BinaxNOW™ COVID-19 Ag CARD HOME TEST

Healthcare Provider Instructions for Use

For Use Under an Emergency Use Authorization (EUA) Only

For use with nasal swab specimens

For *in vitro* Diagnostic Use Only

For Prescription Home Use

INTENDED USE

The BinaxNOW™ COVID-19 Ag Card Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for prescription home use with self-collected observed direct anterior nasal (nares) swab samples from individuals aged 15 years or older who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset or adult collected nasal swab samples from individuals aged four years or older who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. The BinaxNOW COVID-19 Ag Card Home Test is to be performed only with the supervision of a telehealth proctor.

The BinaxNOW™ COVID-19 Ag Card 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 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 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.

Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

BinaxNOW™ COVID-19 Ag Card Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

All prescribing healthcare providers 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 Home Test is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from nasal swabs, without viral transport media. The BinaxNOW™ COVID-19 Ag Card 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 Home Test 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 under observation by or from the patient, 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 (1): A cardboard, book-shaped hinged test card containing the test strip

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

Nasal Swabs (1): Sterile swab for use with BinaxNOW™ COVID-19 Ag 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. Federal Law restricts this device to sale by or on the order of a licensed practitioner (U.S. only).
4. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
5. 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.
6. Proper sample collection and handling are essential for correct results.
7. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
8. Do not touch swab tip when handling the swab sample.
9. Do not use kit past its expiration date.
10. Do not mix components from different kit lots.
11. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.
12. Dispose of kit components and patient samples in household trash.
13. INVALID RESULTS 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.

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 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 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 CARD HOME TEST

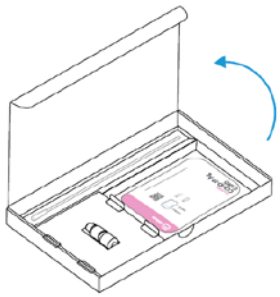
DO NOT OPEN ITEMS UNTIL INSTRUCTED TO DO SO

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

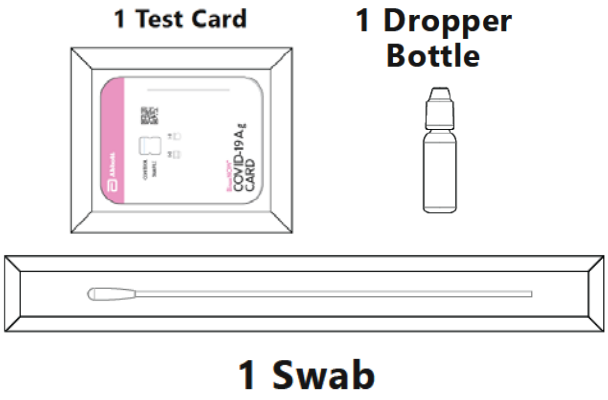
1. Set Up

DO NOT open items until instructed.

A. Open your test kit



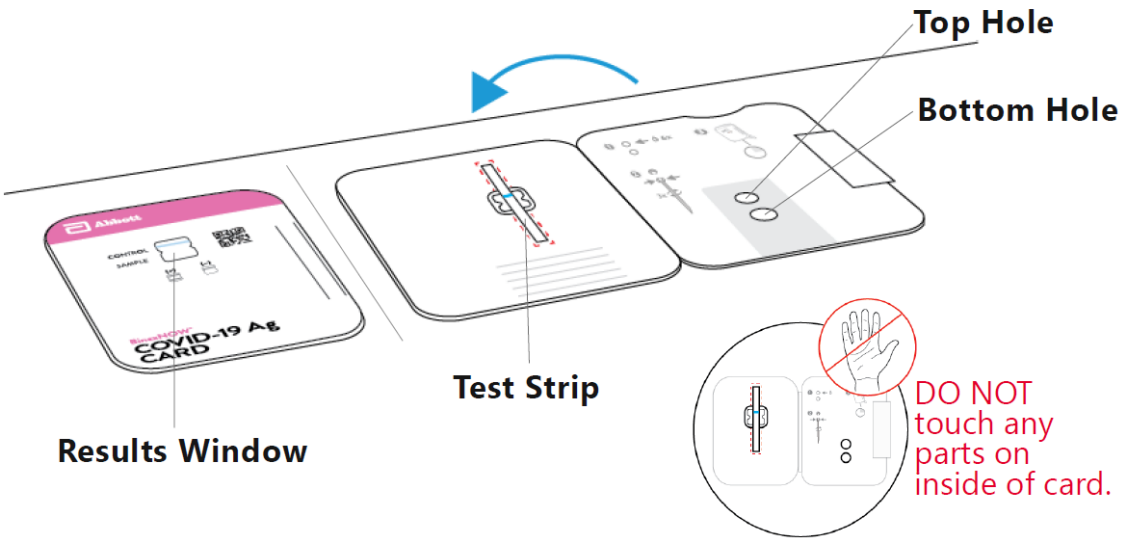
B. You should have:



2. Open Pouch and Scan QR Code on Card

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.

