



BinaxNOW™

# COVID-19 Ag CARD 2 HOME TEST KIT

PROCEDURE CARD



**DO NOT OPEN ITEMS UNTIL INSTRUCTED TO DO SO**

# The BinaxNOW™ COVID-19 Ag Card 2 Home Test is for FDA Emergency Use Authorization (EUA) Only

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## For *In Vitro* Diagnostic (IVD) Use

- This product 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 IVDs 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.
- For more information on EUAs go here: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- For the most up to date information on COVID-19, please visit: [www.cdc.gov/COVID19](http://www.cdc.gov/COVID19)

- For detailed instructions, please visit: [BinaxNOWhometest.abbott.com](https://BinaxNOWhometest.abbott.com)

# Frequently Asked Questions

## Will this test hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

## What are the known and potential risks and benefits of this test?

### Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Results section).

### Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

## Hazardous Ingredients for the Reagent Solution

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%

The solution in the tube contains a hazardous ingredient (see table above). **If the solution contacts the skin or eye, flush with**

**plenty of water. If irritation persists, seek medical advice.**

<http://www.poison.org/contact-us> or 1-800-222-1222.

## What is the difference between an antigen and molecular test?

There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation.

## How Accurate is this Test?

Based on the interim results of a clinical study where the BinaxNOW™ COVID-19 Ag Card 2 Home Test was compared to an FDA authorized high sensitivity SARS-CoV-2 test, BinaxNOW COVID-19 Ag Card 2 Home Test correctly identified 91.7% of positive specimens and 100% of negative specimens.

# Frequently Asked Questions

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Due to the relatively small sample size for the home use clinical study, the BinaxNOW COVID-19 Ag Card 2 Home Test is estimated to correctly identify between 73.0% and 98.9% of positive specimens as reflected in the 95% Confidence Interval. This is consistent with the performance established in a separate multi-site clinical 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 correctly identified 84.6% of positive specimens and 98.5% of negative specimens.

The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

Based on this information, negative results may require additional testing to confirm your result. Please talk to your healthcare provider to determine if you need additional testing.

## What is Serial Testing?

COVID-19 Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.



# Indication

The BinaxNOW COVID-19 Ag Card 2 Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for ~~non-prescription~~ home use with self-collected observed direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected nasal swab samples from individuals aged two years or older.

The BinaxNOW COVID-19 Ag Card 2 Home Test is to be performed only with the supervision of a telehealth proctor.

The BinaxNOW COVID-19 Ag Card 2 Home 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 Ag Card Home 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 a patient'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.

The BinaxNOW COVID-19 Ag Home Test is intended for observed 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 Ag Card 2 Home Test is only for use under the Food and Drug Administration's Emergency Use

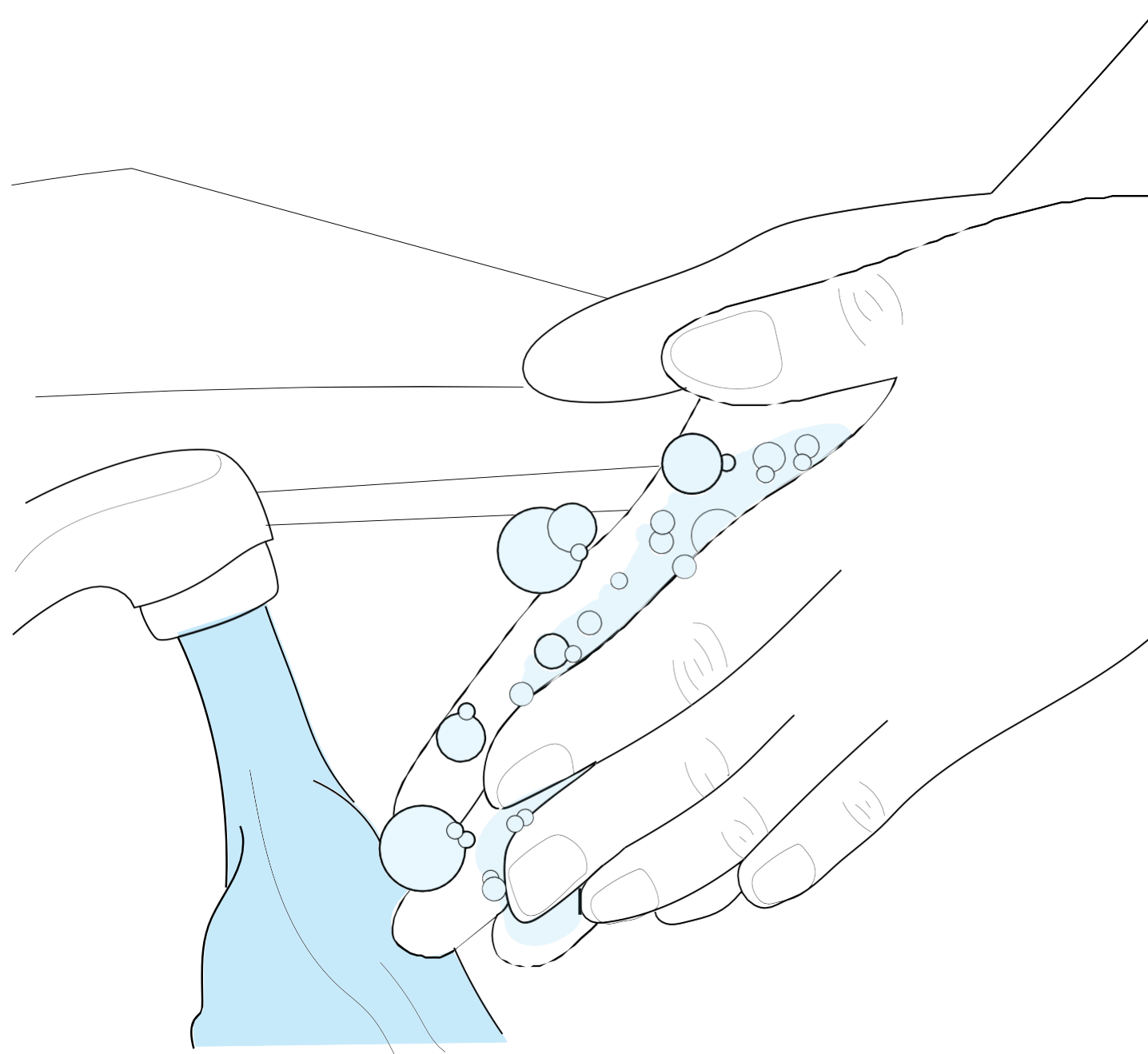
Authorization.

The telehealth provider 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.

# Wash Your Hands

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





# 1 Set Up

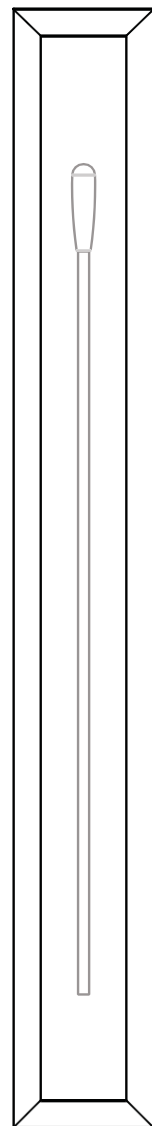
It is recommended gloves (not provided) also be used during testing.



**DO NOT open items until instructed.**

Open your test kit. You will need the following to perform a test:

**1 Swab**



**1 Test Card**



**1 Bottle**



**or**

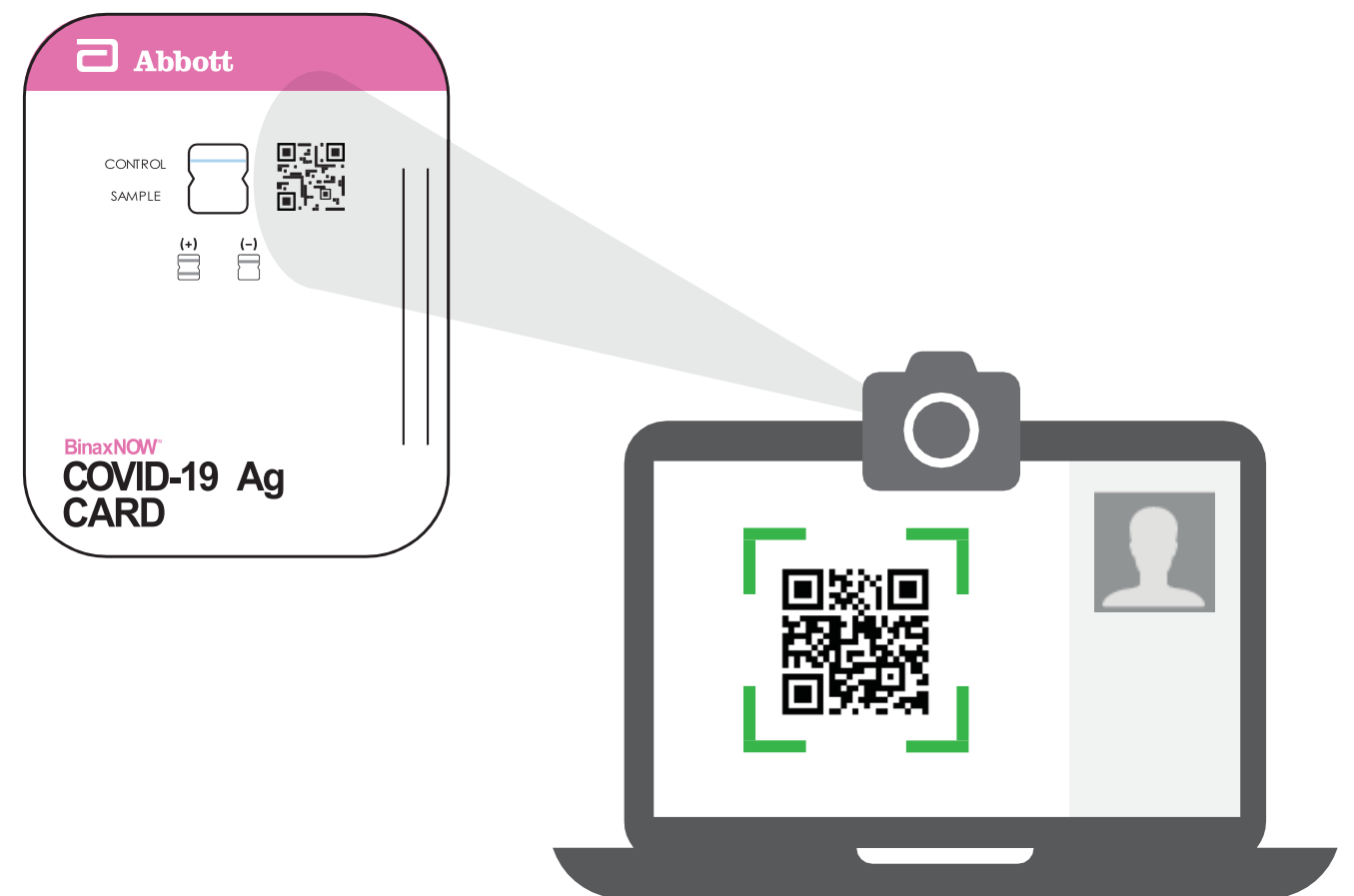


## 2 Open Pouch and Scan QR Code on Card

If using a mobile device:



