# BinaxNOW™ COVID-19 Ag CARD 2 HOME TEST

Healthcare Provider Instructions for Use

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

For use with anterior nasal swab specimens

For *in vitro* Diagnostic Use Only

## INTENDED USE

The BinaxNOW COVID-19 Ag Card 2 Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for non-prescription home use with self-collected observed direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older.

The BinaxNOW COVID-19 Ag Card 2 Home Test is to be performed only with the supervision of a telehealth proctor.

The BinaxNOW COVID-19 Ag Card 2 Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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. Individuals who test positive with the BinaxNOW COVID-19 Ag Card 2 Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results 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. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

The BinaxNOW COVID-19 Ag Card 2 Home Test is intended for observed non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The BinaxNOW COVID-19 Ag Card 2 Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

The telehealth provider will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

## SUMMARY AND EXPLANATION OF THE TEST

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 can cause mild to severe respiratory illness and has spread globally, including the United States.

The BinaxNOW COVID-19 Ag Card 2 Home Test is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from anterior nasal swabs, without viral transport media. The BinaxNOW COVID-19 Ag Card 2 Home Test kit contains all components required to carry out an assay for SARS-CoV-2.



## PRINCIPLES OF THE PROCEDURE

The BinaxNOW COVID-19 Ag Card 2 Home Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from direct anterior 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. The 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, an anterior nasal swab specimen is collected from the individual under observation , then 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient 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. 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.

## REAGENTS AND MATERIALS

### Materials Provided

**Test Cards (2):** A cardboard, book-shaped hinged test card containing the test strip

**Extraction Reagent (2):** Bottle containing <1 mL of extraction reagent

**Nasal Swabs (2):** Sterile swab for use with BinaxNOW COVID-19 Ag 2 Card Home test

### Materials Required but not Provided

Clock, timer or stopwatch
Smart Phone:*Apple is ios11 or newer
Android is version 8 or newer

*Required to download the NAVICA app from the Google play store or Apple app store

## PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA.
3. Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
4. Use of gloves is recommended when conducting testing.
5. Keep testing kit and kit components out of the reach of children and pets before and after use
6. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
7. The emergency use of this product 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 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 declaration is terminated or authorization is revoked sooner.
8. Proper sample collection and handling are essential for correct results.
9. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
10. Do not touch swab tip when handling the swab sample.
11. Do not use kit past its expiration date.
12. Do not mix components from different kit lots.
13. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card or swab.
14. Dispose of kit components and patient samples in household trash.
15. INVALID RESULT can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, ½ inch above the swab well, and add drops slowly.
16. The Reagent Solution contains a harmful chemical (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222

| Chemical Name/CAS | GHS Code for each Ingredient | Concentration |
|---|---|---|
| Sodium Azide/26628-22-8 | Acute Tox. 2 (Oral), H300<br>Acute Tox. 1 (Dermal), H310 | 0.0125% |



## STORAGE AND STABILITY

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

## INITIATING THE TELEHEALTH VISIT

Upon receipt of the BinaxNOW COVID-19 Ag Card 2 Home Test, the patient logs into NAVICA and selects, "I Already Have a Test Kit". The home user then visits the telehealth provider website to start testing and waits in queue to connect to the telehealth proctor.

## DIRECTIONS FOR RUNNING THE BINAXNOW COVID-19 AG 2 CARD HOME TEST

**DO NOT OPEN ITEMS UNTIL INSTRUCTED TO DO SO**

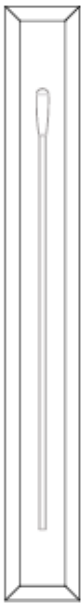
Wash or sanitize your hands. Make sure they are dry before starting.



**1. Set Up**
DO NOT open items until instructed.
It is recommended gloves (not provided) also be used during testing.

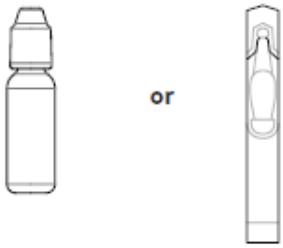
**You will need the following to perform a test:**

1 Swab



1 Test Card


1 Bottle



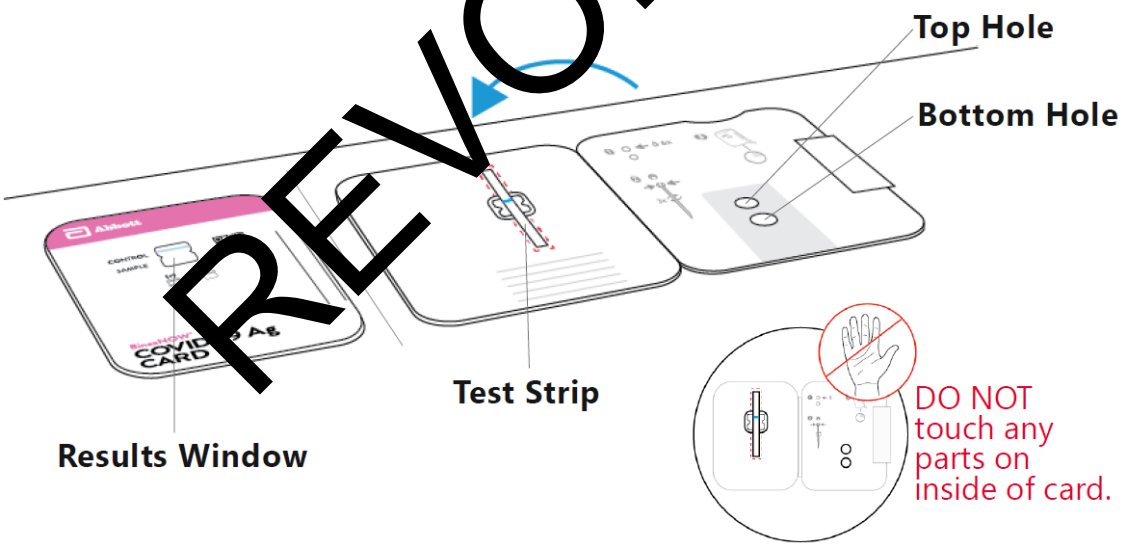
**2. Open Pouch and Scan QR Code on Card**

If using a mobile device:

If using a computer:

**3. Open Card**

Card must stay FLAT on table for entire test.