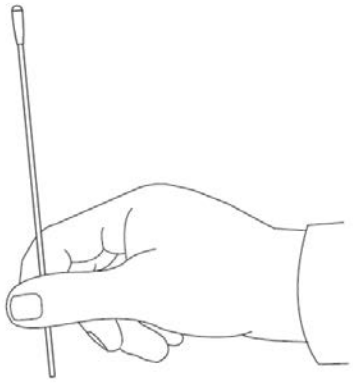
Note: False negative results may occur if less than 6 drops of fluid is used.

5. Open Swab

Keep fingers away from swab end.

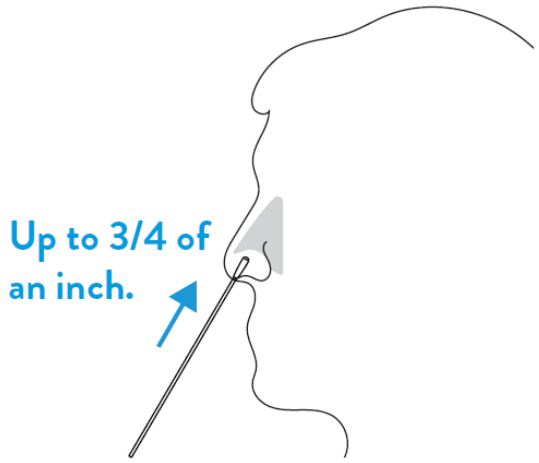
A. Open swab package at stick end.

B. Take swab out.

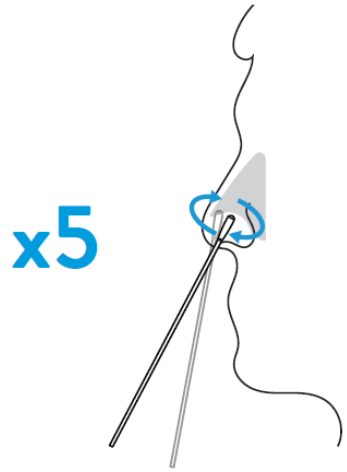


6. Swab Left Nostril

A. Insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into left nostril.



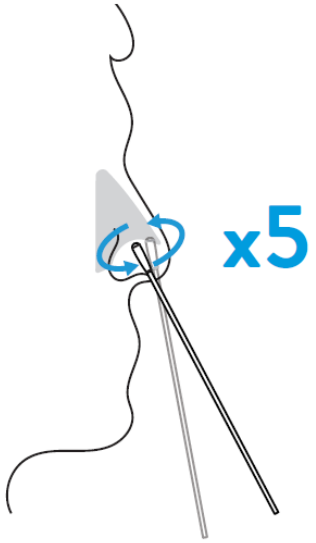
B. Firmly brush against insides of nostril in a circular motion 5 times or more.



7. Swab Right Nostril

A. Remove swab and insert it into right nostril.

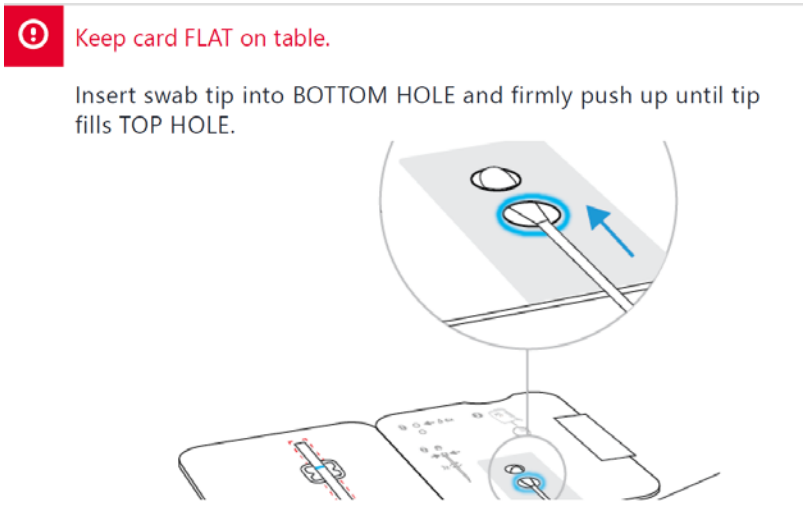
B. Firmly brush against insides of nostril in a circular motion 5 times or more.