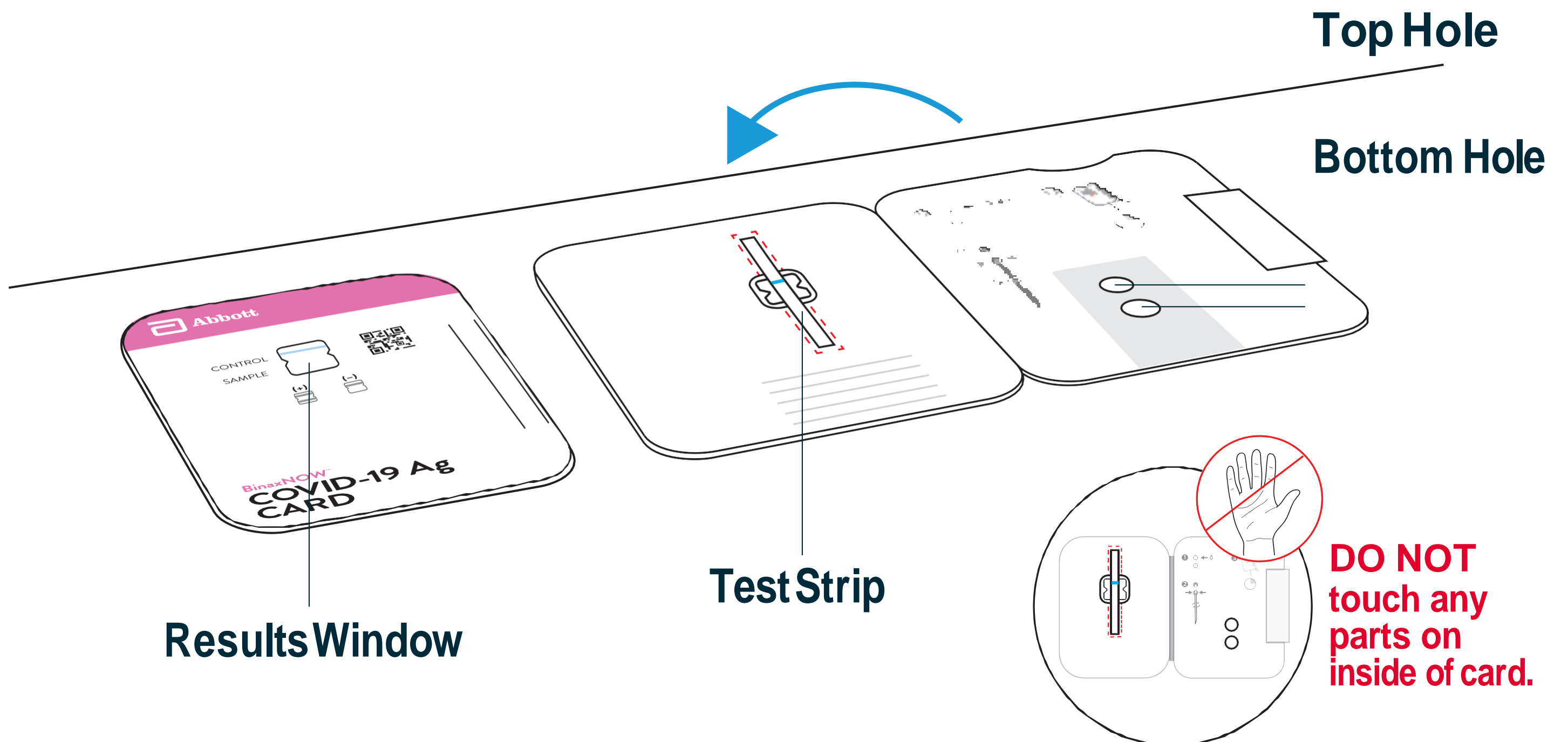
If using a computer:



