

## INSTRUCTIONS - START HERE

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

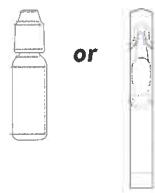
### BEFORE STARTING

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



### A. PREPARE FOR THE TEST

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



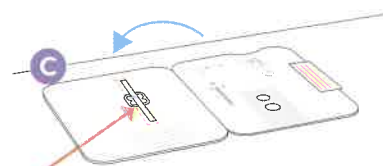
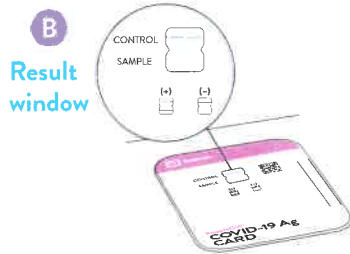
- ! DO NOT touch any parts on the inside. Handle card only by edges.
- ! Card must stay FLAT on table for entire test.

2. Remove test card from pouch and lay flat on table.

The card must stay flat on the table for the entire test.

Make sure the **blue control line** is present in the result window. If a blue line is not present, **do not** use this card.

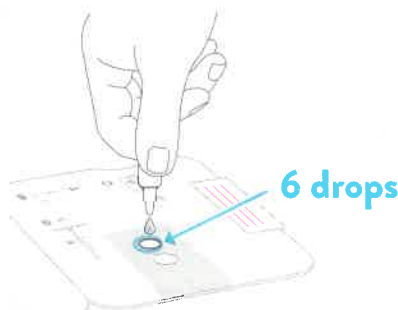
Open card flat on table. You may bend the spine in the opposite direction to help the card lay flat.



DO NOT touch the test strip.

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.

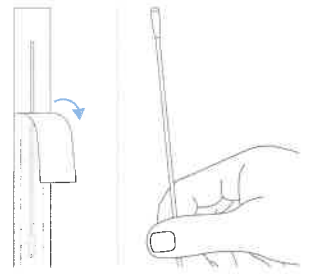


**Note:** False negative result may occur if less than 6 drops of fluid are put in the hole.

## B. COLLECT NASAL SAMPLE

- ! Keep fingers away from the swab end.

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

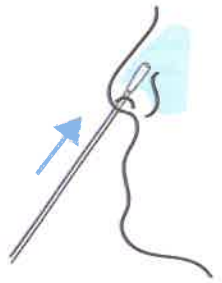


5. Swab both nostrils carefully as shown.

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.

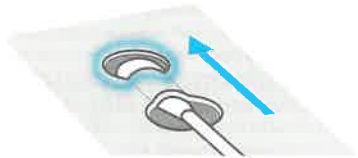
## C. PERFORM THE TEST

! Keep card **FLAT** on table.

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

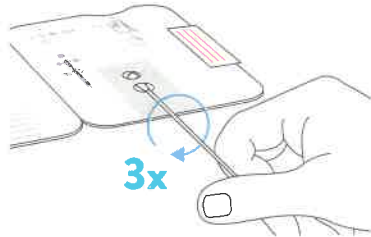


Firmly push the swab tip from the bottom hole until it is visible in the **top hole**.



**Do not** remove the swab from the card.

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



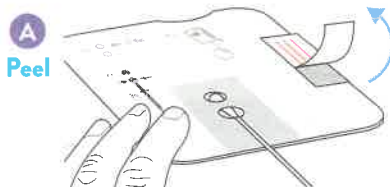
**Do not** skip this step.

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

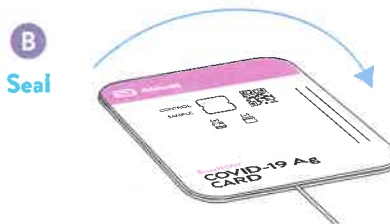
**Note:** False negative result can occur if swab is not turned.

! **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 card to seal.



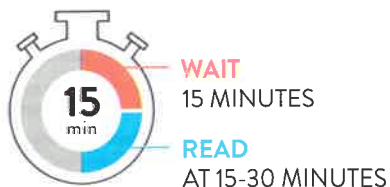
Keep card face up on table.

! **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.

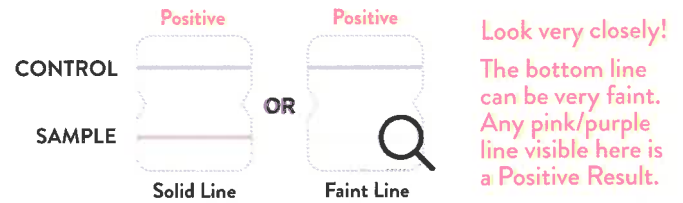
**Note:** Results should not be read after 30 minutes.