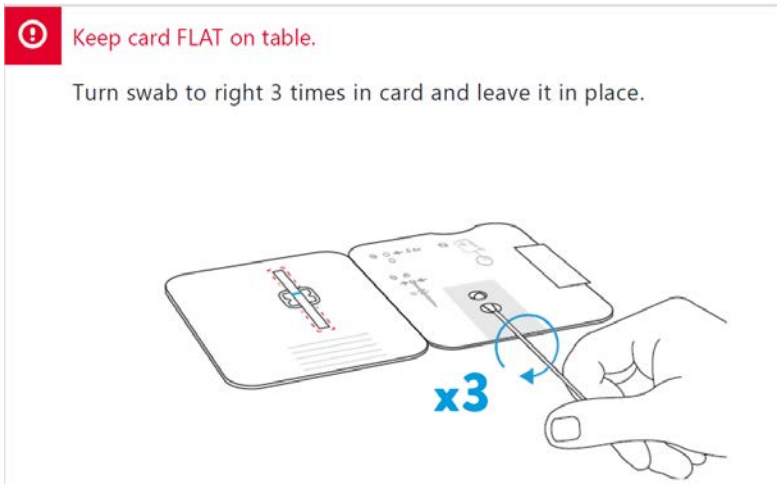
Note: *False negative results may occur if the nasal swab is not properly collected.*

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

8. Insert Swab Into Bottom Hole

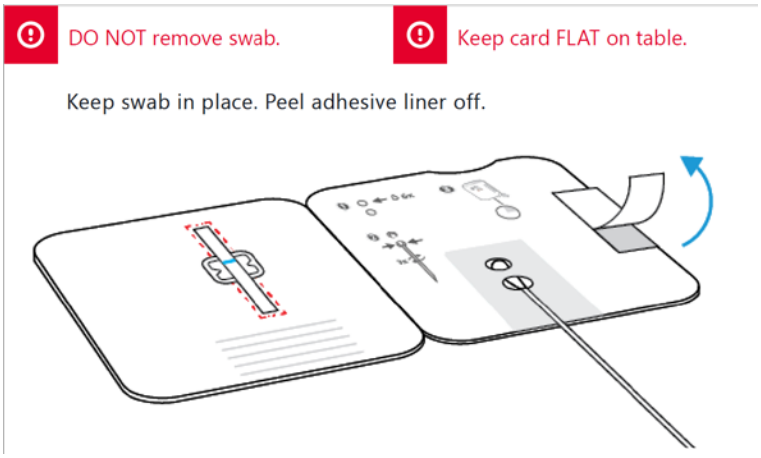


9. Turn Swab 3 Times



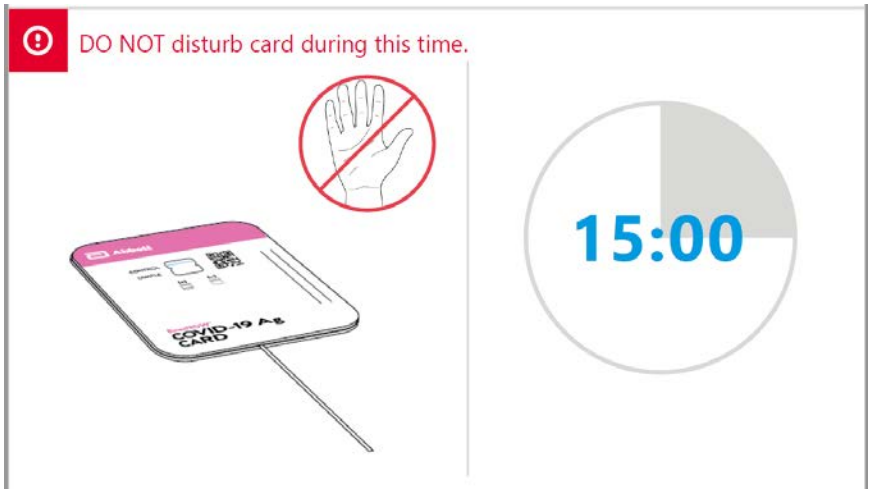
Note: False negative results can occur if the sample swab is not turned prior to closing the card.