### 3 Open Card



**Card must stay FLAT on table for entire test.**

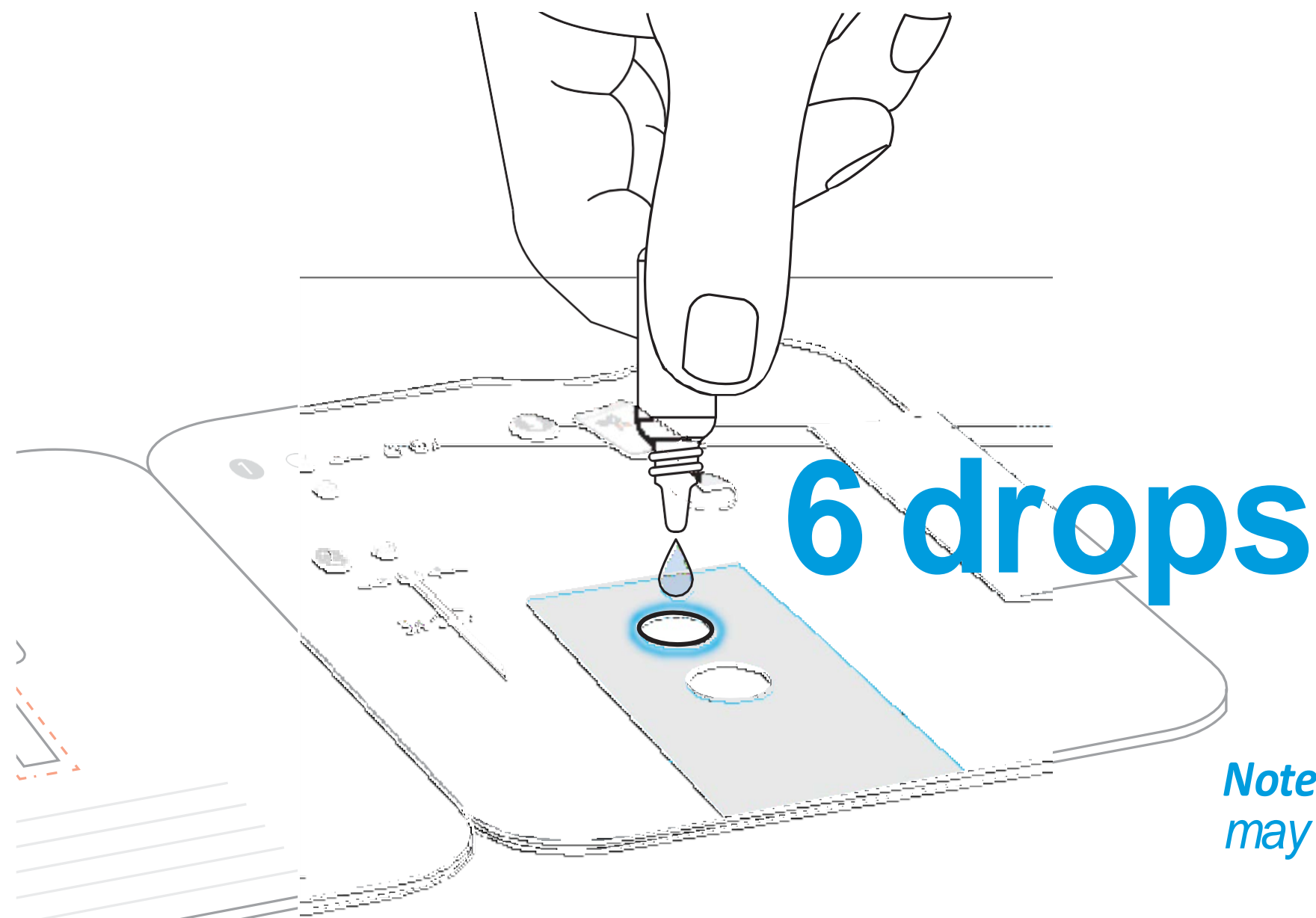


## 4 Apply Fluid to Top Hole

**A.** Removedropper bottle cap.

**B.** Hold dropper bottle straight over TOPHOLE, not at an angle.

**C.** Put 6 DROPS into TOPHOLE. Do not touchcard with tip.



*Note: False negative results may occur if less than 6 drops*

*of fluid is used.*



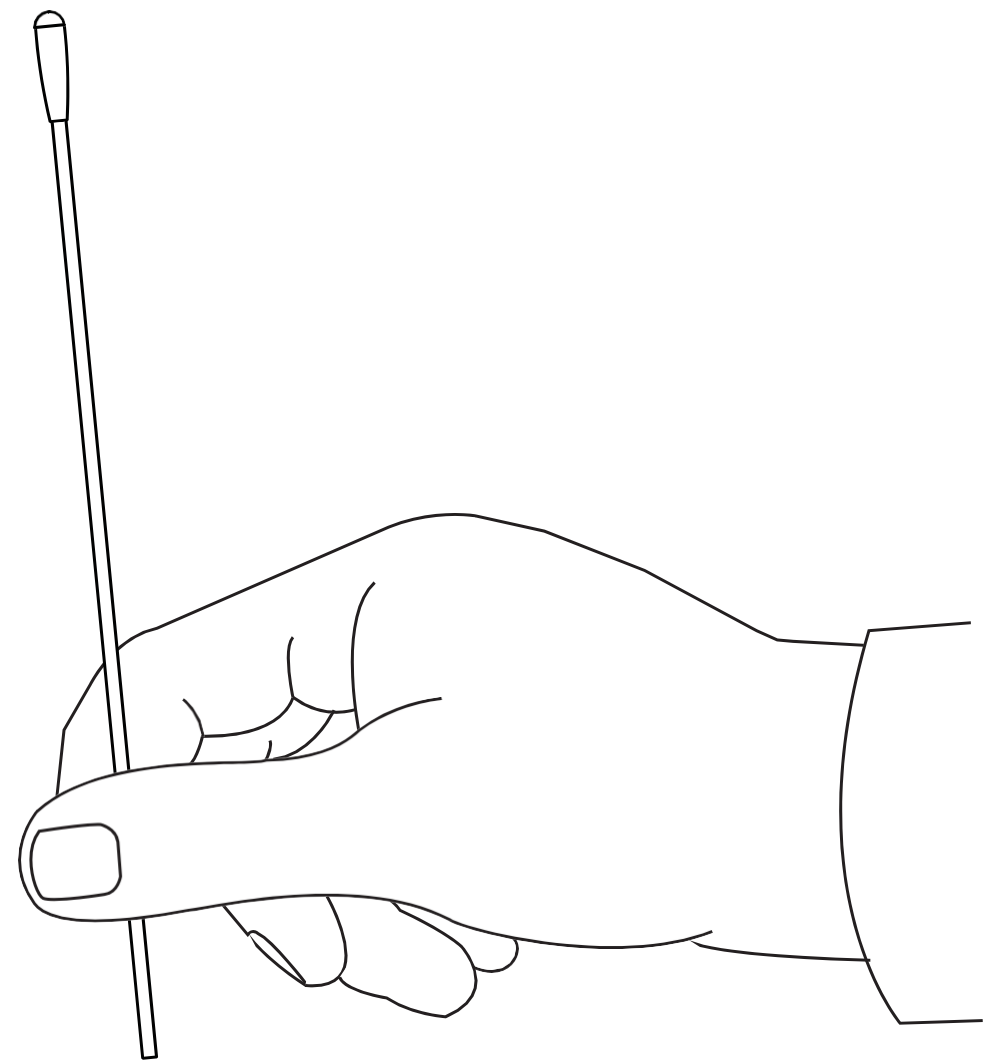
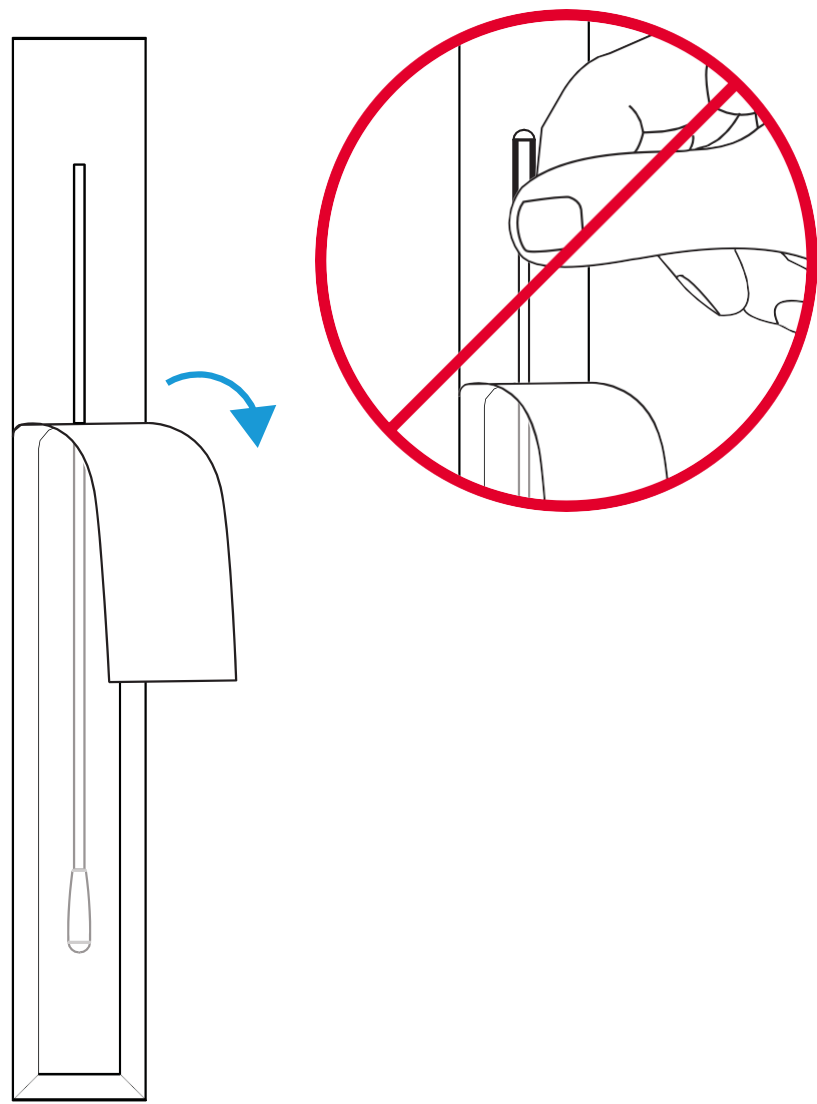
## 5 Open Swab



Keep fingers away from swab end.

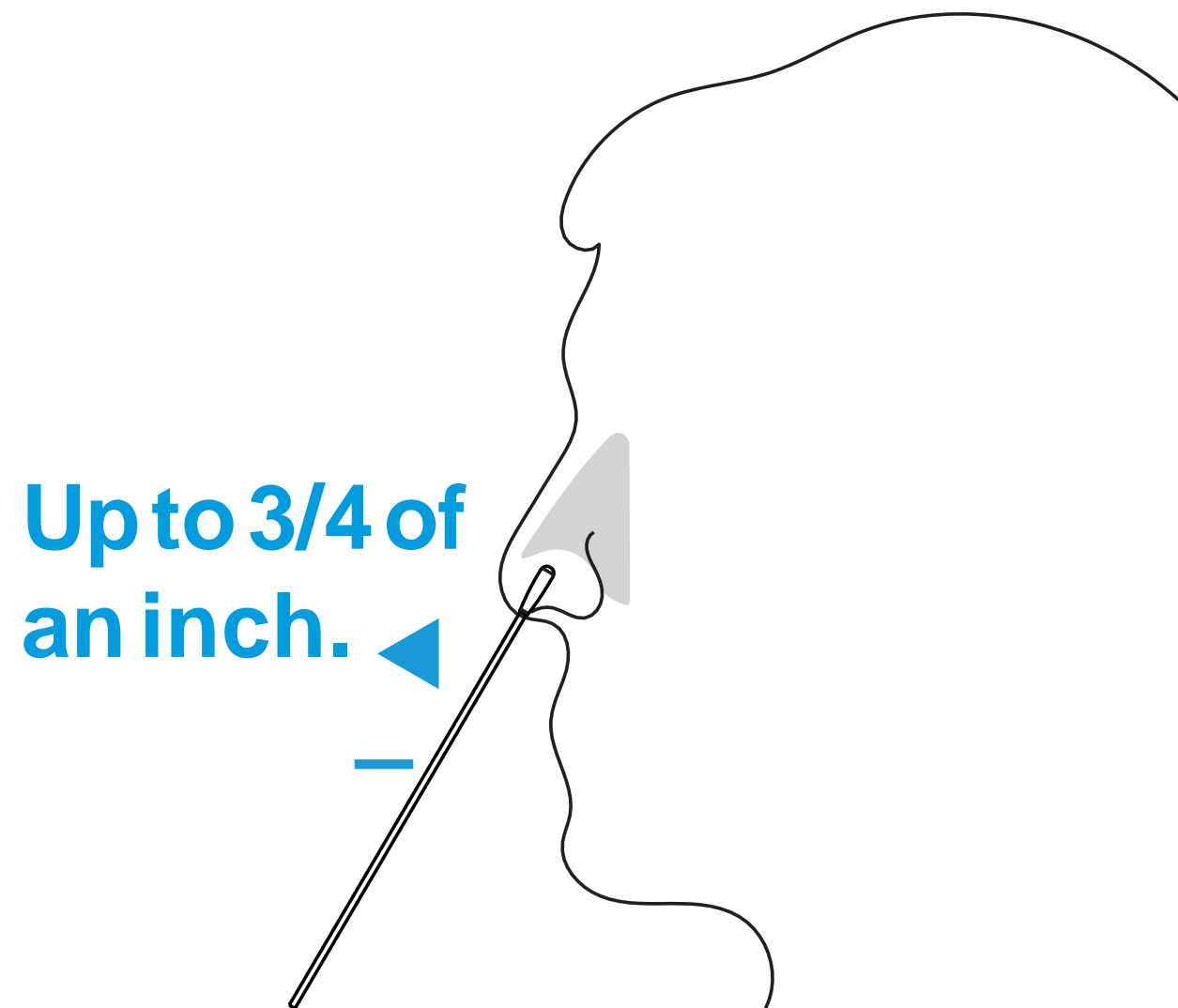
**A.** Open swab package at stick end.

