BinaxNOW™ COVID-19 Antigen Self 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 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first seven days of symptom onset. This test is also authorized for non-prescription home use with adult collected anterior nasal (nares) swab samples from individuals aged two years or older with symptoms of COVID-19 within the first seven days of symptom onset.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult collected anterior nasal (nares) swab samples from individuals aged two years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The BinaxNOW COVID-19 Antigen Self 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 Antigen Self 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 an individual'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.

Individuals should report their test result through the NAVICA app **and** provide all results obtained with this product to their healthcare provider in order to receive appropriate medical care. All 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.

The BinaxNOW COVID-19 Antigen Self Test is intended for 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 Antigen Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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 Antigen Self 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 Antigen Self Test kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLES OF THE PROCEDURE

The BinaxNOW COVID-19 Antigen Self 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. 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, an anterior nasal swab specimen is collected by 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.

BinaxNOW COVID-19 Antigen Self Test instructions for use are provided as a paper copy within the test kit, available digitally via website link (www.binaxnow-selftest.abbott) or digitally via the NAVICA app downloaded to a compatible smart phone. Compatible smart phone includes Apple

iPhone running Operation System (iOS): latest major version and two prior major versions (iPhone running iOS v12 or later), and Android Phones: latest major version and two prior major versions (Android phone running Android OS v9 or later).

REAGENTS AND MATERIALS

Materials Provided

Test Cards (1, 2, or 10): A cardboard, book-shaped hinged test card containing the test strip

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

Nasal Swabs (1, 2, or 10): Sterile swab for use with BinaxNOW COVID-19 Antigen Self Test

Patient Instructions for Use (1)

Individual Fact Sheet (1)

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. Do not use a kit that has been opened and/or tampered with.
10. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
11. Do not dip the swab into the liquid reagent or other liquid before inserting the swab into the nose.
12. Do not touch swab tip when handling the swab sample.
13. Do not use kit past its expiration date.
14. Do not mix components from different kit lots.
15. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card or swab.
16. Dispose of kit components and patient samples in household trash.
17. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold bottle vertically, 1/2 inch above the swab well, and add drops slowly.

18. 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 Acute Tox. 1 (Dermal), H310	0.0125%

STORAGE AND STABILITY

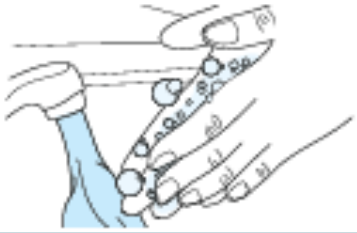
Store kit between 35.6-86°F (2-30°C). Ensure all test components are at room temperature before use. The BinaxNOW COVID-19 Antigen Self Test is stable until the expiration date marked on the outer packaging and containers.

DIRECTIONS FOR RUNNING THE BINAXNOW COVID-19 AG CARD SELF TEST

Carefully read instructions prior to starting the test. It is recommended gloves (not provided) also be used during testing.

BEFORE STARTING

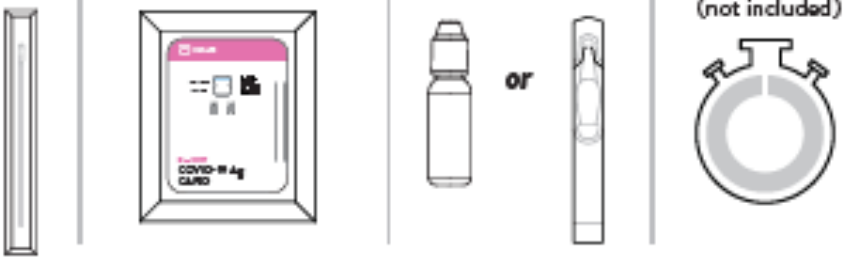
1. Wash or sanitize your hands. Make sure they are dry before starting.



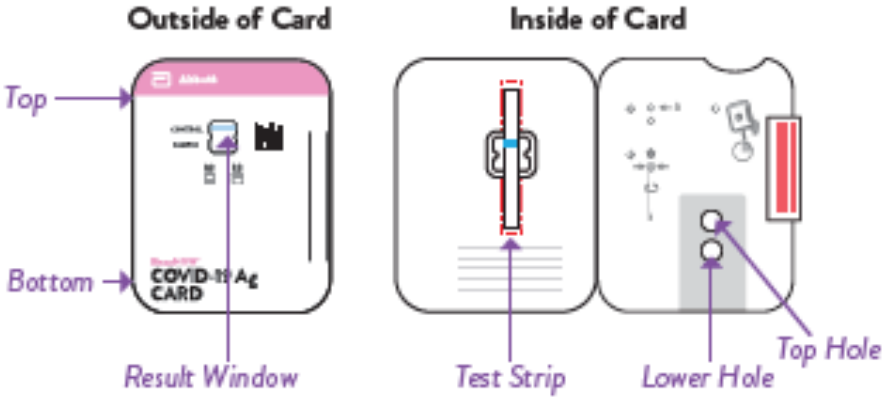
A. PREPARE FOR THE TEST

Your box may contain more than one test kit.
Use only 1 of each of the following for each test:

1 Swab | 1 Test Card in Pouch | 1 Dropper Bottle | Timing Device (not included)

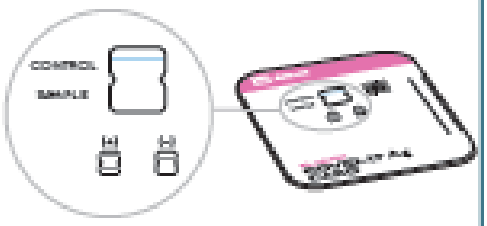


! DO NOT touch any parts on the inside. Handle card only by edges.