10. Peel Strip



11. Close Card and Seal

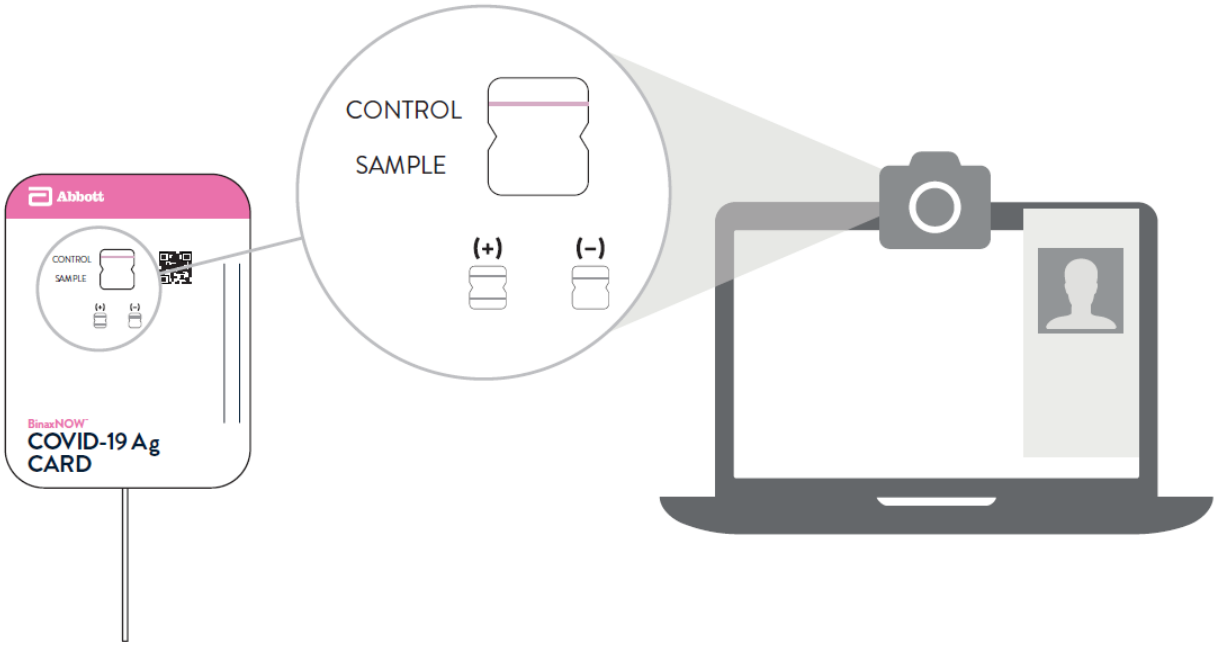
12. Wait 15 Minutes



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

13. Scan QR Code

14. Show Result to Your Proctor



RESULT INTERPRETATION

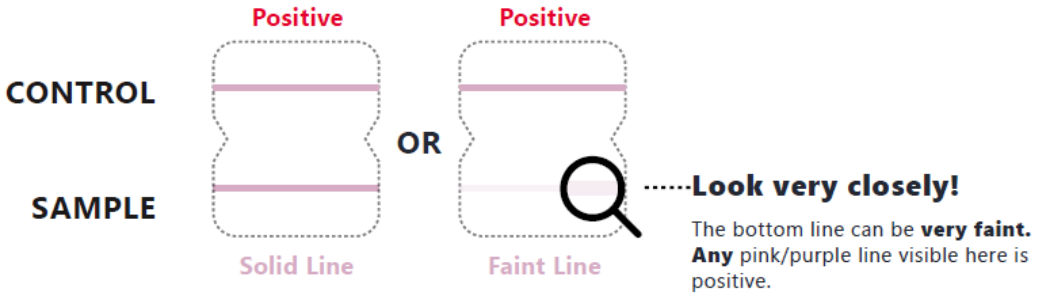
There are three types of results possible. You will be instructed how to read each type in a specific order. Follow this order with your proctor:

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

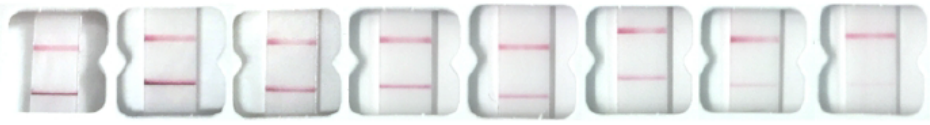
Check for Positive COVID-19 Result

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.