## 4. Apply Fluid to Top Hole

**A.** Remove dropper bottle cap.

**B.** Hold dropper bottle straight over TOP HOLE, not at an angle.

**C.** Put 6 DROPS into TOP HOLE. Do not touch card with tip.

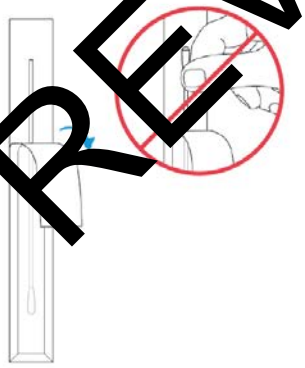

***Note:*** *False negative results may occur if less than 6 drops of fluid is used.*



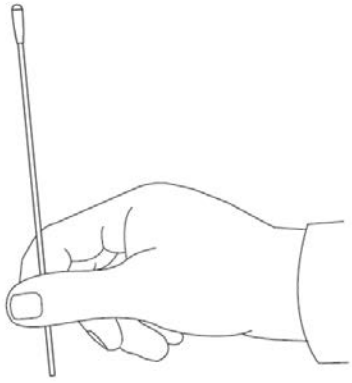
## 5. Open Swab

Keep fingers away from swab end.

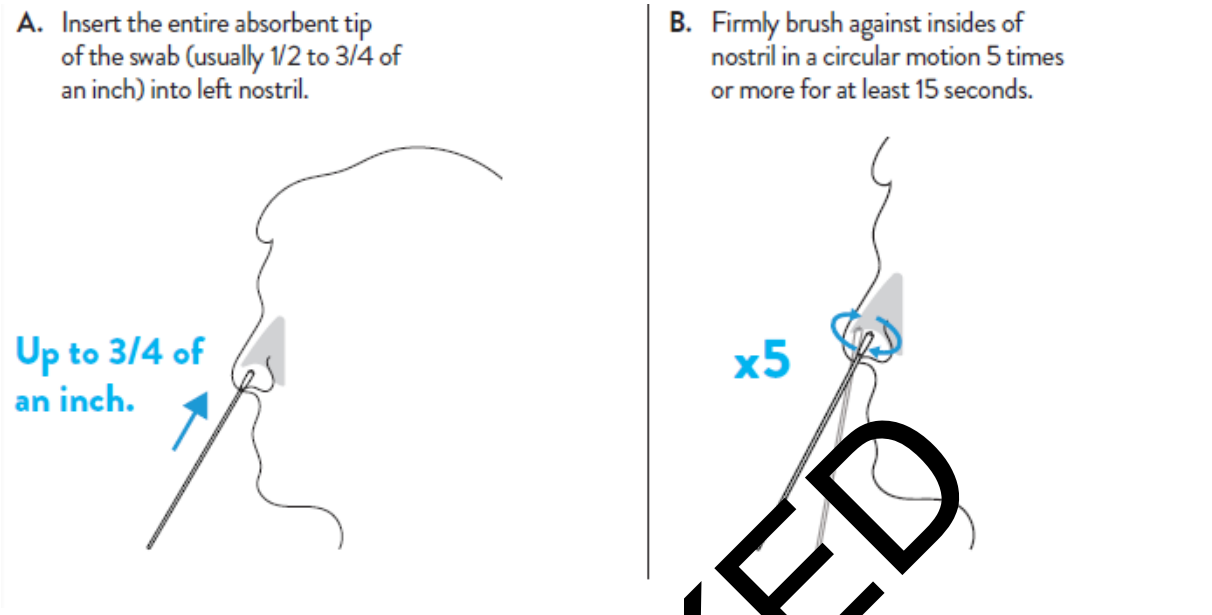
**A.** Open swab package at stick end.



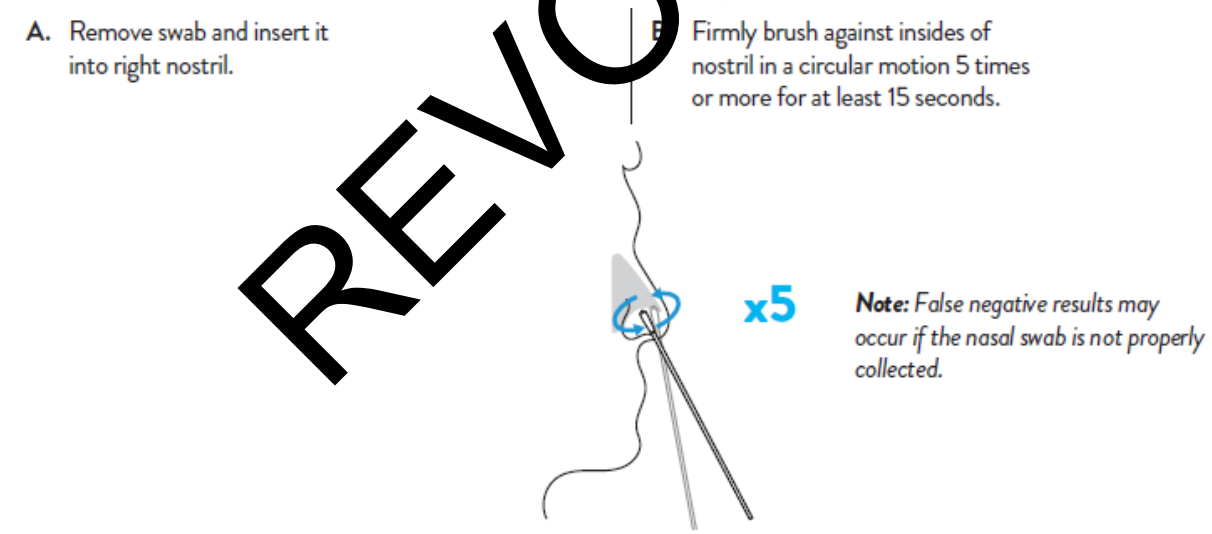
**B.** Take swab out.



