Individuals using assistive technology may not be able to fully access the information contained in this document. For assistance, please call 1(800) 638-2041 or (301) 796-7100 or send an email to CDRH's Division of Industry and Consumer Education (DICE). Please include "**508 Accommodation**" and the **title of the document** in the subject line of your e-mail.

Abbott

Visit www.globalpointofcare.abbott/us/en/support/binaxnow-covid-19-antigen-self-test-us.html to report your results and view instructions for use.

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 or adult collected anterior nasal (nares) swab samples from individuals 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first seven days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 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, which 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. 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.

All 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 measures such as isolating from others and wearing masks. 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.

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 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. This product has not been FDA cleared or approved.

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 and available digitally via website link (www.binaxnow-selftest.abbott).

REAGENTS and MATERIALS

Materials Provided

Test Cards (1, 2, 4, 5 or 10): A cardboard, book-shaped hinged test card containing the test strip
Extraction Reagent (1, 2, 4, 5 or 10): Bottle containing <1 mL of extraction reagent
Nasal Swabs (1, 2, 4, 5 or 10): Sterile swab for use with BinaxNOW COVID-19 Antigen Self Test
Patient Instructions for Use (1)

WARNINGS, PRECAUTIONS and SAFETY INFORMATION

1. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
2. For *in vitro* diagnostic use.
3. In the USA, this product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.
4. Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
5. Use of gloves is recommended when conducting testing.
6. Keep testing kit and kit components out of the reach of children and pets before and after use.
7. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
8. Incorrect test results may occur if a specimen is incorrectly collected or handled.
9. Do not use if any of the test kit components or packaging is damaged.
10. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open. Once opened, the test card should be used immediately.
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.
19. **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
20. An anterior nasal swab sample can be self-collected by an individual age 15 years and older. Children age 2 to 15 years should be tested by an adult.
21. If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
22. Do not use on anyone under 2 years of age.
23. **Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to false positive, false negative, or invalid result.**
24. 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 COVID-19.

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%

For more information on EUAs please visit: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

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

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

BEFORE STARTING

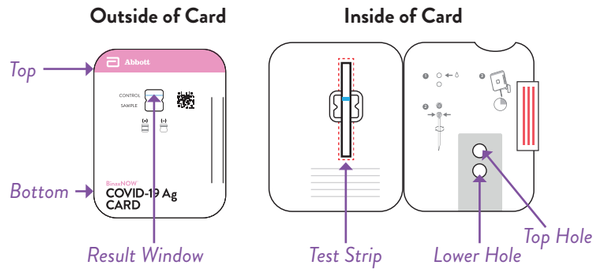
1. Wash or sanitize your hands. Make sure they are dry before starting.

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:

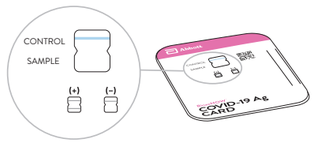
1 Swab | **1 Test Card in Pouch** | **1 Dropper Bottle** | **Timing Device** (not included)

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

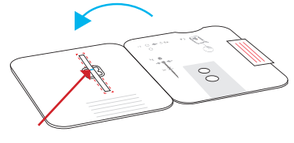


2. Remove test card from pouch.

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.



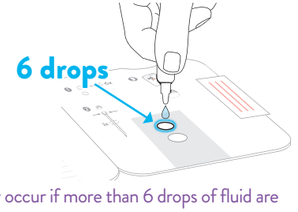
DO NOT touch the test strip.

! **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.

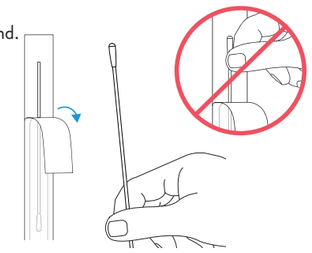


Note: False negative result may occur if more than 6 drops of fluid are put in the hole.

B. COLLECT NASAL SAMPLE

! **Keep fingers away from the swab end.**

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

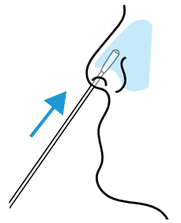


5. **Swab both nostrils carefully as shown.**

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

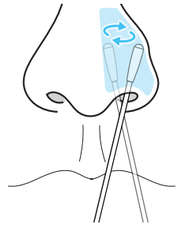


Using medium pressure, rub the swab against all of the inside walls of your nostril.

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

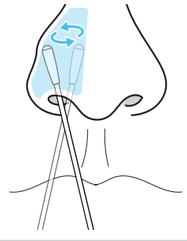
Each nostril must be swabbed for about **15 seconds.**

b At least 5 big circles



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

c At least 5 big circles



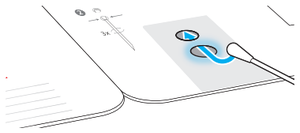
STOP **Check:** Did you swab BOTH nostrils?