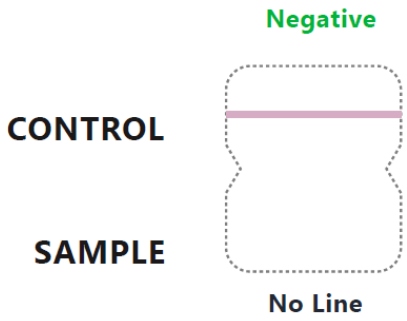


A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local 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.

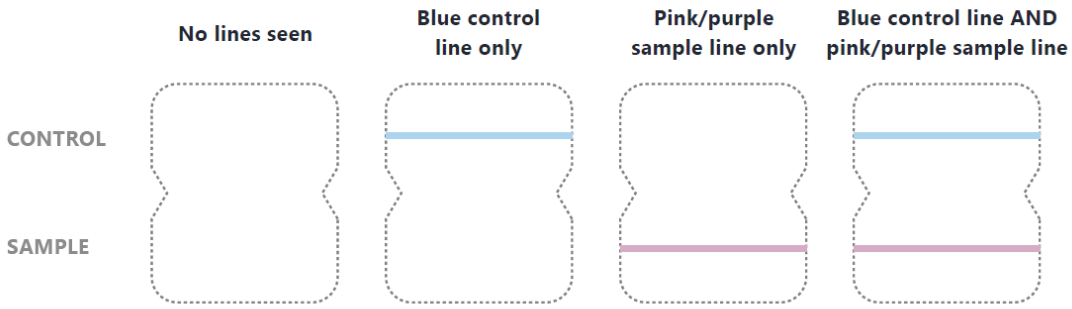
- **Negative Result:** A single pink/purple line on the top half where it says "Control." **COVID-19 was not detected.**



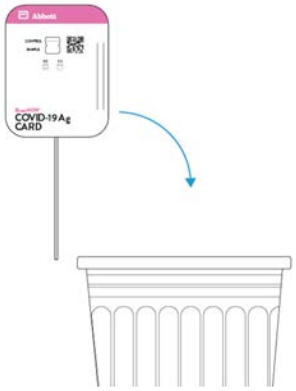
A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control 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.

Check for Invalid Result

If you see any of these, the test is invalid.



Dispose In Trash


COVID-19 Ag
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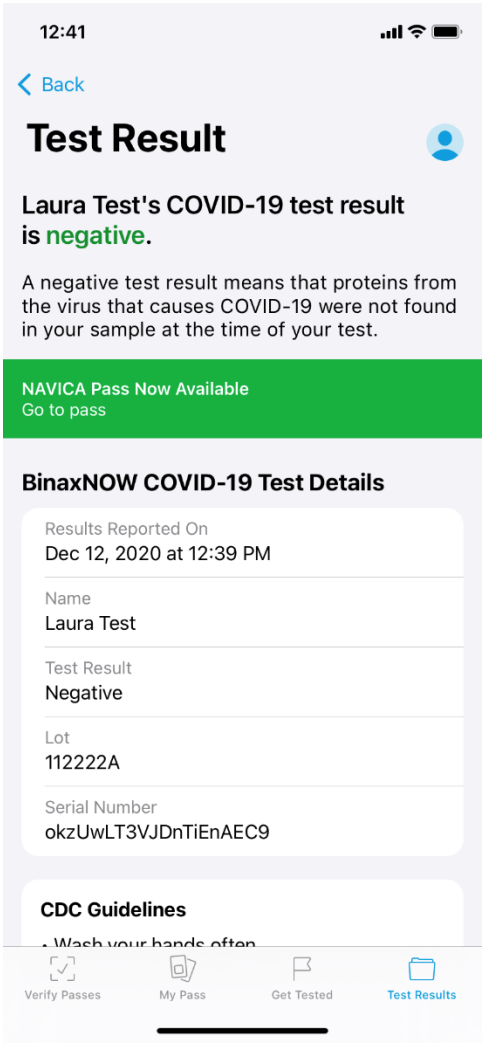
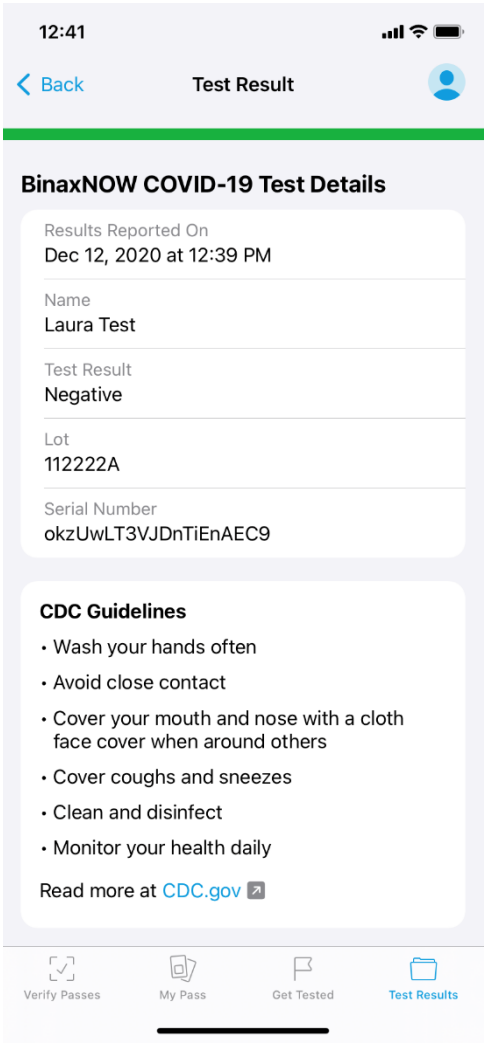
Reporting Patient Results Using the NAVICA app