**B.** Take swab out.

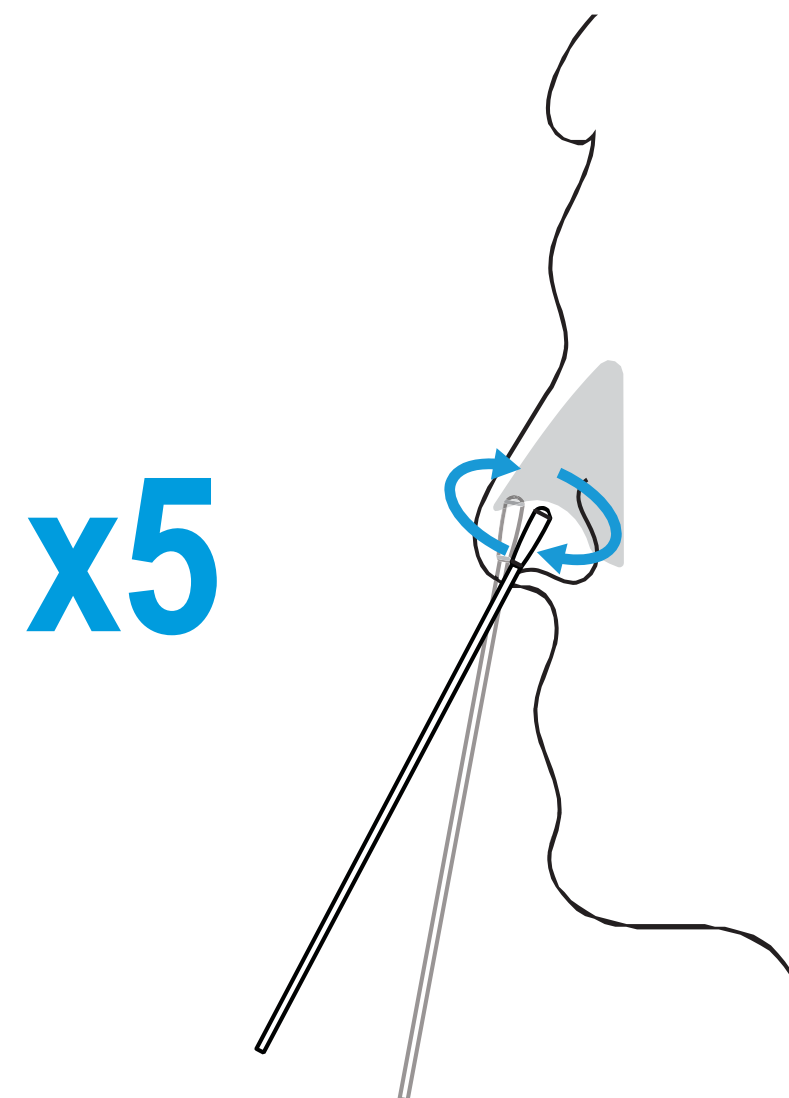


## 6 Swab Left Nostril

**A.** Insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into left nostril.



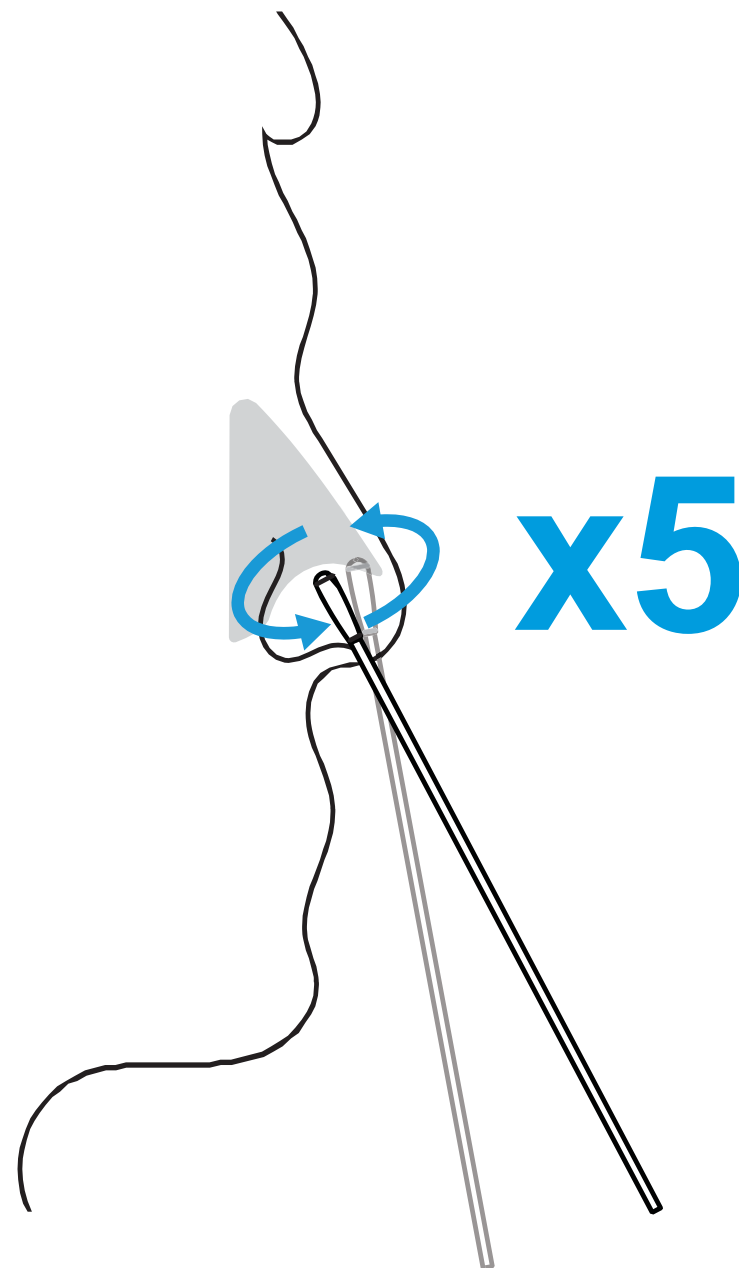
**B.** Firmly brush against inside of nostril in a circular motion 5 times or more for at least 15 seconds.



## 7 Swab Right Nostril

**A.** Remove swab and insert it into right nostril.

**B.** Firmly brush against inside of nostril in a circular motion 5 times or more for at least 15 seconds.



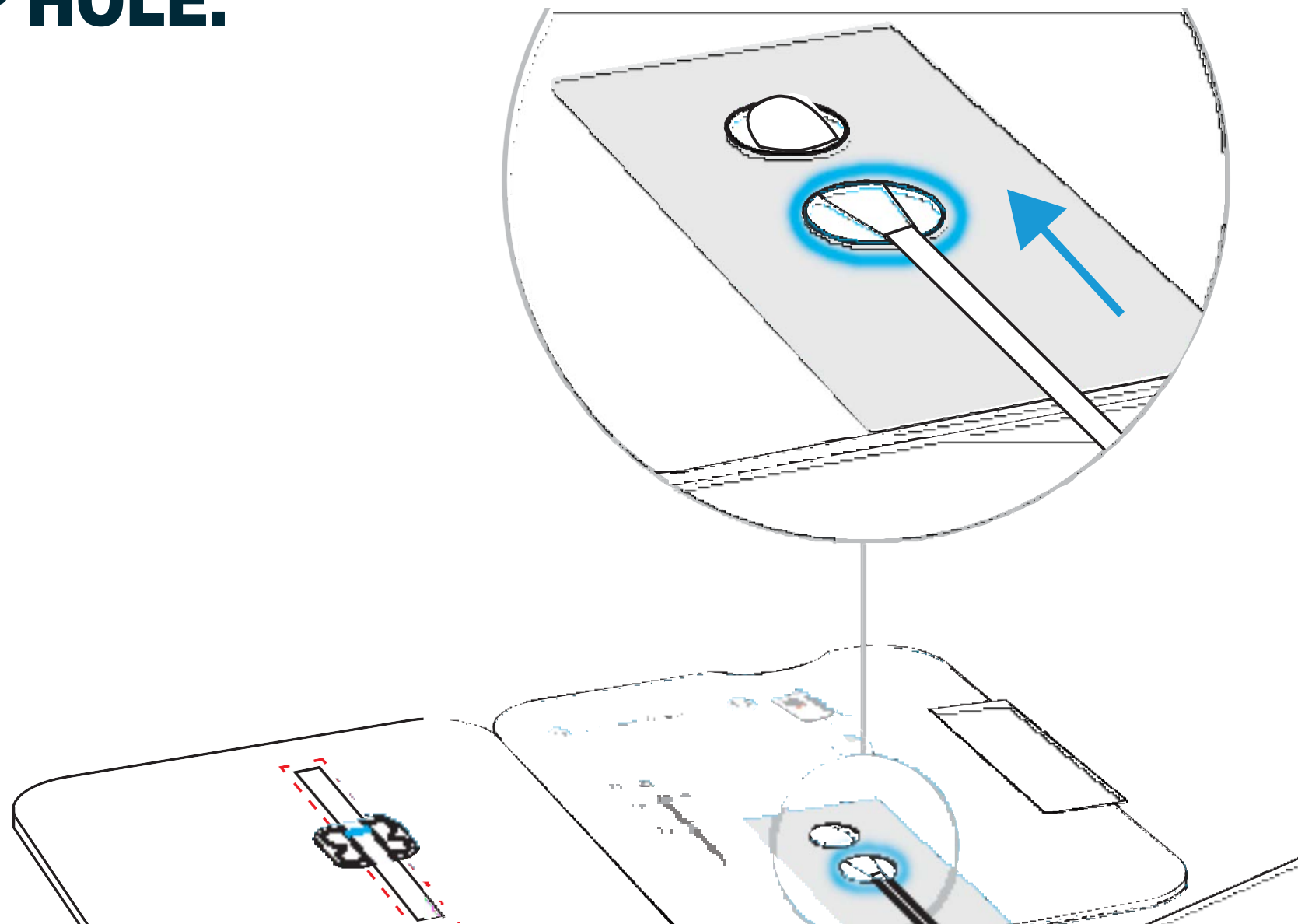
*Note: False negative results may occur if the nasal swab is not properly collected.*

## 8 Insert Swab into Bottom Hole



**Keep card FLAT on table.**

Insert **swab tip** into **BOTTOM HOLE** and **firmly push up** until tip fills **TOP HOLE**.



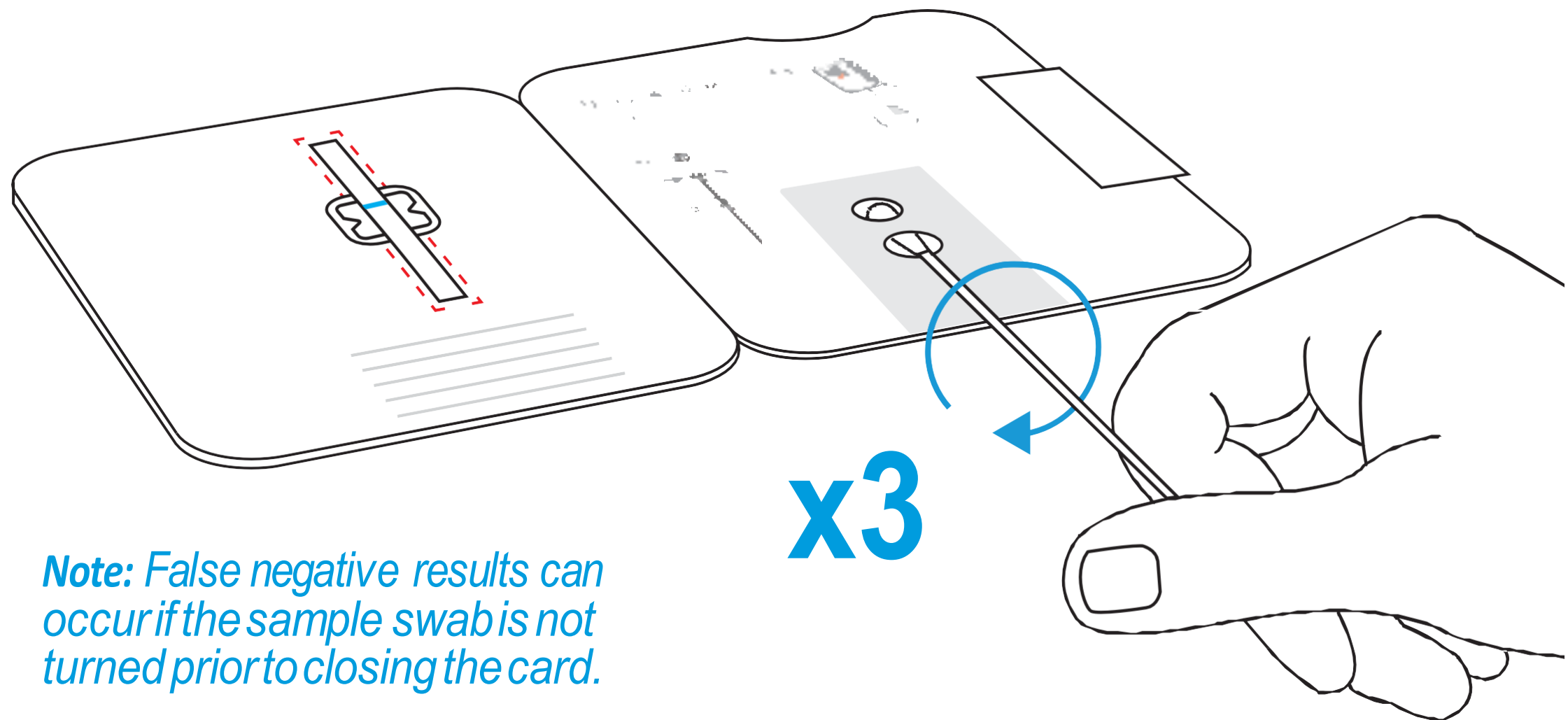


## 9 Turn Swab 3 Times



**Keep card FLAT on table.**

Turn swab to right 3 times in card and leave it in place.