**6. Swab Left Nostril**



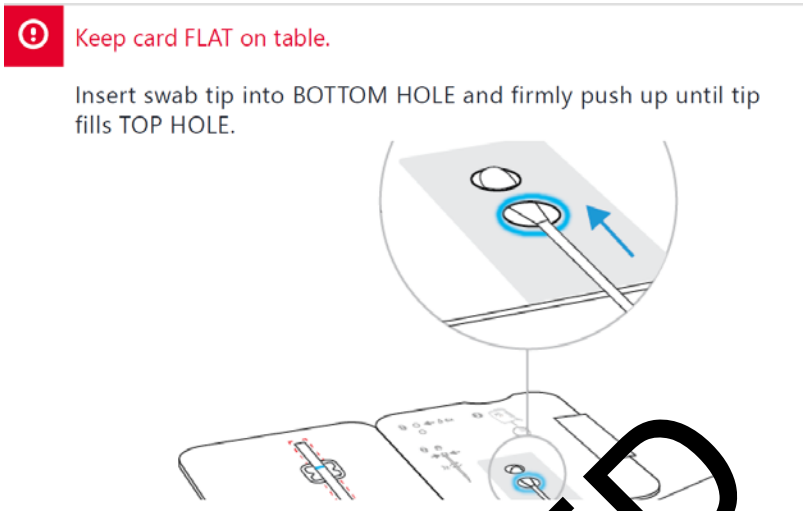

**7. Swab Right Nostril**



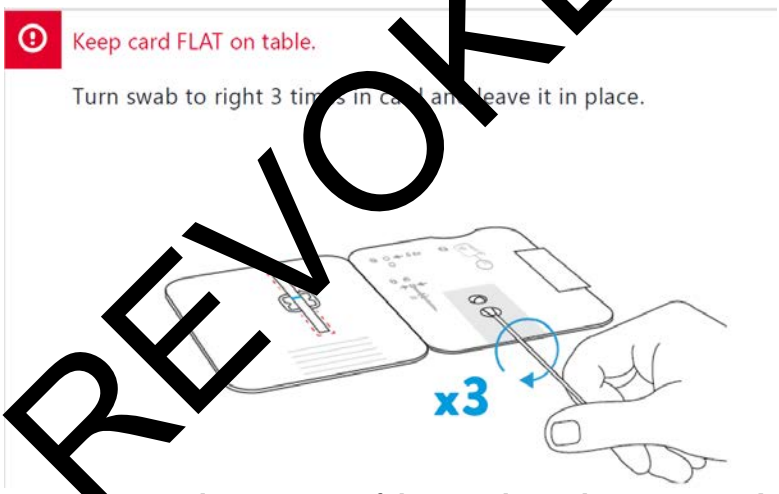



***Note:*** *False negative results may occur if the nasal swab is not properly collected.*

**8. Insert Swab Into Bottom Hole**



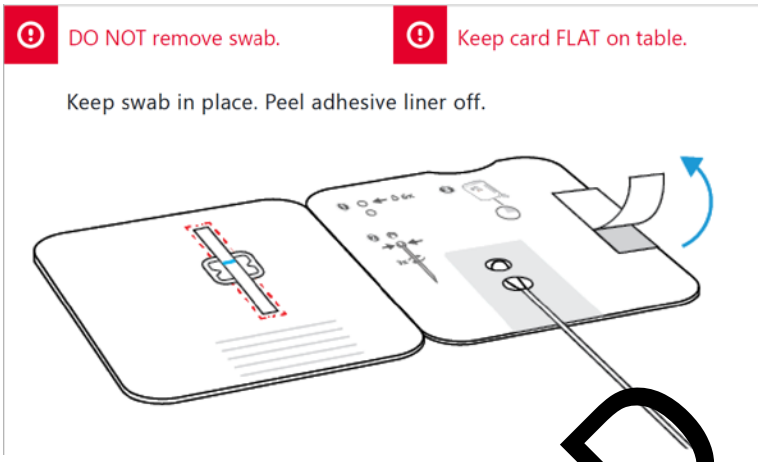

**9. Turn Swab 3 Times**



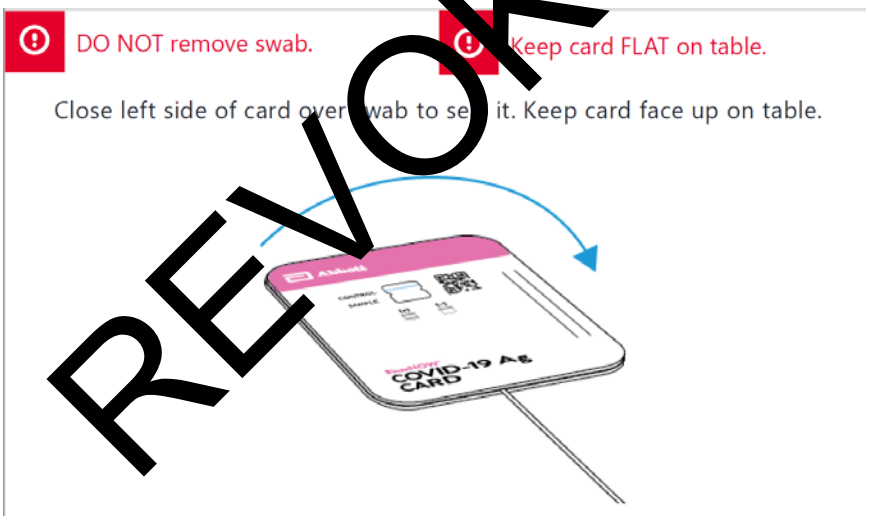



***Note:*** *False negative results can occur if the sample swab is not turned prior to closing the card.*

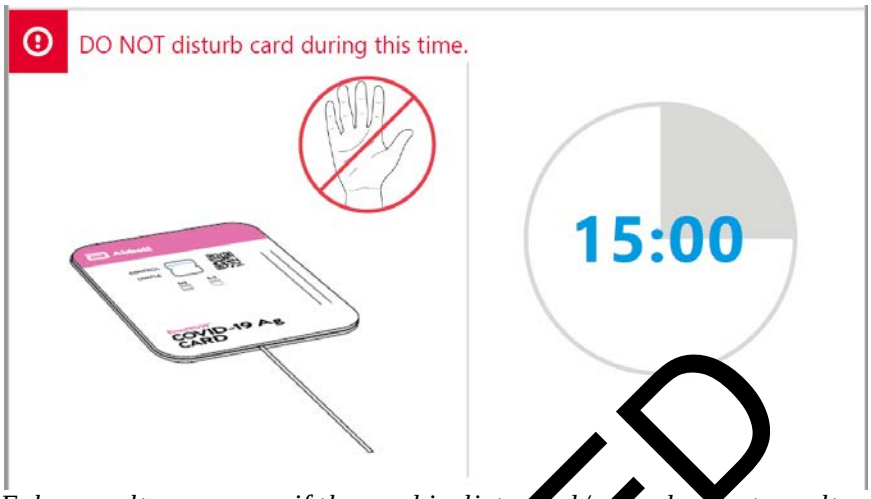
**10. Peel Strip**




**11. Close Card and Seal**



## 12. Wait 15 Minutes



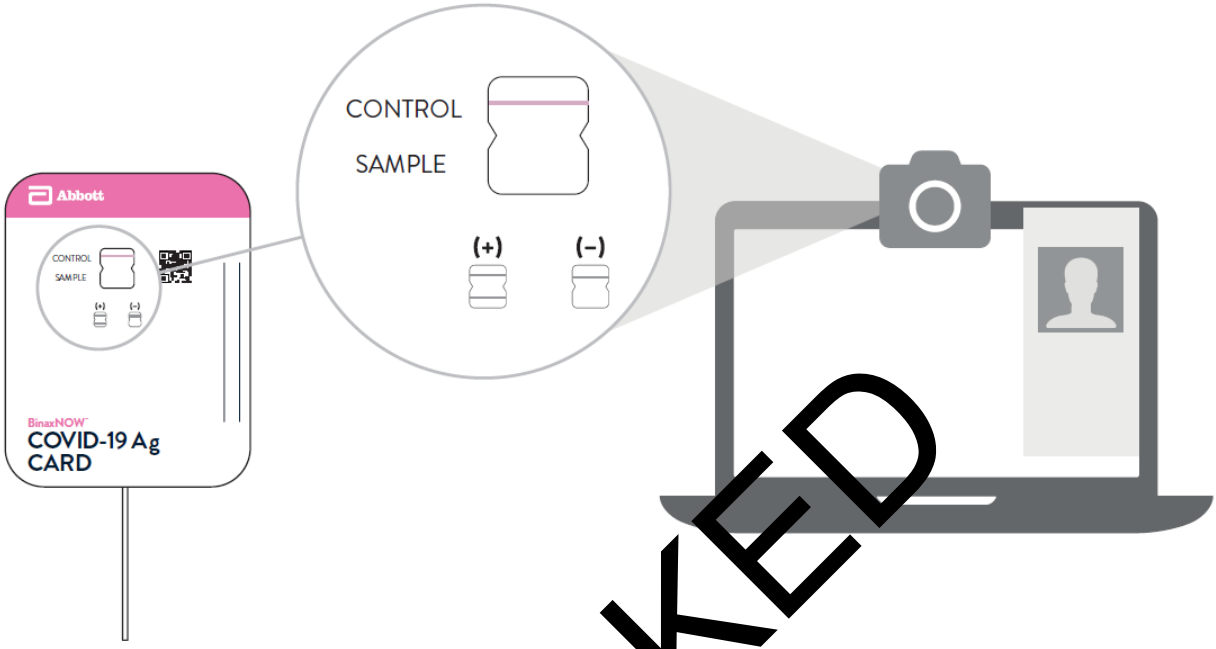

***Note:*** *False results can occur if the card is disturbed/moved or test results are read before 15 minutes.*

***Note:*** *False results can occur if test results are read after 30 minutes.*



## 13. Scan QR Code

## 14. Show Result to Your Proctor






### RESULT INTERPRETATION

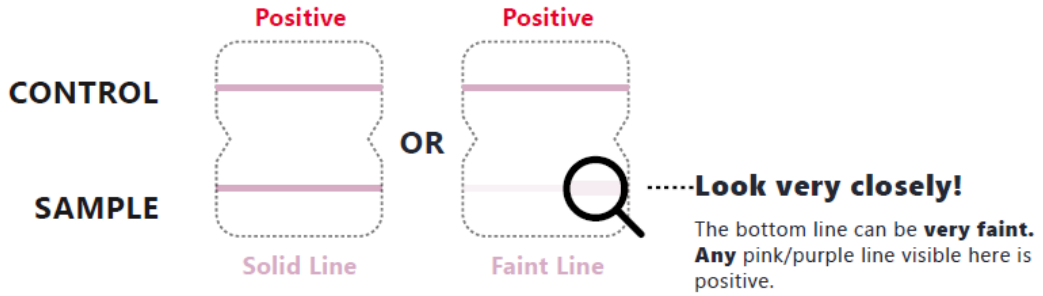