2. Remove test card from pouch.

Make sure the **blue control line** is present in the result window. **Do not use the card if it is not.**



Open the card and lay it flat on the table with the pink side down. You may bend the spine in the opposite direction to help the card lay flat.

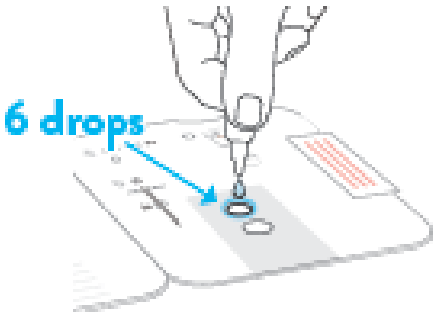
DO NOT touch the test strip.

! Card must stay FLAT on table for entire test.

3. Remove dropper bottle cap.

Hold dropper bottle straight over top hole, not at an angle.

Put 6 drops into top hole.
Do not touch card with tip.

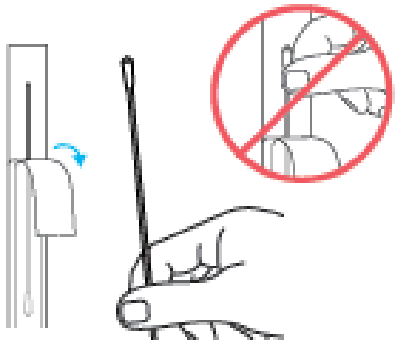


Note: False negative result may occur if more than 6 drops of fluid are put in the hole.

B. COLLECT NASAL SAMPLE

! Keep fingers away from the swab end.

4. Open swab package at stick end. Take swab out.

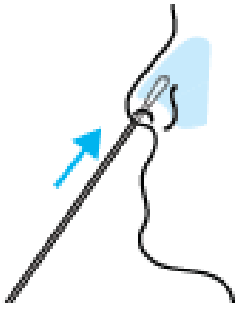


5. Swab both nostrils carefully as shown.

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

You do not need to go deeper.

a Up to 3/4 of an inch

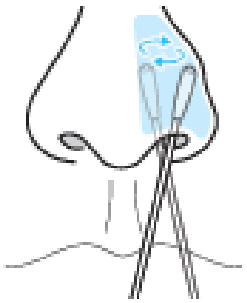


Using medium pressure, rub the swab against all of the inside walls of your nostril.

Make at least 5 big circles. Do not just spin the swab.

Each nostril must be swabbed for about 15 seconds.

b At least 5 big circles



Using the same swab, repeat step 5 in your other nostril.

c At least 5 big circles

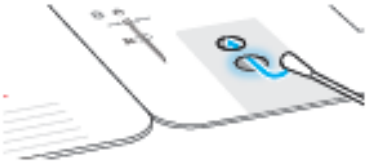
Check:
Did you swab BOTH nostrils?

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

C. PERFORM THE TEST

! Keep card FLAT on table.

6. Insert swab tip into lower hole.



Firmly push the swab tip from the lower hole until it is visible in the top hole.

Do not remove the swab from the card.

7. Turn swab to right 3 times to mix the swab with the drops.

Do not skip this step.

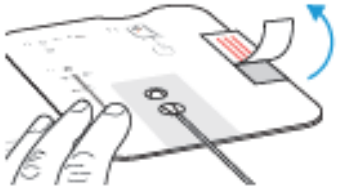
Leave the swab in the card for the remainder of the test.

Note: False negative result can occur if swab is not turned.

! DO NOT remove swab.

8. Peel adhesive liner off. Be careful not to touch other parts of card.

a Peel



Close left side of the card over swab. Press firmly on the two lines on right edge of the card to seal.

b Seal

Keep card face up on table.

! **DO NOT move or touch the card during this time.**

9. **Wait 15 minutes.**

   Read the result at 15 minutes.

   Do not read the result before 15 minutes or after 30 minutes.

Note: A control line may appear in the result window in a few minutes but a sample line may take as long as 15 minutes to appear.

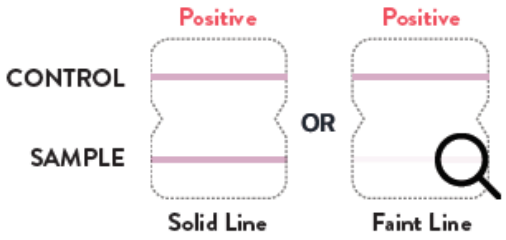
Note: Results should not be read after 30 minutes.