*Note: False negative results can occur if the sample swab is not turned prior to closing the card.*

## 10 Peel Strip

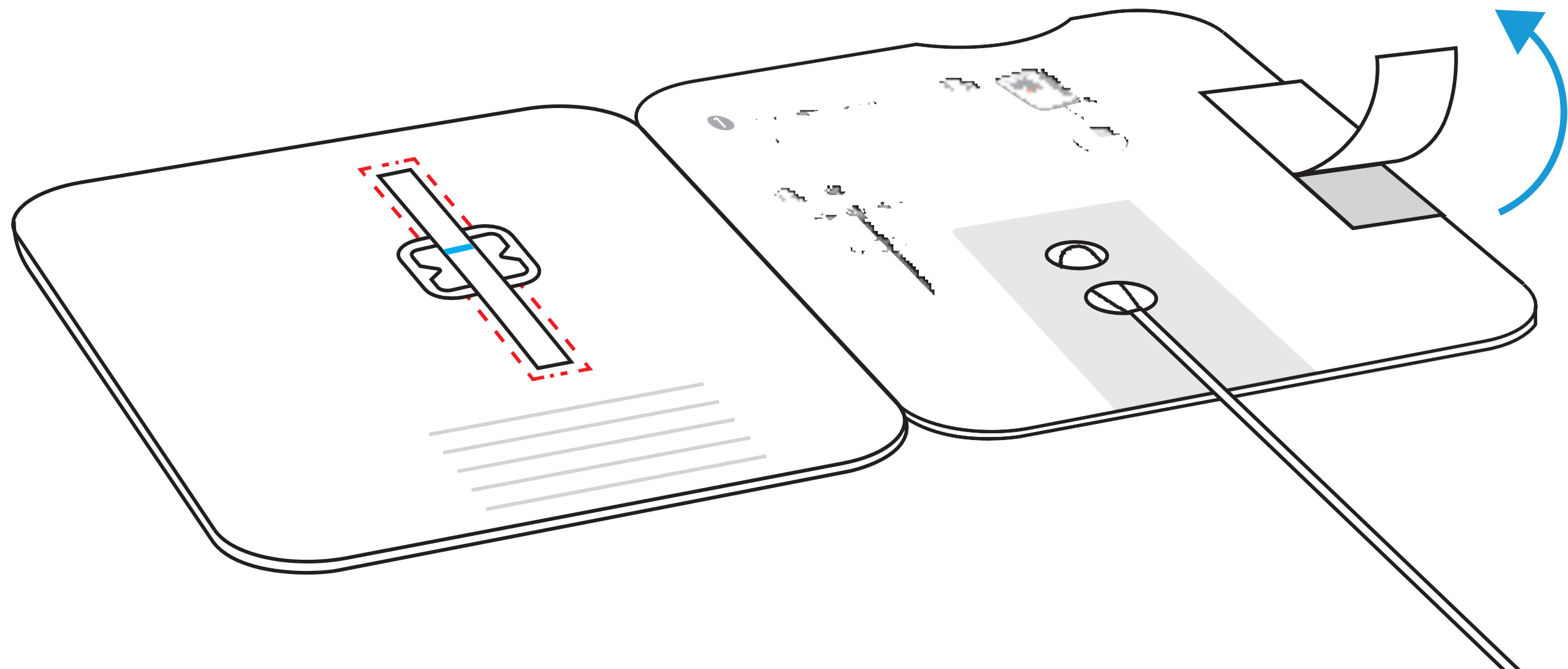


**DO NOT remove swab.**



**Keep card FLAT on table.**

Keep swab in place. Peel adhesive liner off.



## 11 Close Card and Seal

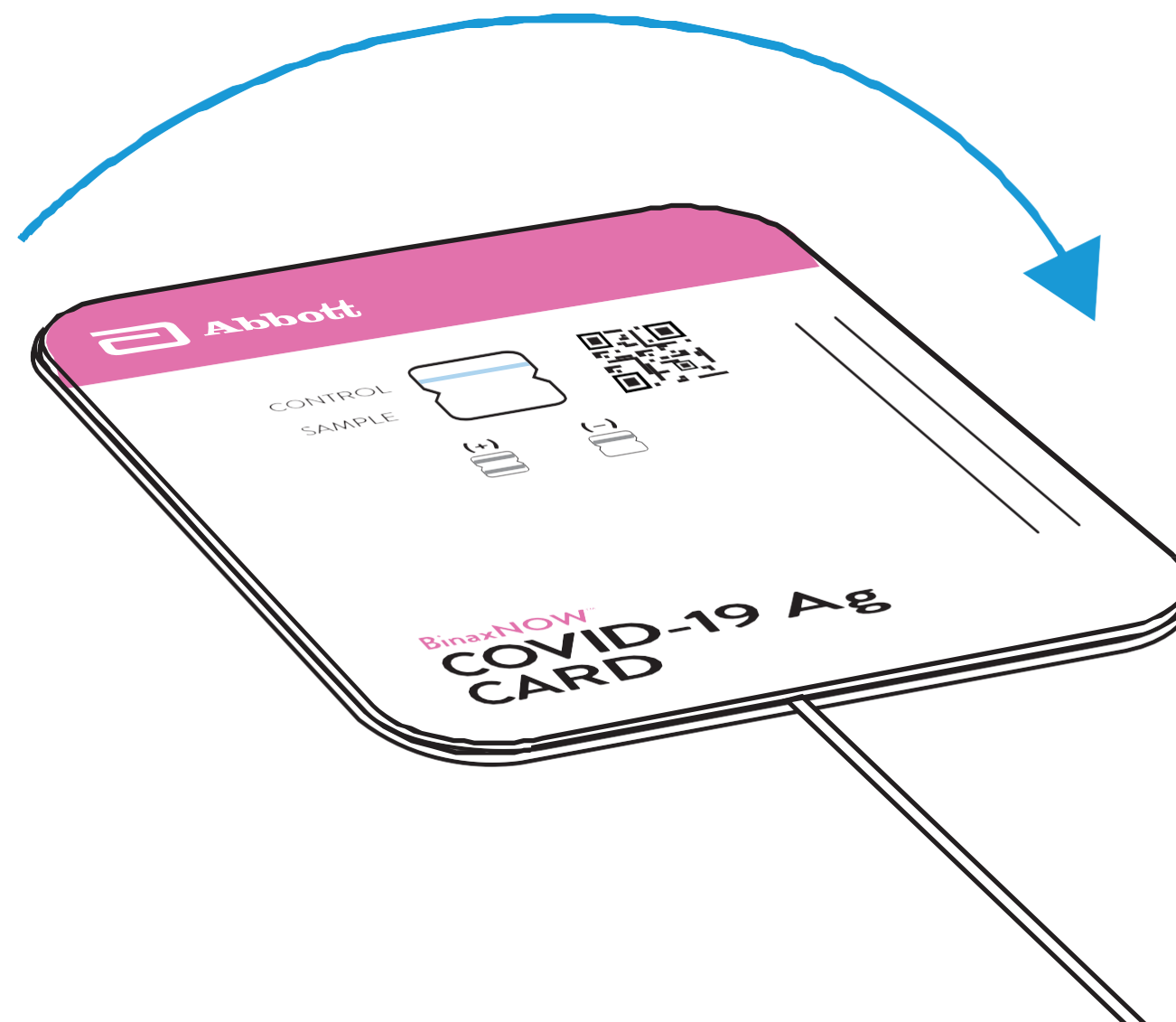


**DO NOT remove swab.**



**Keep card FLAT on table.**

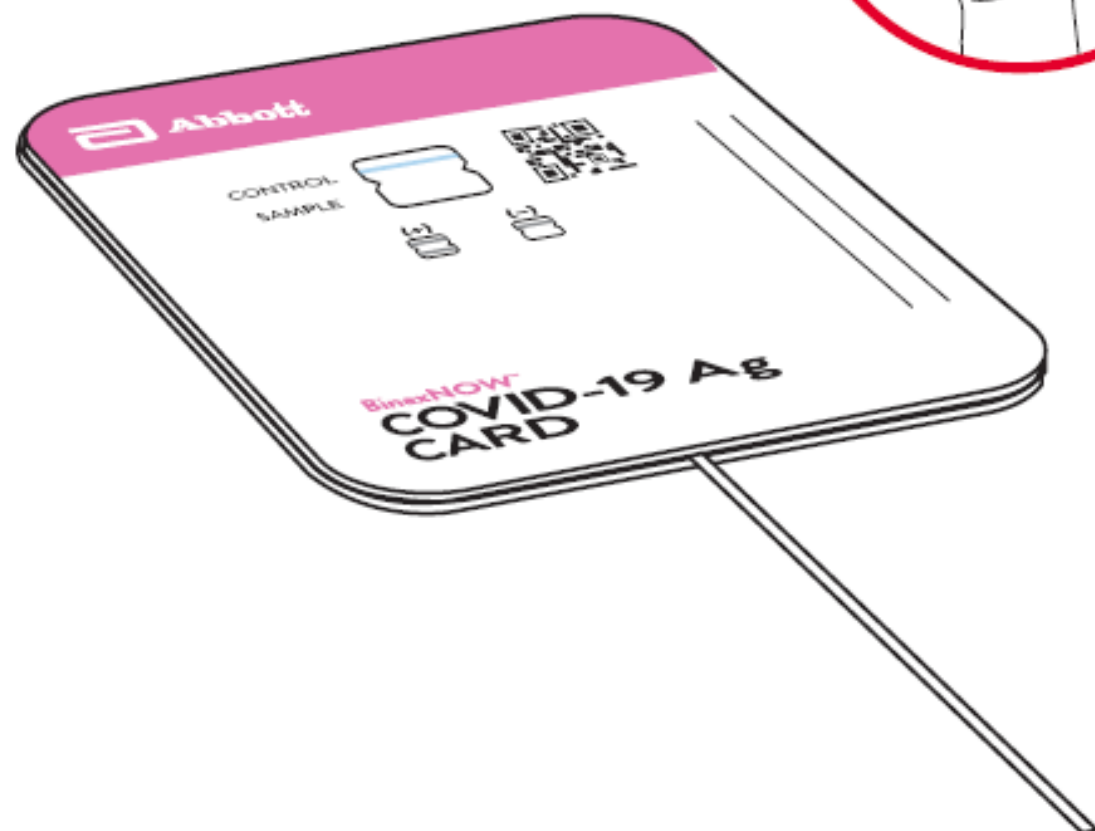
Close left side of card over swab to seal it. Keep card face up on table.