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

C. PERFORM THE TEST

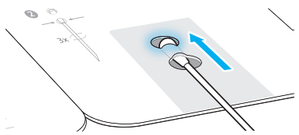
! **Keep card FLAT on table.**

6. Insert swab tip into **lower hole.**



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

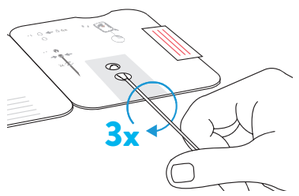
Do not remove the swab from the card.



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.

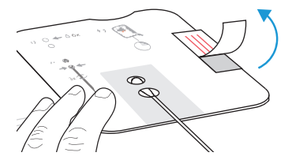


Note: False negative result can occur if swab is not turned.

! **DO NOT remove swab.**

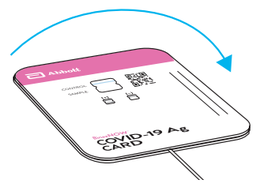
8. Peel adhesive liner off. Be careful not to touch other parts of card.

a **Peel**



Close left side of 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.

WAIT
15 MINUTES

READ
AT 15-30 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

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

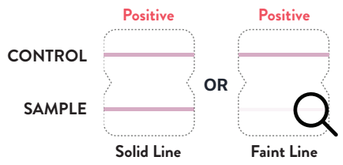
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

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.

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.

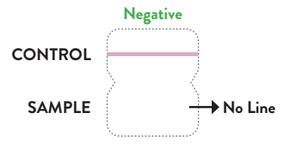
Below are photos of actual positive tests. On the right, note how faint the bottom line can get.

Repeat testing does not need to be performed if patients have a positive result at any time.

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.**



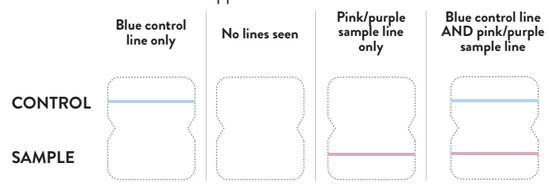
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

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. Re-test with a new swab and new test device.

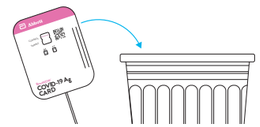
Please contact Technical Support at +1 833-637-1594



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

Visit www.globalpointofcare.abbott/us/en/support/binaxnow-covid-19-antigen-self-test-us.html to report your results.

RESULT INTERPRETATION

Positive Result

A positive test result means that the virus that causes COVID-19 was detected in the sample and it is very likely the individual has COVID-19 and is contagious. Please contact the doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive result).

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 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.

Negative Result

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

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.
- Incorrect test 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.
- 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 compared to a molecular test, especially in samples with low viral load.
- 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 January, 2021 and May, 2022. The clinical performance has not been established for 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.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

Days After First Pcr Positive Test Result	Asymptomatic On First Day Of Testing			Symptomatic On First Day Of Testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after the first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performed an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

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 (1,125 $TCID_{50}$/mL) 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 in the test. Based upon the testing procedure for this study the LOD of 140.6 $TCID_{50}$/mL in the test equates to 22.5 $TCID_{50}$/swab.

Limit of Detection (LoD) Study Results

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

Omicron Testing

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx team using pooled clinical samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to any devices tested with a different specimen pool and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the Binax NOW COVID-19 Ag Card detected 100% of live virus Omicron samples at a Ct-value of 28.7 (n=5). Testing was also compared to additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 28.7) were not detected by the Binax NOW COVID-19 Ag Card in this study.

Omicron Pool 1 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	Binax NOW COVID-19 Ag Card Percent Positive (n=5)
Dilution 1	19.9	100	100	100
Dilution 2	21.0	100	100	100
Dilution 3	22.3	100	100	100
Dilution 4	23.4	100	100	100
Dilution 5	25.0	100	100	100
Dilution 6	26.6	100	100	100
Dilution 7	27.3	0	100	100
Dilution 8	28.7	0	0	100
Dilution 9	30.1	0	0	0
Dilution 10	31.0	0	0	0
Dilution 11	32.1	0	0	0

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 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 B4	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	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
	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 pnuemophila	1.0 x 10^6 cells/mL
	Mycoplasma pneumoniae	1.0 x 10^6 U/mL
Bacteria	*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 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 x 10^5 $TCID_{50}$/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, Luffa opperculata	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.
www.globalpointofcare.eifu.abbott	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.
REF	This symbol indicates the product's catalog number.
IVD	For *In Vitro* Diagnostic Use.
	This symbol indicates the total number of tests provided in the kit box.

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Abbott
BinaxNOW
COVID-19 Antigen Self Test

HCP PI - EN

Size:
Flat size: 17 in x 11 in
Folded size: 4.25 in x 5.50 in

Electronic Only

Incoming Inspection Colors

PMS 2995 U
Primary Blue

PMS 224 U
Magenta-Pink

PMS 303 U
Dark Blue

PN: IN195151
Rev: 6
SAP: 40004151

Date of Last Revision:
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