



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

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>.

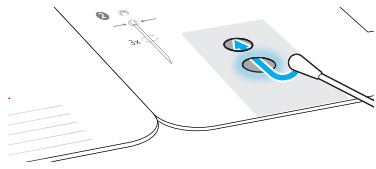
**Note:** False negative result may occur if more than 6 drops of fluid are put in the hole.

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

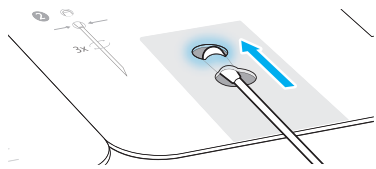
C. PERFORM THE TEST

! Keep card FLAT on table.

6. Insert swab tip into lower hole.

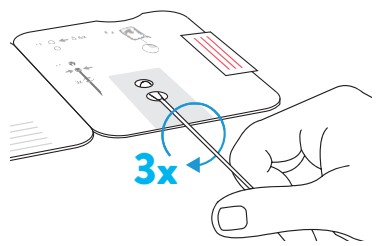


Firmly push the swab tip from the bottom hole until it is visible in the top hole.



Do not remove the swab from the card.

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



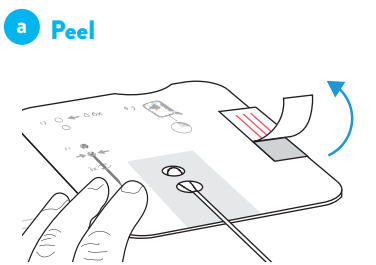
Do not skip this step.

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

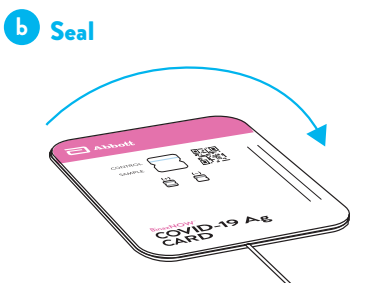
Note: False negative result can occur if swab is not turned.

! DO NOT remove swab.

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



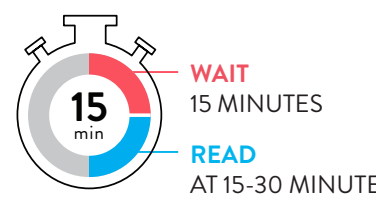
Close left side of card over swab. Press firmly on the two lines on right edge of the card to seal.



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

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

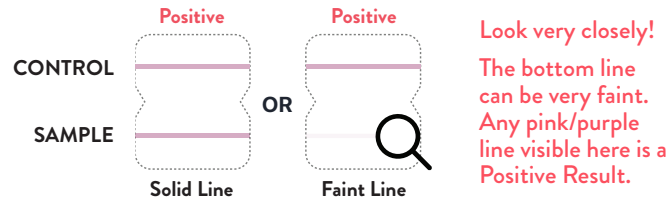
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19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



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

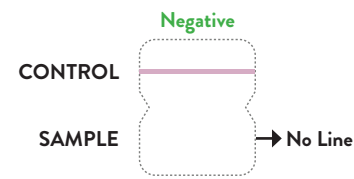


Repeat testing does not need to be performed if patients have a positive result at any time.

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.



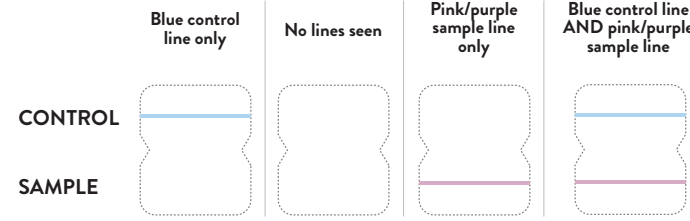
To increase the chance that the negative result for COVID-19 is accurate, you should:

- 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.

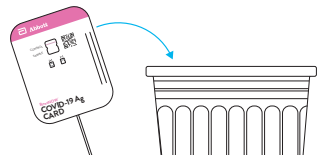
Please contact Technical Support at + 1 833-637-1594



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

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

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.





<p><b>Abbott</b> BinaxNOW COVID-19 Antigen Self Test</p> <p>HCP PI - EN</p> <p><b>Size:</b> Flat size: 17 in x 11 in Folded size: 4.25 in x 5.50 in</p>	<p><b>Electronic Only</b></p>	<p><b>PN:</b> IN195151 <b>Rev:</b> 5</p>
	<p><b>Incoming Inspection Colors</b></p> <div data-bbox="270 276 360 290" style="display: inline-block; width: 100px; height: 60px; background-color: #00BFFF; margin-bottom: 5px;"></div> <div data-bbox="416 276 475 290" style="display: inline-block; vertical-align: top;"> <p>PMS 2995 U Primary Blue</p> </div> <div data-bbox="270 304 360 318" style="display: inline-block; width: 100px; height: 60px; background-color: #FF69B4; margin-bottom: 5px;"></div> <div data-bbox="416 304 475 318" style="display: inline-block; vertical-align: top;"> <p>PMS 224 U Magenta-Pink</p> </div> <div data-bbox="270 332 360 348" style="display: inline-block; width: 100px; height: 60px; background-color: #004D60; margin-bottom: 5px;"></div> <div data-bbox="416 332 475 348" style="display: inline-block; vertical-align: top;"> <p>PMS 303 U Dark Blue</p> </div>	<p><b>Date of Last Revision:</b> 5.3 2022/12/13</p>