## 12 Wait 15 Minutes



DO NOT disturb card during this time.



15:00

**Note:** False results can occur if the card is disturbed/moved or test results are read before 15 minutes.

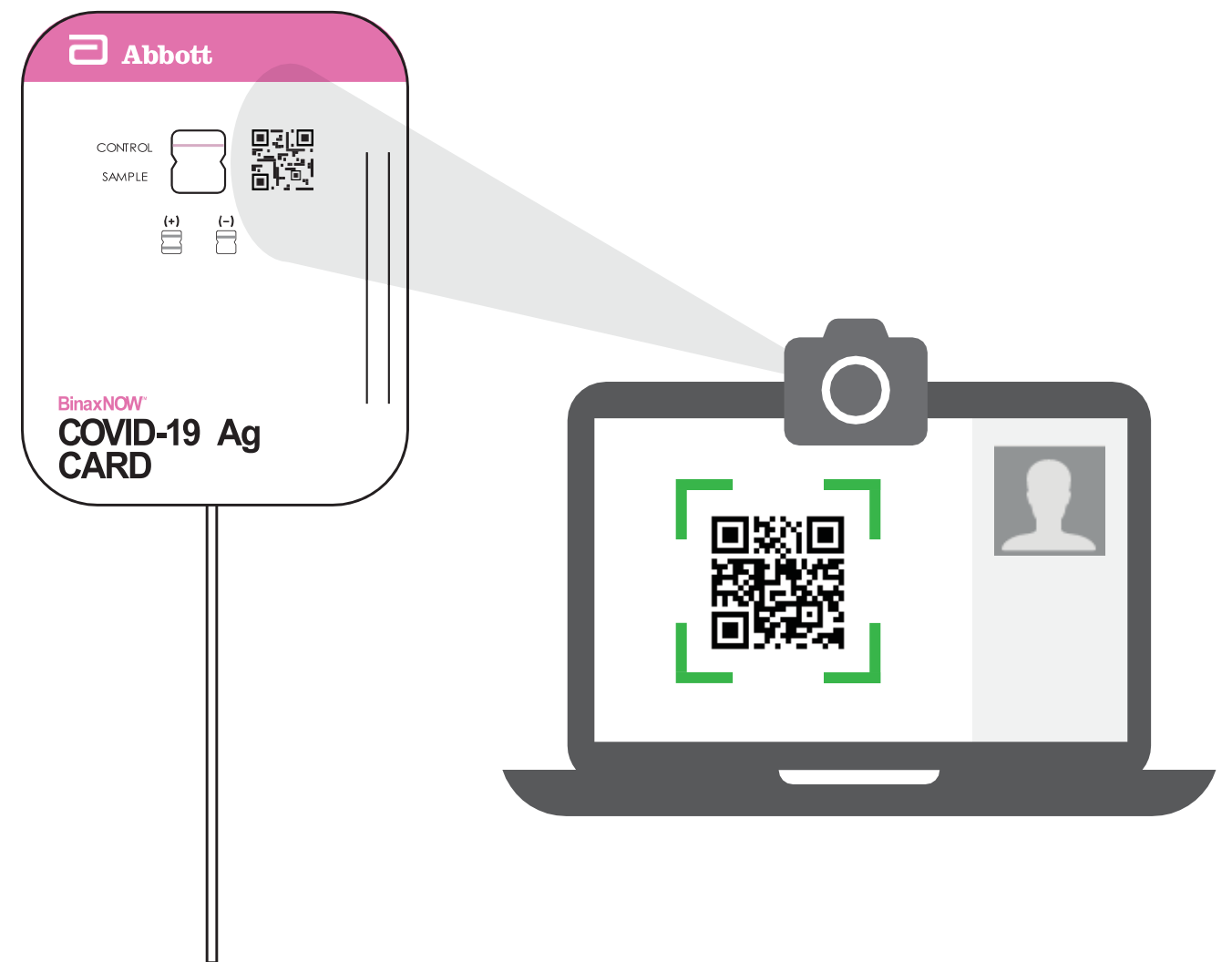
*Results should not be read after 30 minutes*

## 13 Scan QR Code

If using a mobile device:

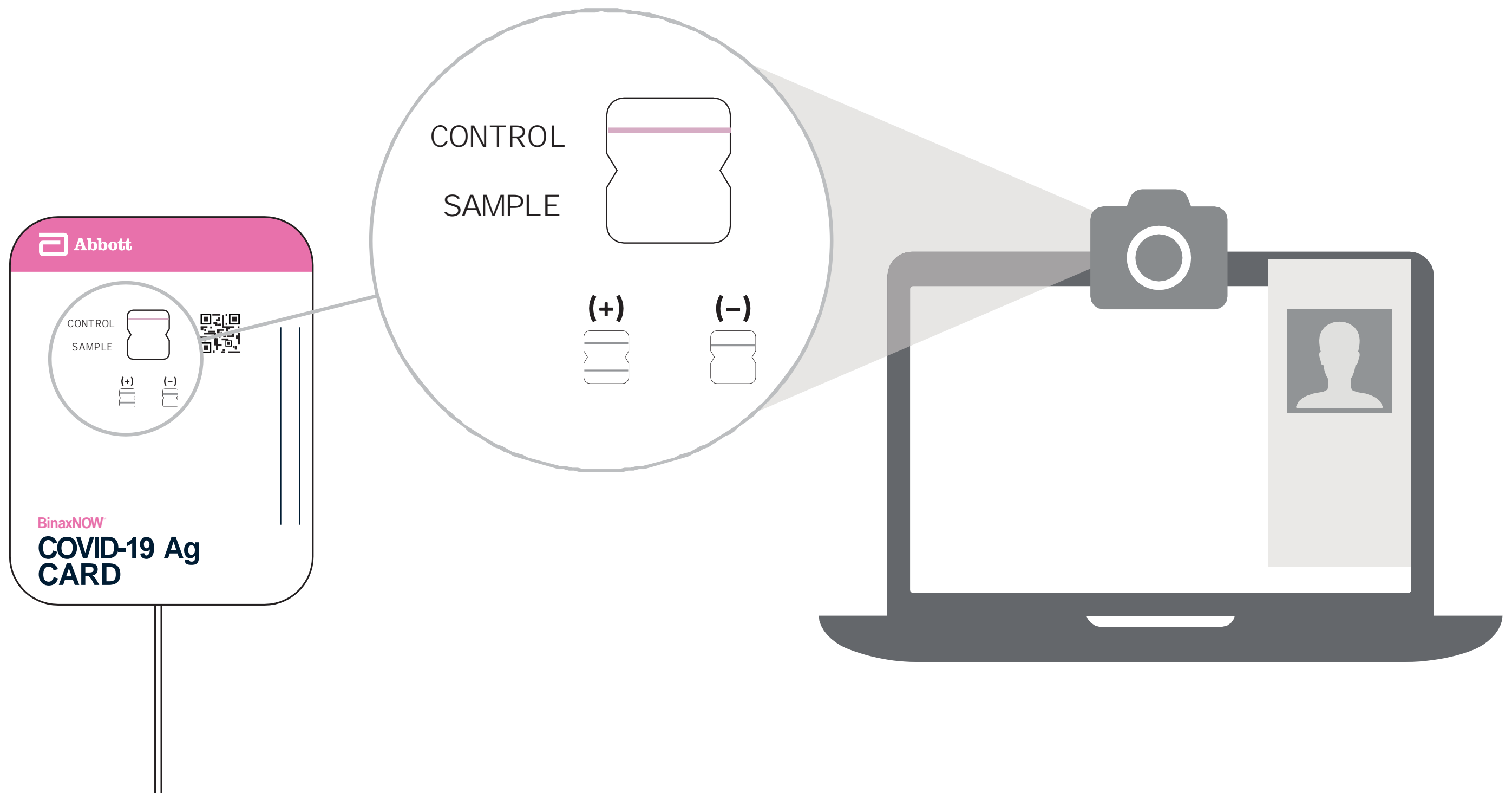


If using a computer:





# 14 Show Result to Your Proctor



# **15 Steps to Check Your Results**

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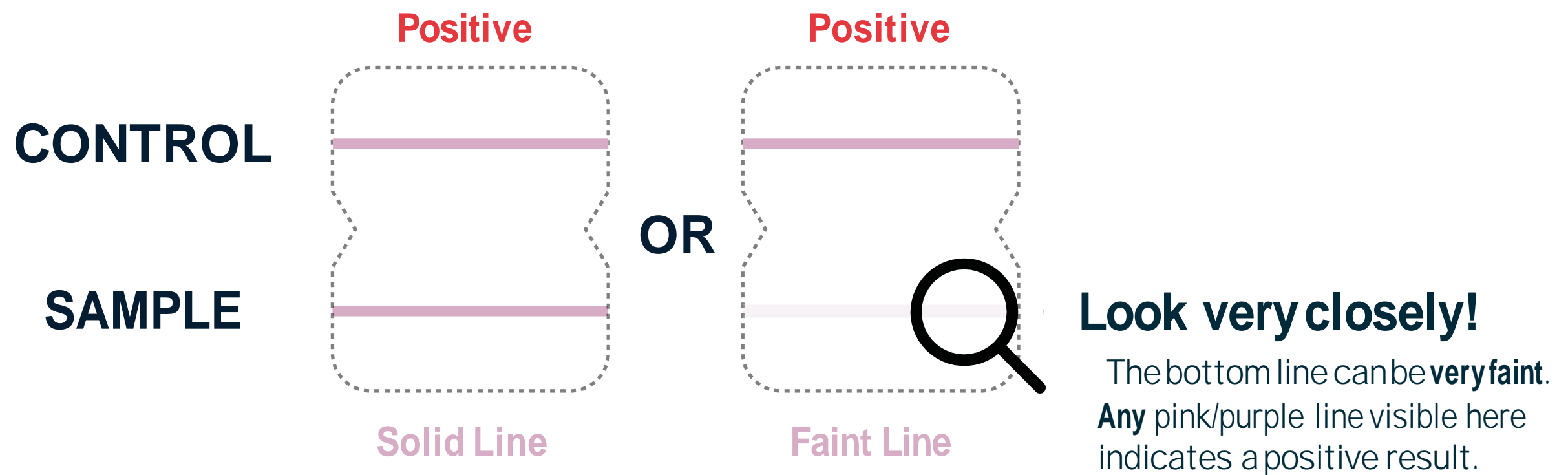
There are three types of results possible. You will be instructed how to read each type in a specific order. Follow this order with your proctor:

- 1. Check for a Positive Result**
- 2. Check for a Negative Result**
- 3. Check for an Invalid Result**

# 16 Check for Positive COVID-19 Result

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

- **Positive Result:** Two pink/purple lines will appear. One on the top half and one on the bottom half. **COVID-19 was detected.**