## D. INTERPRET RESULTS

### 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**.



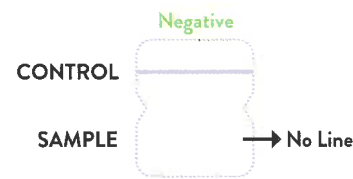
Below are photos of actual positive tests. On the right, note how faint the bottom line can get.



### B. Check for Negative COVID-19 Result

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

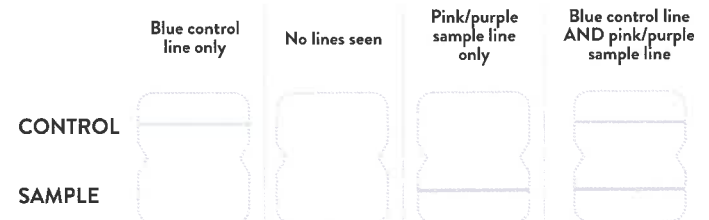
**Negative Result:** If you see **only** one pink/purple line on the top half, where it says "Control" this means **COVID-19 was not detected**.



### 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.

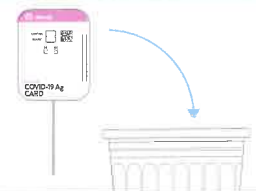
Please contact Technical Support at +1 833-637-1594



**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

Please share your test result with your health care provider. **A second test should be obtained over three days with at least 36 hours between tests.**

See other side for important information.

If both your first and second tests are negative, you may not have COVID-19, however, you should follow-up with your healthcare provider if you are at high risk for COVID-19 infection or have known contacts with COVID-19. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19 or need other testing.

## PRECAUTIONS

- For *in vitro* diagnostic use.
- Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
- Use of gloves is recommended when conducting testing.
- Keep testing kit and kit components out of the reach of children and pets before and after use.
- This test has not been FDA cleared or approved but has been authorized by FDA under an EUA.
- 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.
- Proper sample collection and handling are essential for correct results.
- Do not use a kit that has been opened and/or tampered with.
- Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
- Do not dip the swab into the liquid reagent or other liquid before inserting the swab into the nose.
- Do not touch swab tip when handling the swab sample.
- Do not use kit past its expiration date.
- Do not mix components from different kit lots.
- All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.
- Dispose of kit components and patient samples in household trash.
- 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.
- 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.

## WHAT YOUR RESULTS MEAN

### Positive Result

A positive test result means it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive with the BinaxNOW COVID-19 Antigen Self Test, you should self-isolate and seek follow-up care with your healthcare provider. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

### Negative Result

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath, you should seek follow up care with your healthcare provider. Please consult your healthcare professional if you develop symptoms, symptoms persist or become more severe. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

If the presence of a faint line and/or the presence of a line is uncertain, additional confirmatory testing should be conducted. It is important that you work with your healthcare provider to help you understand the next steps you should take.

### Invalid Result

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.

## KIT COMPONENTS OVERVIEW

**!** Do not touch before reading instructions (flip over sheet).

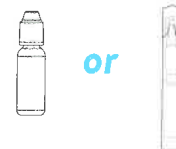
### Swab(s)



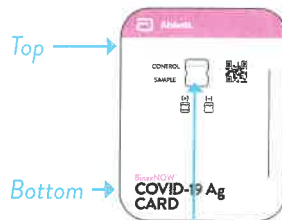
### Test Card in Pouch(es)



### Dropper Bottle(s)

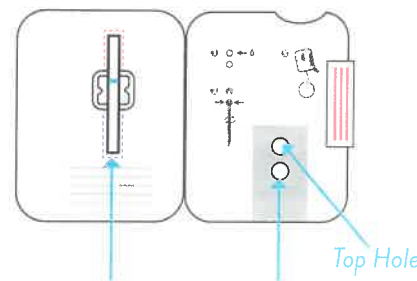


### Outside of Card



Result Window

### Inside of Card



Test Strip

Bottom Hole

### Abbott Rapid Diagnostics Technical Support

US  
+ 1-833-637-1594

[ts.scr@abbott.com](mailto:ts.scr@abbott.com)

**Abbott Diagnostics Scarborough, Inc.**  
10 Southgate Road  
Scarborough, Maine 04074 USA  
[www.binaxnow-selftest.abbott](http://www.binaxnow-selftest.abbott)

© 2021 Abbott. All rights reserved.

All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners.