There are three types of results possible. You will be instructed how to read each type in a specific order. Follow this order with your proctor:

1. **Check for a Positive Result**
2. **Check for a Negative Result**
3. **Check for an Invalid Result**

**Check for Positive COVID-19 Result**

Find result window and look carefully for two pink/purple lines in window.

- **Positive Result:** Two pink/purple lines will appear. One on the top half and one on the bottom half. **COVID-19 was detected.**




Here are photos of actual positive tests. On the right, note how faint the bottom line can get.

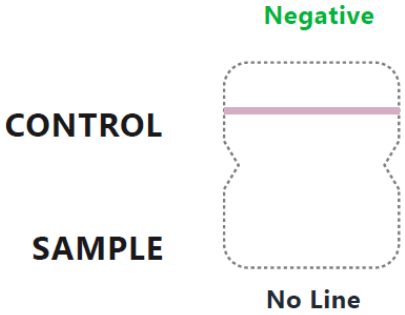
A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.



**Check for Negative COVID-19 Result**

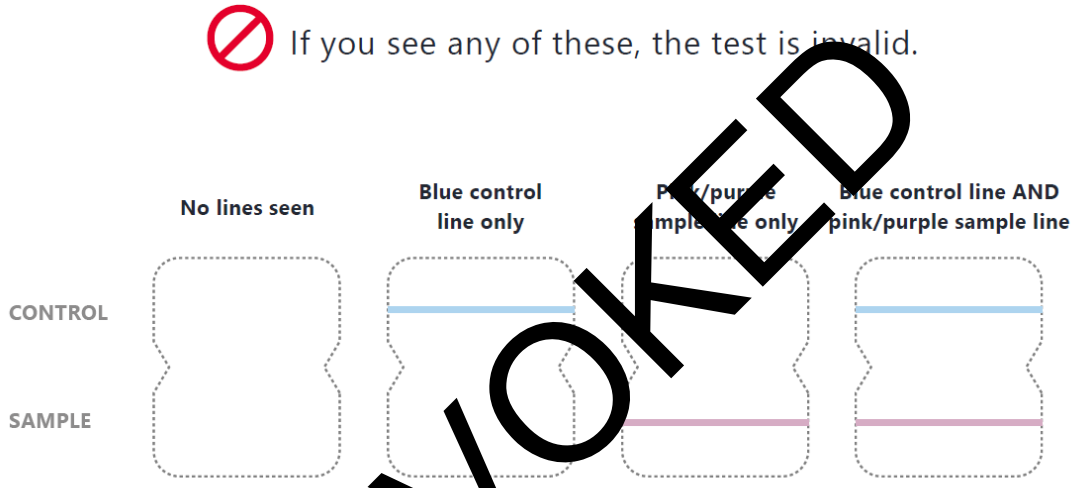
Find result window and look for a single pink/purple line in window.

