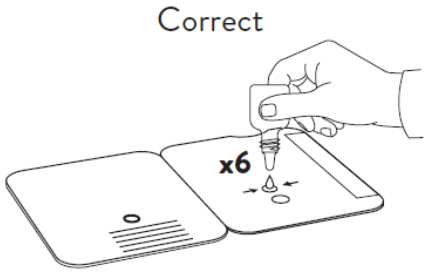
7. Instruct individual to move mask down so that the nose is exposed but covering the mouth.

8. Ask the individual to tilt head back slightly to straighten the nasal passage.

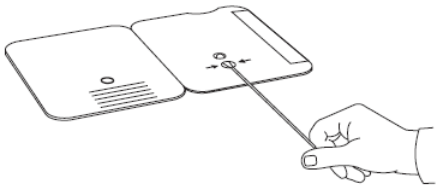
9. Insert the entire absorbent tip of the swab (about 1-1.5 cm) into the nostril. Rotate the swab in a circular path against the nasal wall 5 times or more for 15 seconds.
Using the same swab, repeat the procedure in the other nostril

10. Instruct individual to hand the self-collected swab to the observer

11. Observer slowly adds 6 drops of extraction reagent to the top hole of the swab well. Do not touch the card with the dropper tip.

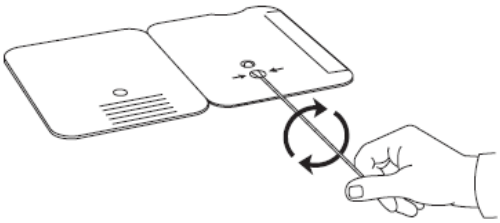



12. Insert sample into Bottom Hole and firmly push upwards so that the swab tip is visible in the Top Hole

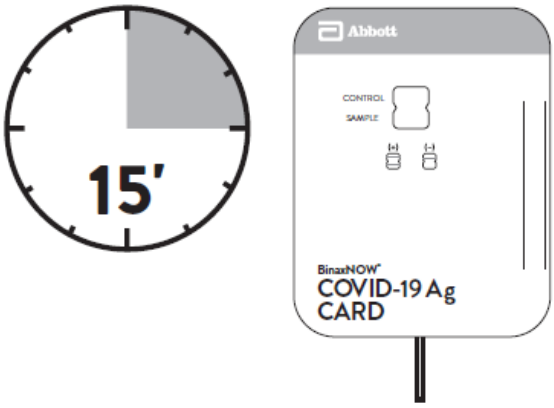


13. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.

13.1 False negative results may can occur if the sample swab is not rotated



14. Peel off the adhesive liner from the right edge of the test card. Close and securely seal the card. Leave the card flat and undisturbed.



15. Read the result (see below for interpretation).
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.

16. Document result and control line on the Quality Control Log (Attachment 1) and in medical or Health record.

17. Clean work area after each test

## 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 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.


No Control Line


Sample Line Only


Blue Control Line Only


Blue Control Line
Sample Line

**REFERENCE RANGE**

- Normal Range: COVID-19 Negative
- Abnormal Value: COVID-19 Positive

## RESULT REPORTING

**Negative Results**

- If individual is symptomatic: Advise individual of need to collect another specimen for an **alternative molecular testing by the laboratory**. Follow current SARS-CoV-2 Testing Procedure for asymptomatic and symptomatic patients and HCWs in collecting the new specimen.

- If individual is asymptomatic: document as negative.

**Positive Results**

- If individual is symptomatic: documents as positive.

- If individual is asymptomatic: Advise individual of need to collect another specimen for **alternative molecular testing by the laboratory**. Follow current SARS-CoV-2 Testing Procedure for asymptomatic and symptomatic patients and HCWs in collecting the new specimen.

## COMPETENCY ASSESSMENT

All operators must read the procedure manual and complete the Abbott ID NOW COVID-19 Competency Assessment during initial training.

Competency is assessed at orientation and annually using at least two of the following methods:

1. Performing a test on a blind specimen.
2. Unit Expert observes performance of routine work.
3. Each user's quality control performance is monitored.
4. Written testing specific to the method.

The name and operator ID of newly documented operators must be provided to the POCT program. Only approved operators are allowed to run the test.

Expired Operators: Operators who fail to meet competency requirements within 365 days will be required to undergo retraining and competency assessment according to above.

## CONTACTS

The Point of Care Coordinators are accessible by phone or email and may be contacted with any questions and concerns regarding Point of Care testing and/or equipment. Support can be obtained after hours by contacting the main laboratory and requesting assistance. If out of the office, emails are encouraged. All calls will be returned as soon as possible.

**Santa Clara Valley Medical Center and Custody Health:**
Open Hours: M-F 7:30am – 4:00pm
751 S. Bascom Ave San Jose CA 95128 | C Building Basement BC055
Office: 408-885-6321
Fax: 408-885-6366
Email: HHSLabPOCT@hhs.sccgov.org

**O'Connor Hospital:**
2105 Forest Ave, San Jose, CA 95128
Office: 408-947-2965
Email: luke.wang@hhs.sccgov.org

**St. Louise Regional Hospital:**
9400 No Name Uno, Gilroy, CA 95020
Office: 408-848-8630
Email: thomas.mendall@hhs.sccgov.org

If unexplained, invalid, dual positive or false test results continue to be obtained, please contact Abbott BinaxNOW Technical Support for assistance:
1-855-731-2288
ts.scr@alere.com

**Attachments:**

Attachment 1: P.O.C.I.T. Abbott BinaxNOW Patient and QC Log

**Policies replaced (if applicable)**: None

**Issued:** Hospital Command Center
**Date:** **12.29.20, 8.25.21**

**Approved:**

DocuSigned by:
Paul E. Lorenz
47ECF3A78343489...
Date: 8/25/2021
Paul E. Lorenz
Chief Executive Officer

DocuSigned by:
Elisabeth Mailhot
6519DF89126E4E0...
Date: 8/25/2021
Elizabeth A. Mailhot, M.D.
Chairperson, Dept. of Laboratory Services

DocuSigned by:
Ada Chan
95E47683734B4DA...
Date: 9/1/2021
Ada Chan, M.D.
Medical Director Clinical Laboratory

# P.O.C.I.T. Abbott BinaxNOW Patient and QC Log

**Location _____**

| | **BinaxNOW Kit** | | **Positive Control Swab** | | | **Negative Control Swab** | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Date** | Lot # | Exp. Date | Lot # | Exp. Date | **Result** | **Lot #** | Exp. Date | **Result** | **Initials** |
| | | | | | **Pass** **Fail** | | | **Pass** **Fail** | |

Note: If QC test result is out of range, please call POC Lab (see *Contacts* in Test Procedure)

| Patient Sticker/two (2) Identifier | Control Line (Circle One) | Specimen Result (Circle One) | Initials |
|---|---|---|---|
| | Valid Invalid | Positive Negative | |
| | Valid Invalid | Positive Negative | |
| | Valid Invalid | Positive Negative | |