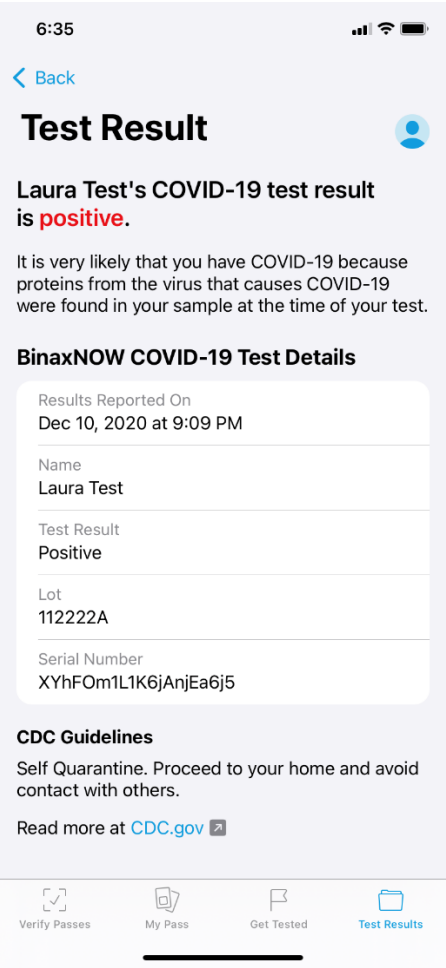
Upon completion of the test and result interpretation by the user, the telehealth proctor will send the results to the user via the NAVICA app and the telehealth provider will report results to relevant public health authorities. The user will be notified by email and on their mobile device that their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

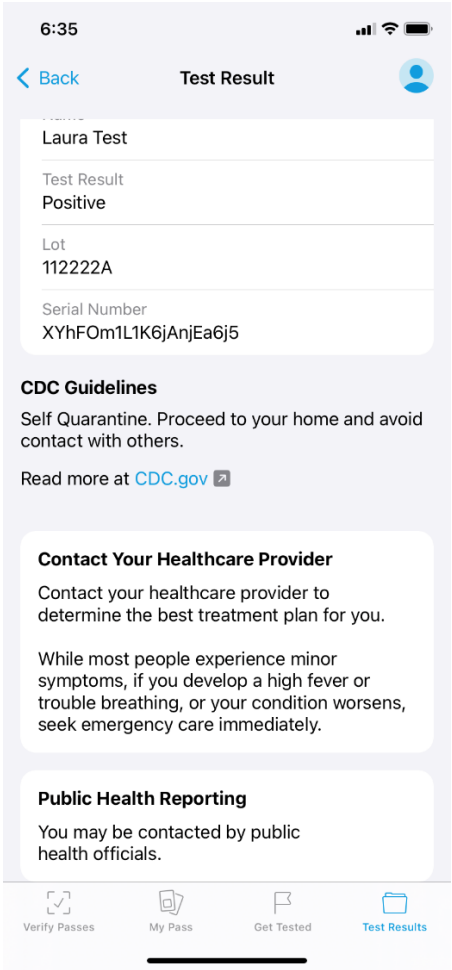
If the BinaxNOW COVID-19 Ag Card Home Test result is Negative, the user will receive the following:



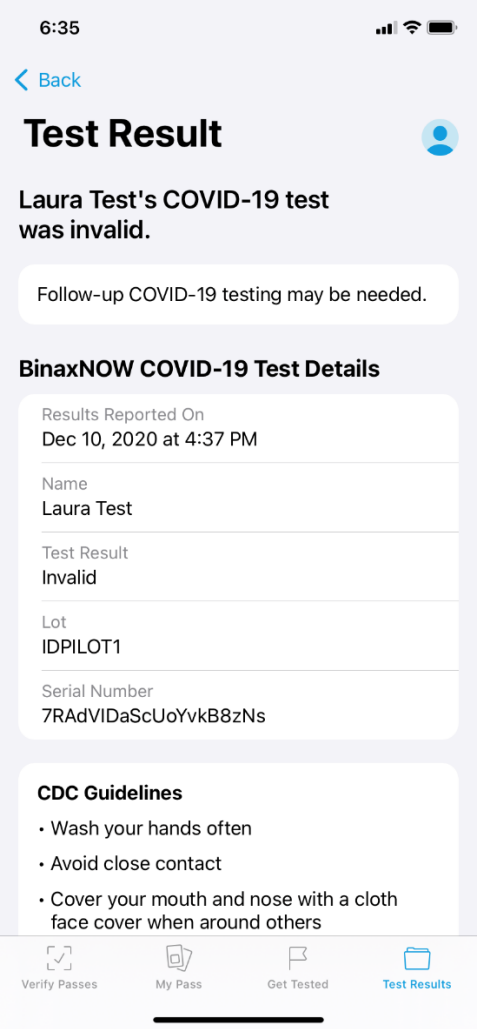


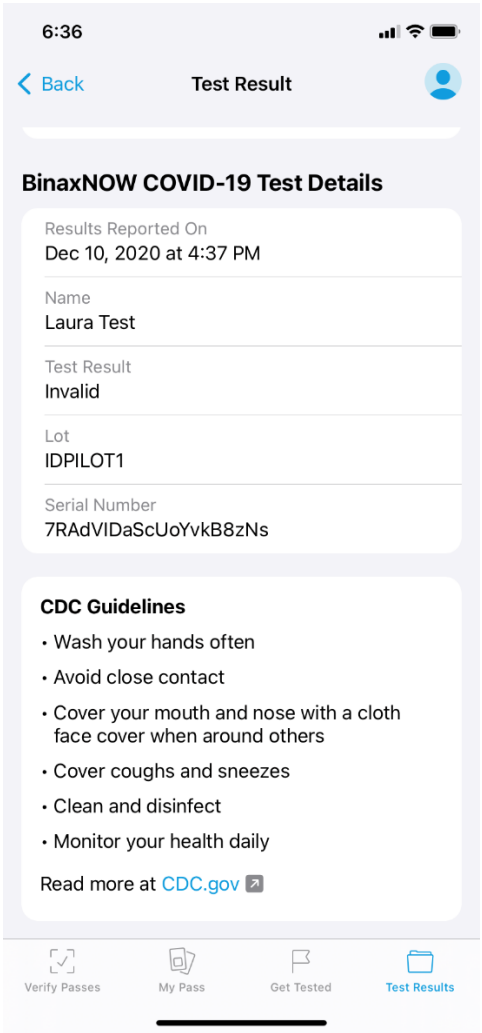
If the BinaxNOW COVID-19 Ag Card Home Test result is Positive, the user will receive the following:





If the BinaxNOW COVID-19 Ag Card 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 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 test and may cause false negative results.
- Negative results 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. .
- Performance of nasal swabs collected by an adult caregiver from a pediatric patient has not been determined, a study to support use in a pediatric population is ongoing.