- **Negative Result:** A single pink/purple line on the top half where it says "Control." **COVID-19 was not detected.**



A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19n, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection

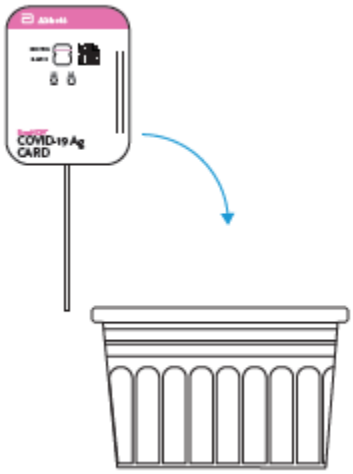
**Check for Invalid Result**






**Remind the patient that a second BinaxNOW COVID-19 Ag Card 2 Home Test is required to be performed within 3 days with at least 36 hours between tests.**

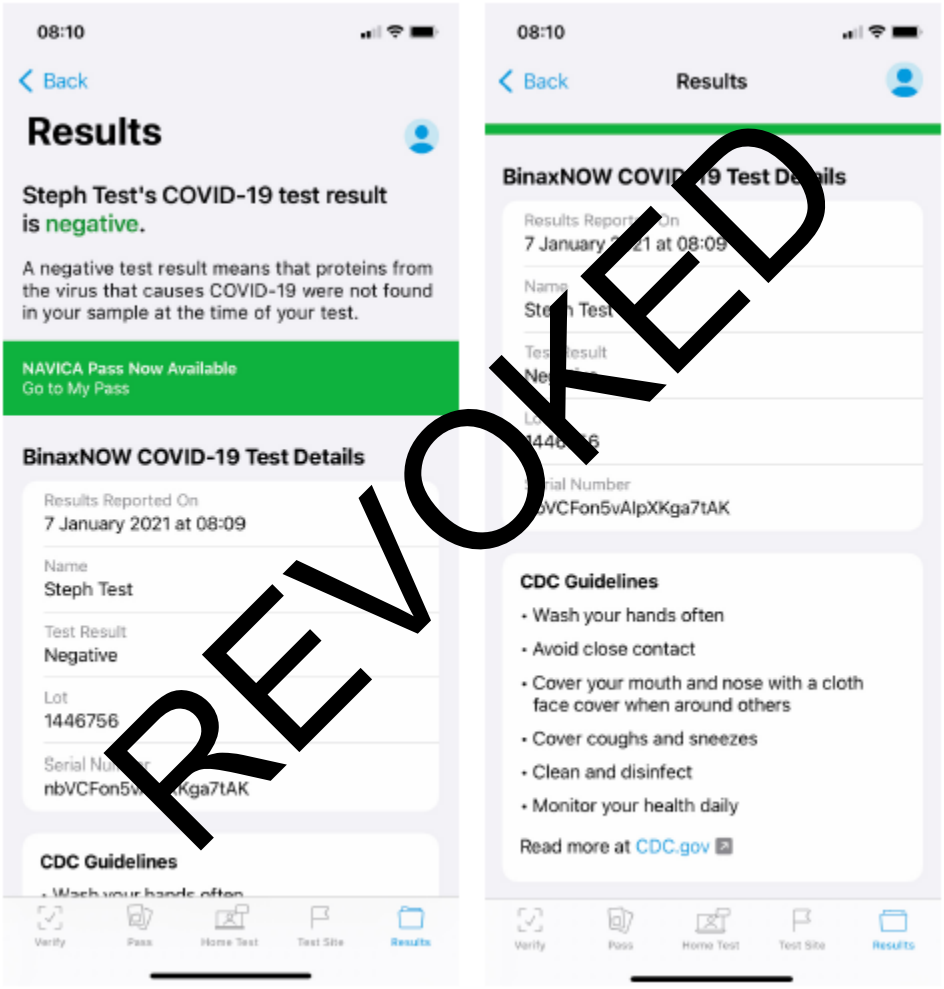
**Dispose In Trash**



**Reporting Patient Results Using the NAVICA app**

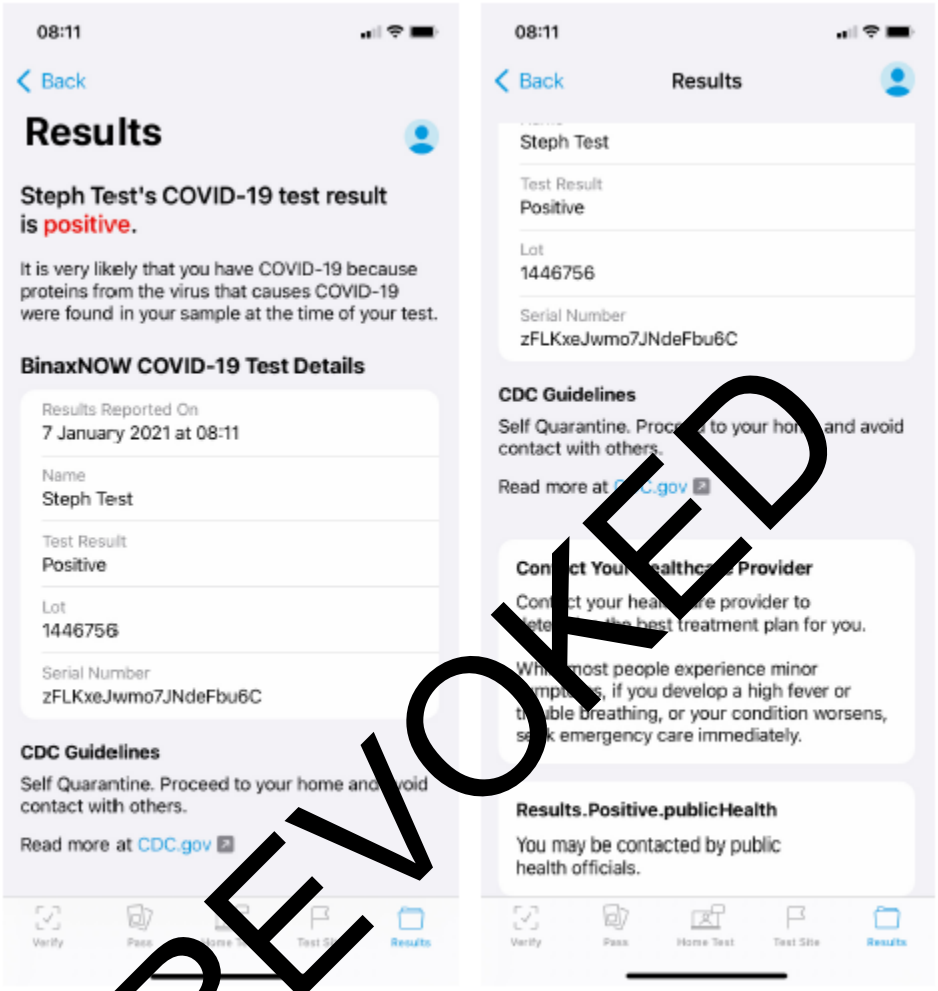
Upon completion of the test and result interpretation by the user, the telehealth proctor will send the results to the user via the NAVICA app and the telehealth provider will report results to relevant public health authorities. The user will be notified by email and on their mobile device that their results are ready. The user will go to the results screen in NAVICA to obtain their results.