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



# Positive COVID-19 Result

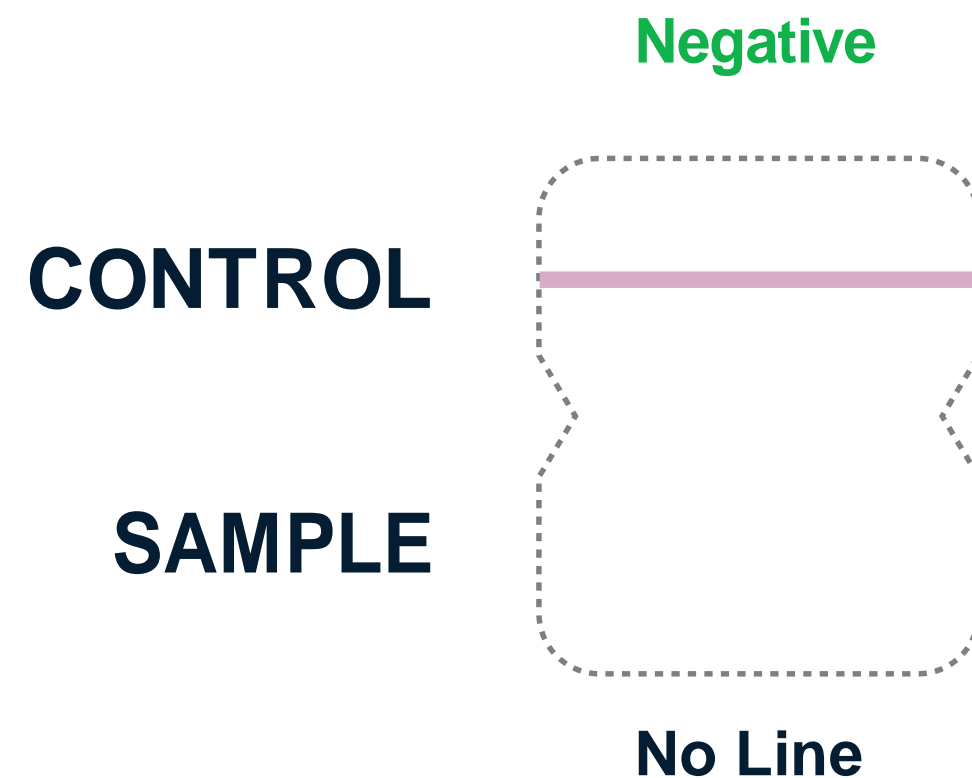
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A positive test result means it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. The telehealth proctor is not a healthcare provider. It is also likely that you may be placed in isolation to avoid 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 Ag Card 2 Home Test kit, 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.

## 17 Check for Negative COVID-19 Result

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

- **Negative Result:** A single pink/purple line on the top half where it says "Control." **COVID-19 was not detected.**





# Negative COVID-19 Result

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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.

The telehealth proctor is not a healthcare provider. 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 you or the telehealth proctor disagree on the presence of a faint line and/or the presence of a line is uncertain, additional testing should be conducted.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

# What do I need to know about Results from Serial Testing?


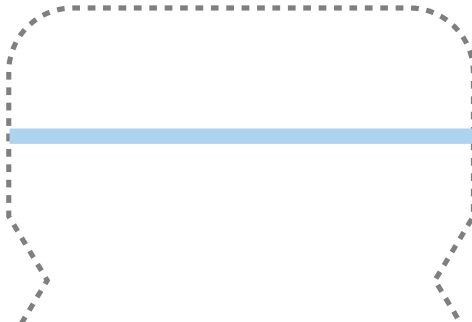

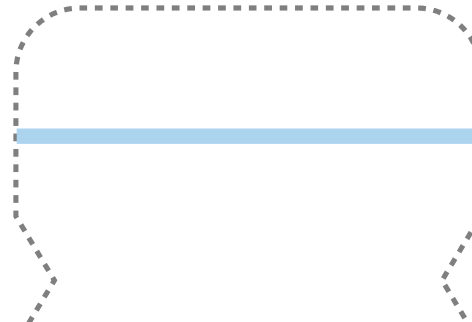




If your first test is negative, you should test again in 24-36 hours.

If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your specimen and you likely have COVID-19. If you test positive with the BinaxNOW COVID-19 Ag Card 2 Home Test with either test, you should self-isolate and seek follow-up care with your healthcare provider to determine the next steps you should take. You may need additional testing, depending on your personal health history and other factors.

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.

## 18 Check for Invalid Result

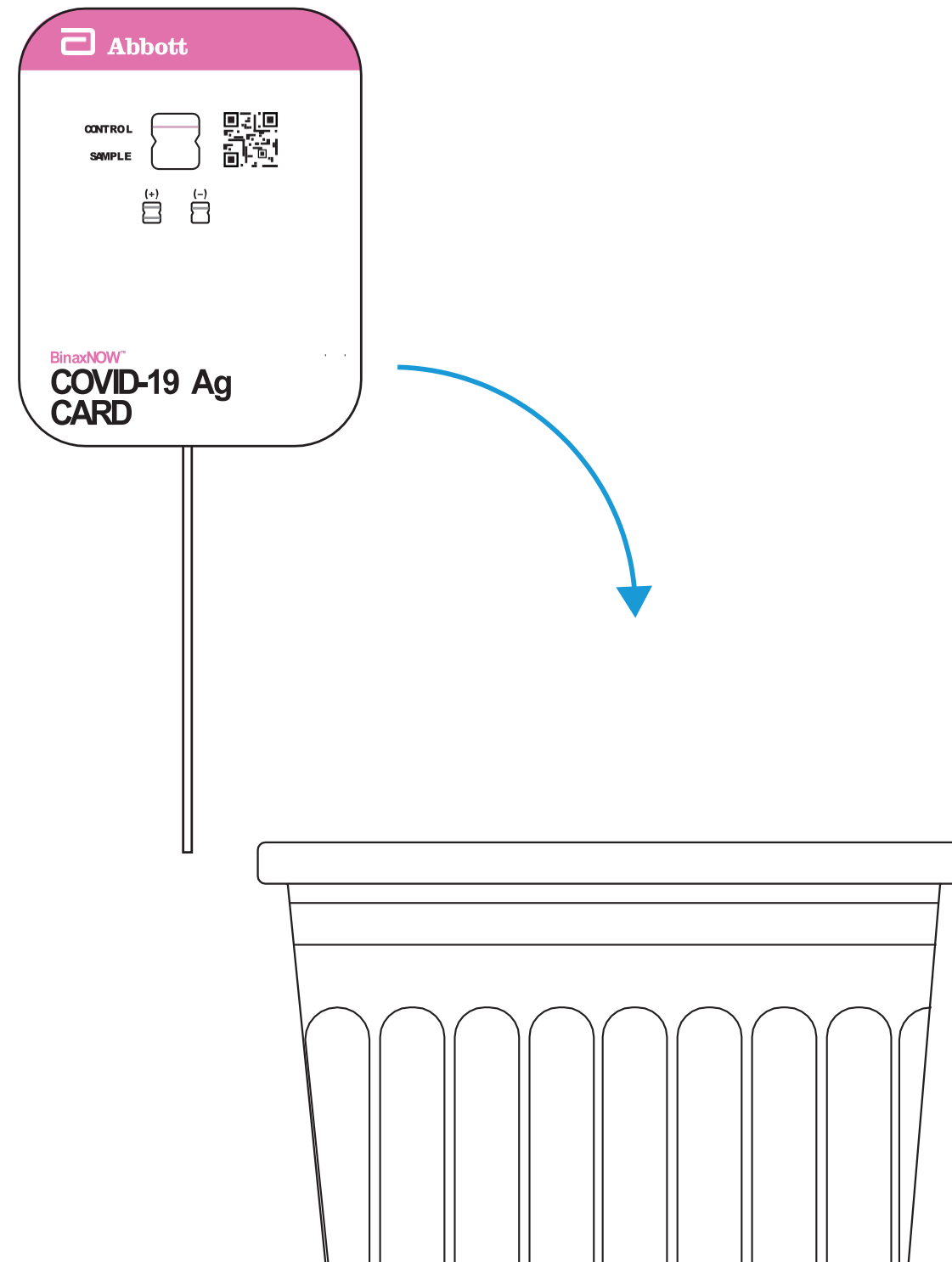
 If you see any of these, the test is invalid.

	No lines seen	Blue control line only	Pink/purple sample line only	Blue control line AND pink/purple sample line
CONTROL				
SAMPLE				

**REMEMBER:** A second BinaxNOW COVID-19 Ag Card 2 Home Test is required to be performed within 3 days with at least 36 hours between tests.