CONDITIONS of AUTHORIZATION for HEALTHCARE PROVIDERS

The BinaxNOW™ COVID-19 Ag Card Home Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

However, to assist Healthcare providers using the BinaxNOW™ COVID-19 Ag Card Home Test, the relevant Conditions of Authorization are listed below:

A. All prescribing healthcare providers must collect information on the performance of your product in the ordinary course of business and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via email: ts.scr@abbott.com, or via phone by contacting Abbott Diagnostics Scarborough, Inc. Technical Service at 1-800-257-9525) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

B. All prescribing healthcare providers must report all test results they receive from patients who use your 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 the Centers for Disease Control and Prevention (available at: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html).

PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

Clinical performance characteristics of BinaxNOW™ COVID-19 Ag Card 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 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 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 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 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 Home Test Performance within 7 days of symptom onset against the Comparator Method

BinaxNOW™ COVID-19 Ag 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%)			

*Both false negative results occurred in patients with reference Ct values (>33).

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

Performance of BinaxNOW™ COVID-19 Ag 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 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%)			

*14 of the discrepant samples had high Ct values (>33) when tested by the comparator method.

The following data is provided for informational purposes:

The performance of BinaxNOW™ COVID-19 Ag Card Home Test with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better

understand the correlation of assay performance to the cycle threshold, as a surrogate for the amount of virus present in the clinical sample. As presented in the table below, the positive agreement of the BinaxNOW™ COVID-19 Ag Card Home Test is higher with samples of a Ct count <33.

BinaxNOW™ COVID-19 Ag Card Home Test Performance against the Comparator Method – by Cycle Threshold Counts

BinaxNOW™ COVID-19 Ag Card Home Test	Comparator Method (POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	22	0
Negative	0	2
Total	22	2
Positive Agreement (95% CI)	100.0 (84.6, 100.0)	0.0 (0.0, 84.2)

Similarly, in the 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. 173 positive specimens were enrolled into the larger multi-site study, and results are stratified by the Ct count in the table below, as a surrogate for the amount of virus present in the clinical sample.

BinaxNOW™ COVID-19 Ag Card Performance against the Comparator Method – by Cycle Threshold Counts

	All Subjects*	
BinaxNOW™ COVID-19 Ag Card	Comparator Method (POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	116	17
Negative	12	28
Total	128	45
Positive Agreement (95% CI)	90.6 (84.2, 95.1)	37.8 (23.8, 53.5)

*In patients presenting within seven (7) days of symptom onset, BinaxNOW COVID-19 Ag Card achieved 95.6% (86/90) positive percent agreement for samples with Ct < 33

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 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 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 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 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	1.0×10^5 $TCID_{50}$/mL
	Human metapneumovirus (hMPV)	1.0×10^5 $TCID_{50}$/mL
	Rhinovirus	1.0×10^5 PFU/mL
	Enterovirus/Coxsackievirus B4	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 2	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 3	1.0×10^5 $TCID_{50}$/mL
	Human parainfluenza virus 4	1.0×10^5 $TCID_{50}$/mL
	Influenza A	1.0×10^5 $TCID_{50}$/mL
	Influenza B	1.0×10^5 $TCID_{50}$/mL
	Respiratory Syncytial Virus A	1.0×10^5 PFU/mL
Bacteria	*Bordetella pertussis*	1.0×10^6 cells/mL
	Chlamydia pneumoniae	1.0×10^6 IFU/mL
	Haemophilus influenzae	1.0×10^6 cells/mL
	Legionella pnuemophila	1.0×10^6 cells/mL
	Mycoplasma pneumoniae	1.0×10^6 U/mL
	Streptococcus pneumoniae	1.0×10^6 cells/mL
	Streptococcus pyogenes (group A)	1.0×10^6 cells/mL
	Mycobacterium tuberculosis	1.0×10^6 cells/mL
	Staphylococcus aureus	1.0×10^6 org/mL
	Staphylococcus epidermidis	1.0×10^6 org/mL
	Pooled human nasal wash	N/A
Yeast	*Candida albicans*	1.0×10^6 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 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 1.6×10^5 TCID50/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW™ COVID-19 Ag Card 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 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 Card 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 Home test result interpretation. Participants were asked to read and interpret a panel of 9 different BinaxNOW COVID-19 Ag Card 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 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 Home Test Kit in which a user was already connected with a proctor, knowledge tasks, and opportunities to provide feedback.

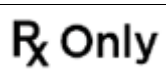
96.7% (58 out of 60) home users produced a valid result (all negative) and 2 participants produced an invalid result. (The causes of the invalid tests were insufficient amount of reagent added, and damage to the test strip). 58 out of 60 participants interpreted their test result correctly and 2 participants 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 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 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.
	For Prescription Use Only.
	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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