If the BinaxNOW COVID-19 Ag Card 2 Home Test result is Negative, the user will receive the following:



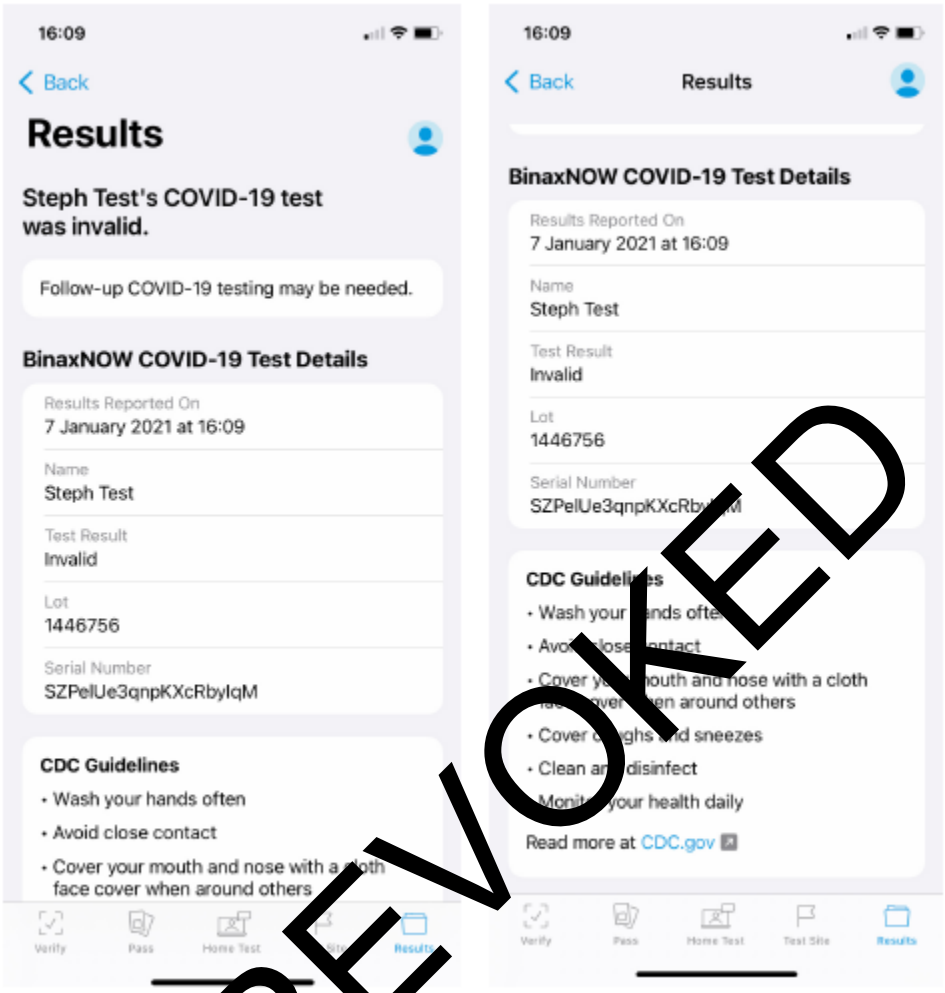

REVOKED

If the BinaxNOW COVID-19 Ag Card 2 Home Test result is Positive, the user will receive the following:




REVOKED

If the BinaxNOW COVID-19 Ag Card 2 Home Test result is Invalid, the user will receive the following:






**LIMITATIONS**

- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- The performance of the BinaxNOW COVID-19 Ag Card 2 Home Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a specimen is improperly collected or handled.
- False negative results may occur if inadequate extraction buffer is used (e.g., <6 drops).
- False negative results may occur if specimen swabs are not twirled within the test card.
- False negative results may occur if swabs are stored in their paper sheath after specimen

collection.

- Positive test results do not rule out co-infections with other pathogens.
- False negative results are more likely after eight days or more of symptoms.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- The presence of mupirocin may interfere with the BinaxNOW COVID-19 Ag Card 2 Home test and may cause false negative results.
- Negative results are presumptive, do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.
- Clinical performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over three days with at least 36 hours between tests has not been determined, a study to support use will be completed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in November 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.



## PERFORMANCE CHARACTERISTICS

## CLINICAL PERFORMANCE

Clinical performance characteristics of BinaxNOW COVID-19 Ag Card 2 Home Test was evaluated in an ongoing multi-site prospective study in the U.S. A total of four (4) investigational sites throughout the U.S. participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with suspected COVID-19 within 7 days of symptom onset. Each Subject was provided a BinaxNOW COVID-19 Ag 2 Card Home Test. Under the observation and coaching of a clinical site staff member trained as a proctor, the Subject self-collected one (1) nasal swab and performed the BinaxNOW COVID-19 Ag 2 Card Home test. Test results were interpreted and recorded by the Subject or other home user and independently by the proctor. Parents of pediatric Subjects under the age of 14 or Legally Authorized Representatives of adult Subjects unable to perform self-collection collected one (1) nasal swab from the Subject, performed the BinaxNOW COVID-19 Ag 2 Card Home test, then interpreted and recorded the result for the patient.

An FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

The performance of BinaxNOW COVID-19 Ag Card 2 Home Test was established with 53 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

**BinaxNOW COVID-19 Ag Card 2 Home Test Performance within 7 days of symptom onset against the Comparator Method***

| BinaxNOW COVID-19 Ag 2 Card Home Test | Comparator Method | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 22 | 0 | 22 |
| Negative | 2 | 28 | 30 |
| Total | 24 | 28 | 52** |
| Positive Agreement: 22/24 91.7% (95% CI: 73.0% - 98.9%) | | | |
| Negative Agreement: 28/28 100.0% (95% CI: 87.7% - 100.0%) | | | |

* The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.

**1 sample generated an invalid BinaxNOW COVID-19 Ag 2 Card result (0.1% invalid rate)



Performance of BinaxNOW COVID-19 Ag Card 2 Home Test, with the test performed and results interpreted by the home user is similar to performance obtained by test operators with no laboratory experience. Due to the relatively small sample size for the home use clinical study, at the time of the interim analysis, the BinaxNOW COVID-19 Ag Card 2 Home Test positive agreement established in this ongoing clinical study is estimated to be between 73.0% and 98.9% as reflected in the 95% Confidence Interval. This is consistent with the performance established in a separate multi-site study in the US, where the BinaxNOW COVID-19 Ag Card test was performed and results interpreted by test operators with no laboratory experience. In that study, BinaxNOW COVID-19 Ag Card test positive agreement was 84.6% (95% CI: 76.8% - 90.6%), refer below:

The performance of BinaxNOW COVID-19 Ag Card was established with 460 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

**BinaxNOW COVID-19 Ag Card Performance within 7 days of symptom onset against the Comparator Method***

| BinaxNOW COVID-19 Ag Card | Comparator Method | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 99 | 5 | 104 |
| Negative | 18 | 338 | 356 |
| Total | 117 | 343 | 460 |
| Positive Agreement: 99/117 84.6% (95% CI: 76.8% - 90.6%) | | | |
| Negative Agreement: 338/343 98.5% (95% CI: 96.6% - 99.5%) | | | |

* The performance of this test has not yet been clinically validated for use in patients without signs and symptoms of respiratory infection, or for serial screening applications and performance may differ in these populations.

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Patient demographics, time elapsed since onset of symptoms for all patients enrolled in the above study, are presented in the table below. Positive results broken down by days since symptom

onset:

| Days Since Symptom Onset | Cumulative RT-PCR Positive (+) | Cumulative BinaxNOW COVID-19 Ag Card 2 Home Test Positive (+) | PPA | 95 % Confidence Interval | |
|---|---|---|---|---|---|
| 1 | 12 | 10 | 83.3% | 51.6% | 97.9% |
| 2 | 34 | 28 | 82.4% | 65.5% | 93.2% |
| 3 | 50 | 41 | 82.0% | 68.6% | 91.4% |
| 4 | 63 | 50 | 79.4% | 67.3% | 88.5% |
| 5 | 78 | 63 | 80.8% | 70.3% | 88.8% |
| 6 | 90 | 75 | 83.3% | 74.0% | 90.4% |
| 7 | 117 | 99 | 84.6% | 76.8% | 90.6% |
| 8 to 10 | 144 | 118 | 81.9% | 74.7% | 87.9% |
| 11 to 14 | 161 | 126 | 78.3% | 71.1% | 84.4% |
| All specimens | 167 | 129 | 77.2% | 70.1% | 83.4% |

A cohort of patients who presented with symptom onset greater than seven days were enrolled in the clinical study (n = 161). The positive agreement in patients with symptoms greater than seven days was 60% (30/50) and negative agreement was 98% (109/111). Therefore, negative results in patients with symptom onset greater than seven days should be interpreted with caution, as the sensitivity of the assay decreases over time.

## ANALYTICAL PERFORMANCE

### Limit of Detection (Analytical Sensitivity)

BinaxNOW COVID-19 Ag Card 2 Home Test limit of detection (LOD) was determined by evaluating different concentrations of heat inactivated SARS-CoV-2 virus. Presumed negative natural nasal swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this natural nasal swab matrix pool to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure.

The LOD was determined as the lowest virus concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The BinaxNOW COVID-19 Ag Card 2 Home Test LOD in natural nasal swab matrix was confirmed 140.6 $TCID_{50}$/mL.

**Limit of Detection (LoD) Study Results**

| Concentration $TCID_{50}$/mL | Number Positive/Total | % Detected |
|---|---|---|
| 140.6 | 20/20 | 100% |

## Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross reactivity and potential interference of BinaxNOW COVID-19 Ag Card 2 Home Test was evaluated by testing 37 commensal and pathogenic microorganisms (8 bacteria, 14 viruses, 1 yeast and pooled human nasal wash) that may be present in the nasal cavity. Each of the organism, viruses, and yeast were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (45 $TCID_{50}$/swab). No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

| Potential Cross-Reactant | | Test Concentration |
|---|---|---|
| Virus | Adenovirus | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human metapneumovirus (hMPV) | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Rhinovirus | 1.0 x $10^5$ PFU/mL |
| | Enterovirus/Coxsackievirus B | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human coronavirus OC43 | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human coronavirus 229E | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human coronavirus NL63 | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human parainfluenza virus | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human parainfluenza virus 2 | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human parainfluenza virus 3 | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Human parainfluenza virus 4 | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Influenza A | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Influenza B | 1.0 x $10^5$ $TCID_{50}$/mL |
| | Respiratory Syncytial Virus A | 1.0 x $10^5$ PFU/mL |
| Bacteria | *Bordetella pertussis* | 1.0 x $10^6$ cells/mL |
| | *Chlamydia pneumoniae* | 1.0 x $10^6$ IFU/mL |
| | *Haemophilus influenzae* | 1.0 x $10^6$ cells/mL |
| | *Legionella pneumophila* | 1.0 x $10^6$ cells/mL |
| | *Mycoplasma pneumoniae* | 1.0 x $10^6$ U/mL |
| | *Streptococcus pneumoniae* | 1.0 x $10^6$ cells/mL |
| | *Streptococcus pyogenes (group A)* | 1.0 x $10^6$ cells/mL |
| | *Mycobacterium tuberculosis* | 1.0 x $10^6$ cells/mL |
| | *Staphylococcus aureus* | 1.0 x $10^6$ org/mL |
| | *Staphylococcus epidermidis* | 1.0 x $10^6$ org/mL |
| | Pooled human nasal wash | N/A |
| Yeast | *Candida albicans* | 1.0 x $10^6$ cells/mL |

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45% homology across 18% of the sequence, making cross-reactivity in the BinaxNOW COVID-19 Ag Card 2 Home Test highly unlikely.
- No protein sequence homology was found between *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein, MERS-CoV and human coronavirus HKU1 revealed that cross-reactivity cannot be ruled out. Homology for KHU1 and MERS-CoV is relatively low, at 37.8% across 95% of the sequence and 57.14% across 87% of the sequence, respectively.

