Abbott

BinaxNOW™ COVID-19 Ag CARD

Technical Support Advice Line
Further information can be obtained from your distributor, or by contacting Technical Support on:
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PROCEDURE CARD

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

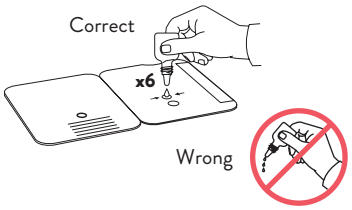
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from anterior nasal (nares) swab specimens.

IMPORTANT: See Product Insert, including QC section, for complete use instructions, warnings, precautions and limitations. Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results. **False negative results may occur if specimens are tested past 1 hour of collection. Specimens should be tested as quickly as possible after specimen collection. 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.** Open the test card prior to use, lay it flat, and perform assay as follows.

Part 1 - Sample Test Procedure

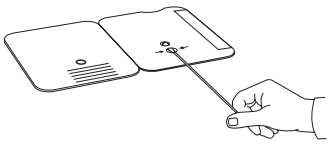
Patient Samples require 6 drops of Extraction Reagent.

1



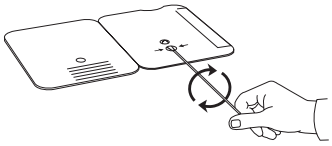
Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

2



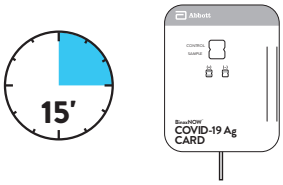
Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

3



Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.

4



Used test cards should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.

Part 2 - Result Interpretation

Negative Result

Pink/Purple Control Line

A **negative specimen** will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

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

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

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 tests. 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.

Positive Result

Pink/Purple Control Line

Pink/Purple Sample Line

A **positive specimen** will give two pink/purple colored lines. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.

This 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 patient's 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).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the BinaxNOW COVID-19 Ag Card 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.

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

Invalid Result

No Control Line

Blue Control Line Only

Sample Line Only

Blue Control Line

Sample Line

If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated with a new swab and a new test device.

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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

Procedure for External Quality Control Testing

External Controls require 8 drops of Extraction Reagent

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.
2. Follow Steps 2 – 4 of the Test Procedure shown.

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 the virus that causes 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.

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IVD

IN195001 Rev. 3 2023/02

Abbott
BinaxNOW
COVID-19 Ag

ProCard

Size:
8.5 in x 11 in

Printed Colors

CMYK

Incoming Inspection Colors
(For Reference Only)
Colors below are not used for printing

PMS 2995 U
Primary Blue

PMS 2995 U
Primary Blue 70%

PMS 224 U
Magenta Pink

PMS 303 U
Dark Blue

PMS 185 U
Red

PMS 185 U
Red 70%

PN: IN195001
Rev: 3

Date of Last Revision:
3.13 2023/02/13