D. INTERPRET RESULTS

A. Check for Positive COVID-19 Result

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

Positive Result: If you see two pink/purple lines (one on the top half and one on the bottom half), this means **COVID-19 was detected.**



Look very closely!

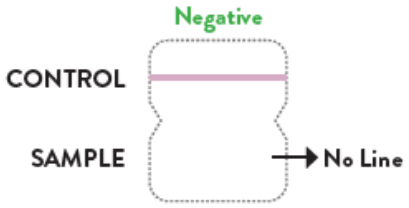
The bottom line can be very faint. Any pink/purple line visible here is a Positive Result.

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

B. Check for Negative COVID-19 Result

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

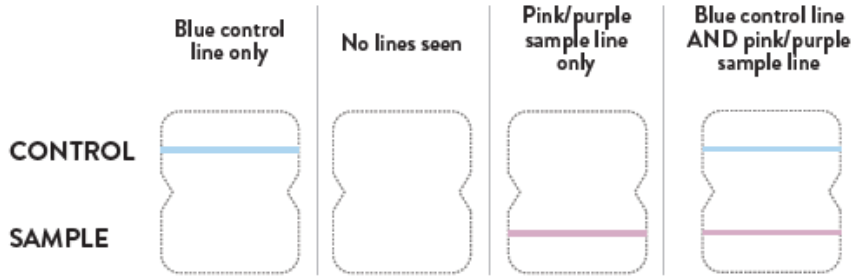
Negative Result: If you see **only** one pink/purple line on the top half, where it says "Control" this means **COVID-19 was not detected.**



C. Check for Invalid Result

If you see any of these, the test is invalid. An invalid result means this test was unable to determine whether you have COVID-19 or not. A new test is needed to get a valid result.

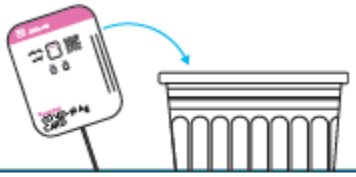
Please contact Technical Support at +1 833-637-1594



Note: See other side to read about what your results mean.

E. DISPOSE THE TEST KIT

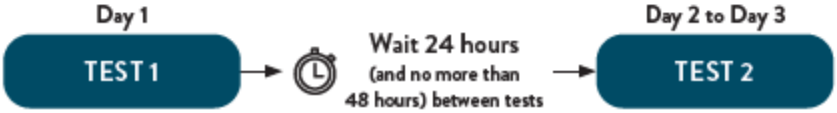
Throw away all used test kit components in the trash.



F. REPORT YOUR RESULTS

Report your test result through the NAVICA app and by contacting your healthcare provider.

Note: If you do not have symptoms, a second test should be taken at least 24 hours (and no more than 48 hours) between tests.



RESULT INTERPRETATION

Positive Result

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.

Negative Result

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-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.

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 Antigen Self 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 Antigen Self 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.
- 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 24 hours (but no more than 48 hours) between tests has not been determined, a study to support use will be completed.

- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have a COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- 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 Antigen Self 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 Antigen Self 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 Antigen Self 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 Antigen Self 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 Antigen Self 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 Antigen Self 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%)

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

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.

Performance of BinaxNOW COVID-19 Antigen Self 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 Antigen Self 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%)		

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 Antigen Self 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 Antigen Self 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 Antigen Self 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 Antigen Self 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 Antigen Self 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 1.6×10^5 TCID50/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW COVID-19 Antigen Self 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 Antigen Self 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.

Usability Study

Abbott conducted a study to evaluate whether a home user can follow instructions and successfully perform the test steps for the BinaxNOW COVID-19 Antigen Self Test, including nasal swab collection at home, and correctly interpreting the results.

100 home users, including individuals (n=50) and caregivers (n=50), participated in the study. Each individual or caregiver pair participated in a 60-minute session with a single proctor. The usability evaluation session included one simulated use of the BinaxNOW COVID-19 Antigen Self Test and opportunities to provide feedback.

92% (92 out of 100) home users produced a valid result (all negative) and 8 participants produced an invalid result.

100% (99 out of 99) of the home (individual and caregiver) participants correctly understood that failure to follow the test steps correctly would potentially lead to an invalid or inaccurate result or would require another test or consultation with a healthcare provider. (One participant was inadvertently not asked this question by the moderator during the session).

eInstruction Usability Study

The sponsor also submitted an usability study for the eInstruction. The goal of the usability study was to demonstrate that lay users can use paper instructions or digital (mobile app or website) instructions (i.e., paper Quick Reference Guide (QRG), digital app Quick Reference Instructions

(QRI), or website electronic Instructions for Use (eIFU)) to perform the test steps for the BinaxNOW COVID-19 Antigen Self Test successfully.
The study was conducted at usability labs in Chicago, IL, USA on June 15 - June 23, 2021. A total of 60 lay users, including individuals (n=30) and caregivers (n=30), participated in the study. Each individual or caregiver pair participated in a 6-minute session with a study moderator. The usability evaluation session included one simulated use of the BinaxNOW COVID-19 Antigen Self Test, knowledge tasks, and opportunities to provide feedback.

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

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