### High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of $1.6 \times 10^5$ TCID50/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW COVID-19 Ag Card 2 Home Test.

### Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the BinaxNOW COVID-19 Ag Card 2 Home Test at the concentrations listed below and were found not to affect test performance.

| Substance | Active Ingredient | Concentration |
|---|---|---|
| Endogenous | Mucin | 2% w/v |
| | Whole Blood | 1% v/v |
| OTC Nasal Drops | Phenylephrine | 15% v/v |
| OTC Nasal Gel | Sodium Chloride (i.e. NeilMed) | 5% v/v |
| OTC Nasal Spray 1 | Cromolyn | 15% v/v |
| OTC Nasal Spray 2 | Oxymetazoline | 15% v/v |
| OTC Nasal Spray 3 | Fluconazole | 5% w/v |
| Throat Lozenge | Benzocaine, Menthol | 0.15% w/v |
| OTC Homeopathic Nasal Spray 1 | Galphimia glauca, Sabadilla, | 20% v/v |
| OTC Homeopathic Nasal Spray 2 | Zincum gluconium (i.e., Zicam) | 5% w/v |
| OTC Homeopathic Nasal Spray 3 | Alkalol | 10% v/v |
| OTC Homeopathic Nasal Spray 4 | Fluticasone Propionate | 5% v/v |
| Sore Throat Phenol Spray | Phenol | 15% v/v |
| Anti-viral Drug | Tamiflu (Oseltamivir Phosphate) | 0.5% w/v |
| Antibiotic, Nasal Ointment | Mupirocin[1] | 0.25% w/v |
| Antibacterial, Systemic | Tobramycin | 0.0004% w/v |

[1] Testing demonstrated false negative results at concentrations of 5 mg/mL (0.5% w/v). Standard dose of nasal ointment: 20 mg (2% w/w) of mupirocin in single-use 1-gram tubes.

### Human Factors Study

Abbott conducted a human factor's study to evaluate whether home user patients or caregivers (lay user) could perform the test and accurately interpret test results from the BinaxNOW COVID-19 Ag 2 Card Home Test under the supervision of a trained proctor.

In this study, a total of 31 lay users, age 15 and older with either good or corrected vision (far/near-sighted or wear bifocals) participated in a 45-minute session including an introduction, a product overview, and simulated use cases of BinaxNOW COVID-19 Ag Card 2 Home Test result interpretation. Participants were asked to read and interpret a panel of 9 different BinaxNOW COVID-19 Ag Card 2 Home test results, including high positive, low positive, negative, and invalid under the guidance of a virtual proctor. Participants and virtual proctors were blinded to the test card results.

22/30 participants described the process of reading and interpreting the test card results as being easy. However, 8/30 of the participants commented that it was difficult to see some of the fainter line conditions.

A total of 270 trials were recorded in this study. Participants were able to perceive and interpret the results correctly for 239 trials, or 89% of the time. Positive results with stronger intensity lines were easier to read than the positive lines with less intensity. As the line intensity became fainter, the ability to read the result correctly ranged from 83% to 60% with an overall rate 0f 70%.

After the human factors evaluation, participants were asked for their overall impressions of the instructional materials they were provided. Nearly all participants (29/30) thought the instructions were straightforward and easy to understand and follow.

Based on the learnings from this study improvements were made to the Quick Reference Guide and Proctor training.



**Usability Study**

Abbott conducted a study to evaluate whether a home user can follow instructions from a trained proctor through a virtual platform and successfully perform the test steps for the BinaxNOW COVID-19 Ag Card 2 Home Test, including nasal swab collection at home, and correctly interpreting the results.

60 home users, including individuals (n=30) and caregivers (n=30), participated in the study. Each individual or caregiver pair participated in a 45-minute session with a single proctor. The usability evaluation session included one simulated use of the BinaxNOW COVID-19 Ag Card 2 Home Test Kit in which a user was already connected with a proctor, knowledge tasks, and opportunities to provide feedback.

96.7% (58 out of 60) home users produced a valid result (all negative) and 2 participants produced an invalid result. (The causes of the invalid tests were insufficient amount of reagent added, and damage to the test strip). 58 out of 60 participants interpreted their test result correctly and 2 participants interpreted their result incorrectly (where they perceived a faint line in the sample window (as positive) when there was none (all results were verified by the study moderator).

The individual home use group completed 96.8% (1103/1140) of the total tasks/steps correctly. The caregiver home user group completed 97.3% (1109/1140) of the total tasks/steps correctly. The most common use errors observed during critical tasks included incorrectly swabbing the nostril to obtain a nasal sample and contacting the test strip with the hands or with the surface.

90% (56 out of 60) of the home (individual and caregiver) participants had positive impressions of the BinaxNOW COVID-19 Ag Card 2 Home Test Kit. The test was perceived as being easy to use. The mixed feedback from three home user participants included that some of the labeling on the different components was confusing and one participant reported that they would not be comfortable performing this test without a medical professional present.

88% (53 out of 60) participants stated the Quick Reference Guide (QRG) shown on the screen while the participant performed simulated use of the BinaxNOW COVID-19 Ag Card 2 Home Test was clear and easy to understand. 54 out of 60 participants felt their proctor that helped guide them through the workflow was helpful and provided clear instructions.

**SYMBOLS**

| | |
|---|---|
|  | This symbol indicates that the product is for single use only. It is not to be re-used. |
|  | This symbol indicates that you should consult the instructions for use. |
|  | This symbol indicates that the product has a temperature limitation. |
|  | This symbol indicates the name and location of the product manufacturer. |
|  | This symbol indicates the product's catalog number. |
|  | For In Vitro Diagnostic Use |
|  | This symbol indicates that the total number of tests provided in the kit box |



**Technical Support Advice Line**
Further information can be obtained from your Telehealth provider, or by contacting Technical Support on:

**US**
+ 1 800 257 9525 ts.scr@abbott.com

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IN195105 Rev. 1 2021/03