# 19 Dispose in Trash

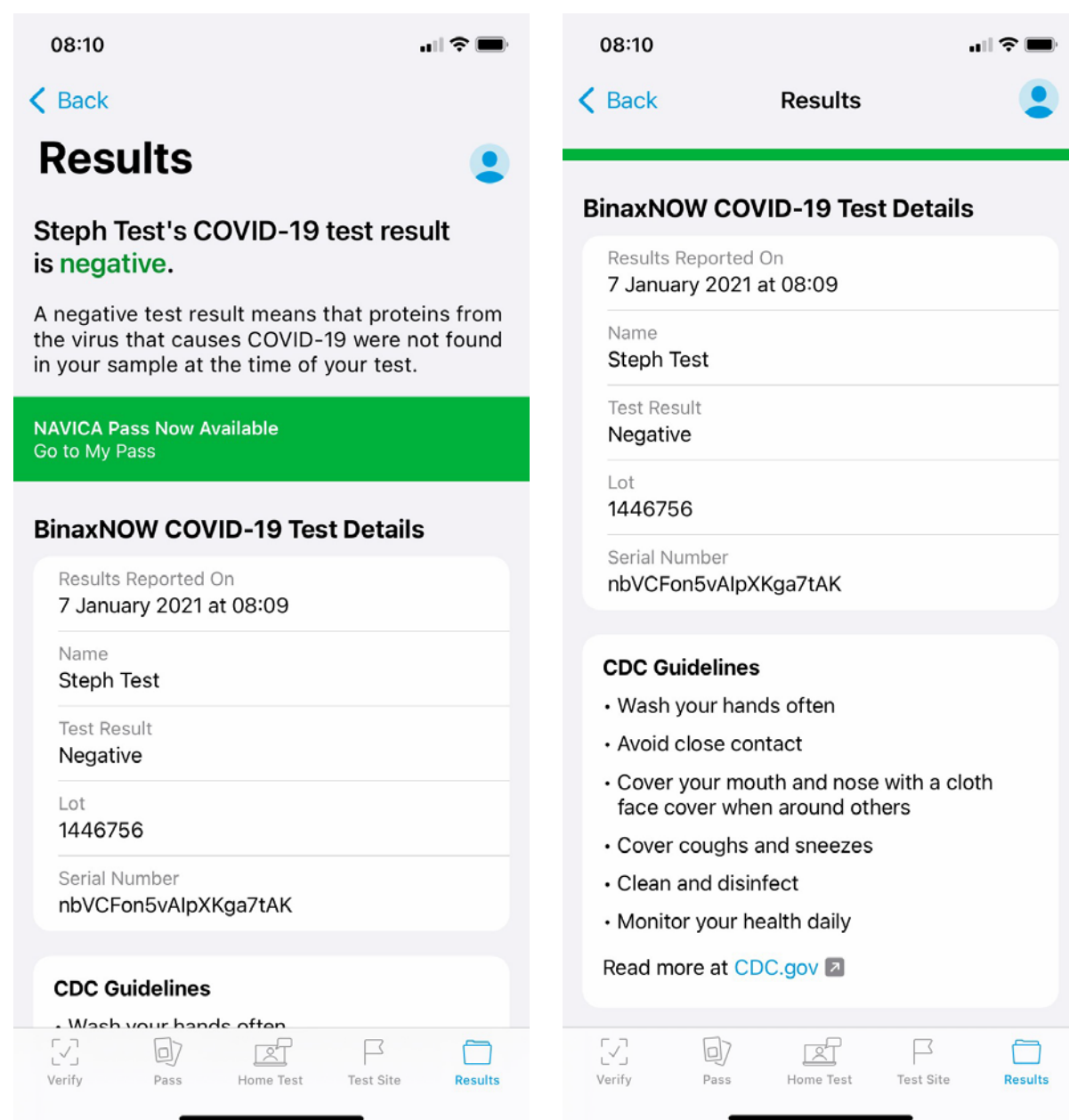
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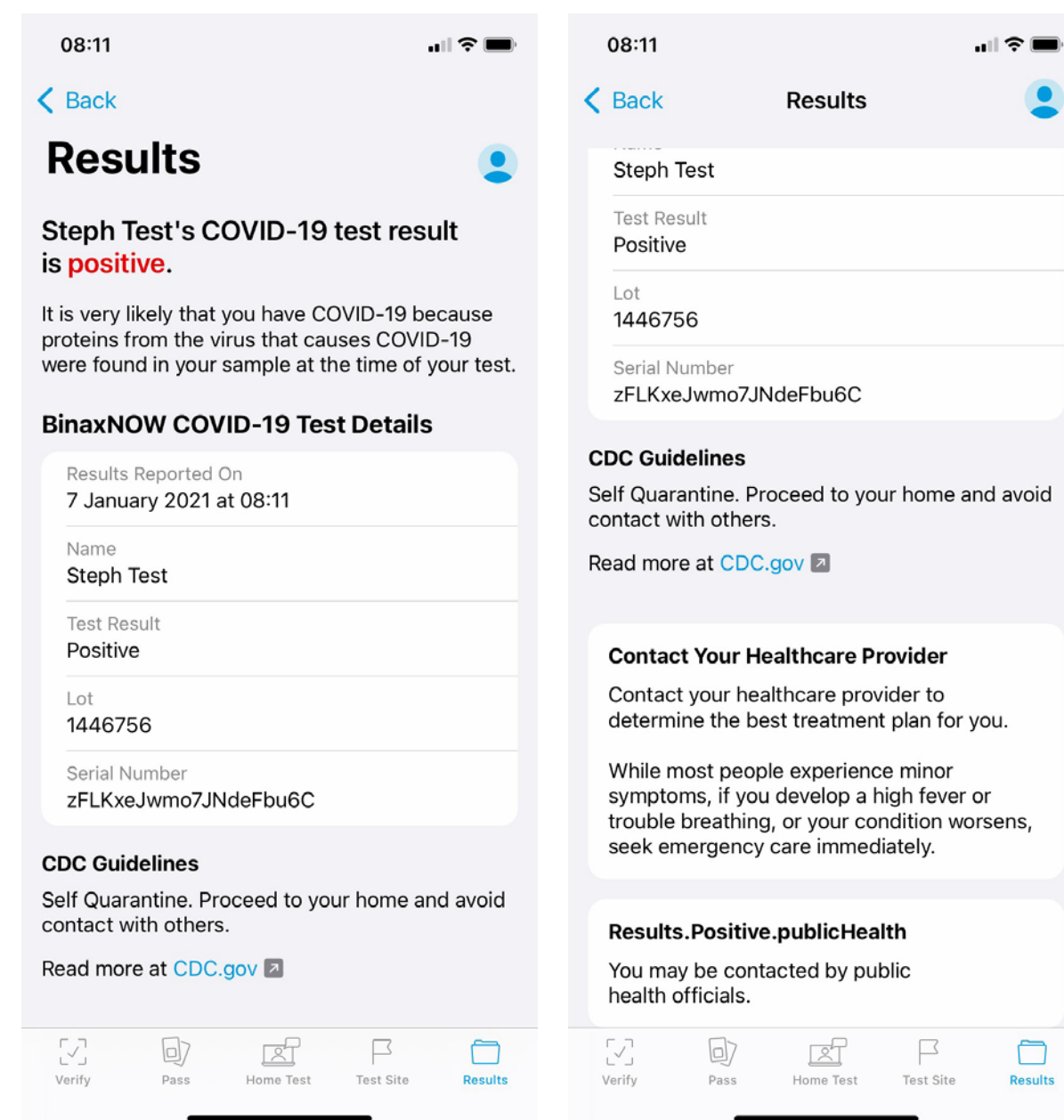
# Reporting Patient Results Using NAVICA

Upon completion of the test and result interpretation, the telehealth proctor will send your test results via the NAVICA app. You will be notified by email and on your mobile device that your results are ready. You will go to the results screen in NAVICA to obtain your test results.

If your BinaxNOW COVID-19 Ag Card 2 Home Test result is **Negative**, you will receive the following:



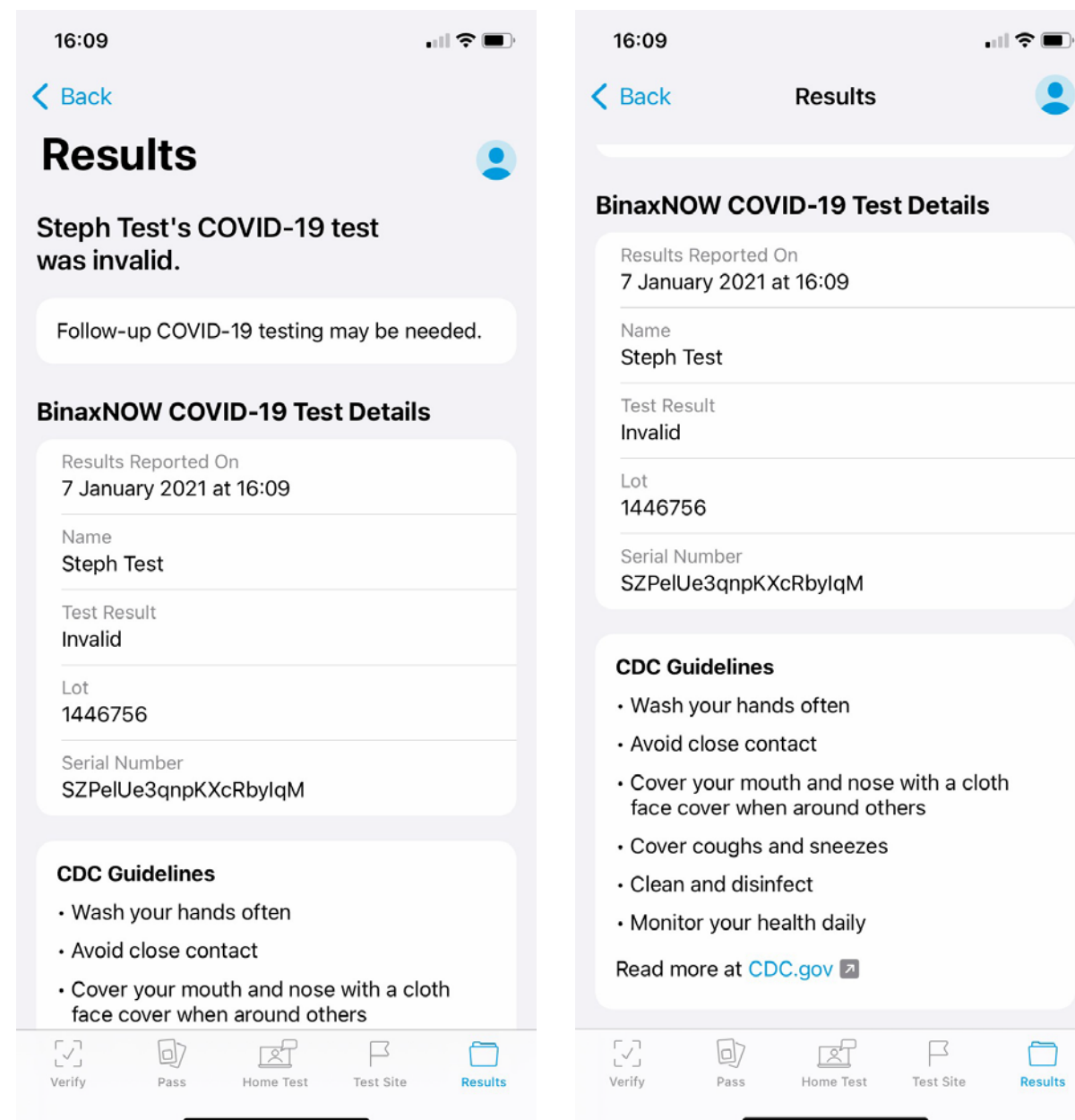
If your BinaxNOW COVID-19 Ag Card 2 Home Test result is **Positive**, you will receive the following:



# Reporting Patient Results Using NAVICA

Upon completion of the test and result interpretation, the telehealth proctor will send your test results via the NAVICA app. You will be notified by email and on your mobile device that your results are ready. You will go to the results screen in NAVICA to obtain your test results.

If the BinaxNOW COVID-19 Ag Card 2 Home Test result is **Invalid**, you will receive the following:



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BinaxNOW COVID-19 Ag CARD 2 HOME TEST KIT



<div>Abbott</div> <div>BinaxNOW</div> <div>COVID-19 Ag Card 2 Home Test</div> <div>Procedure Card</div> <div>Size:</div> <div>16.35 in. x 12.21 in.</div>	<div>Colors</div> <div><div><div></div><div></div><div></div></div><div>RGB</div></div>	<div>PN: IN195106</div> <div>Rev: 1</div> <div>Date of Last Revision:</div> <div>1.3 2021/03/26</div>
	<div>For Reference Only</div> <div><div><div></div><div></div><div></div></div><div><div>PMS 2995 C</div><div>Primary Blue</div><div>PMS 303 C</div><div>Dark Blue</div><div>PMS 224 C</div><div>Magenta-Pink</div></div></div>	