AT-HOME COVID RAPID TEST KITS AVAILABLE @ ICP

COVID RAPID TEST KIT: KNOW BEFORE YOU GO

1) For this type of RAPID TEST:
- **If you get a NEGATIVE RESULT, you could still be POSITIVE**
- Results tend to be more accurate if you have symptoms at the time of testing
- For a more reliable test result after testing negative, contact your local health dept. for a location offering a free PCR Test

2) **If you get a POSITIVE RESULT, it is ACCURATE**.
- Follow CDPHE guidelines re: notifications and next steps at QR CODE below

3) **TESTING TIPS**
- **Keep kit at room temperature (50-80F).**
  - o Don't leave in your car when it's cold
- Keep test card flat on an even surface during test
- Wait 15 minutes before reading the result
- For step-by-step instructions, download the Navica app or see handout (via QR CODE below).

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This test has not been FDA cleared or approved but has been authorized by FDA under an EUA.
3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
5. 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.
6. Proper sample collection and handling are essential for correct results.
7. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
8. Do not touch swab tip when handling the swab sample.
9. Do not use kit past its expiration date.
10. Do not mix components from different kit lots.
11. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.
12. Wash hands thoroughly or use hand sanitizer after handling.
13. Dispose of kit components and patient samples in household trash.
14. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, 1/2 inch above the swab well, and add drops slowly.

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 Ag Card Home Test is stable until the expiration date marked on the outer packaging and containers.

INITIATING the TELEHEALTH VISIT

Upon receipt of the BinaxNOW COVID-19 Ag Home Test, the patient logs into NAVICA and selects, "I Already Have a Test Kit". The home user then visits the telehealth provider website to start testing and waits in queue to connect to the telehealth proctor.

DIRECTIONS for RUNNING the BinaxNOW™ COVID-19 Ag CARD HOME TEST

DO NOT OPEN ITEMS UNTIL INSTRUCTED TO DO SO

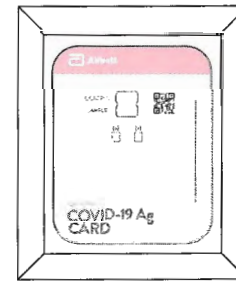Wash or sanitize your hands. Make sure they are dry before starting.
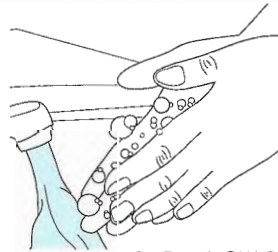
1 **Set Up**

It is recommended gloves (not provided) also be used during testing.
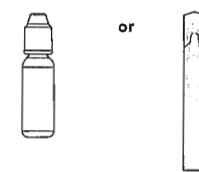
DO NOT open items until instructed.

1 Swab	1 Test Card	1 Bottle

COVID-19 Ag CARD

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.**

Top Hole
Bottom Hole

Result Window

Test Strip

🚫 **DO NOT touch any parts on inside of card.**
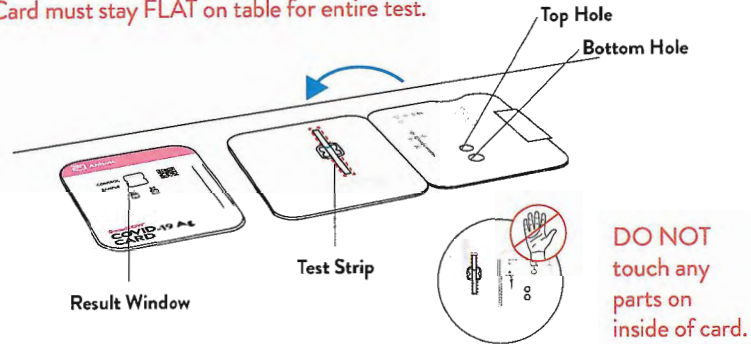
4 Apply Fluid to Top Hole

A. Remove dropper bottle cap.

B. Hold dropper bottle straight over TOP HOLE, not at an angle.

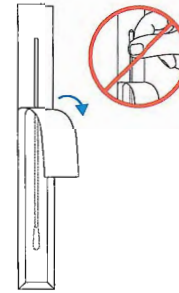**C.** Put 6 DROPS into TOP HOLE. Do not touch card with tip.

6 drops

Note: *False negative results may occur if less than 6 drops of fluid is used.*
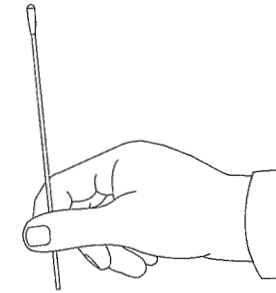
5 Open Swab

⊙ **Keep fingers away from swab end.**

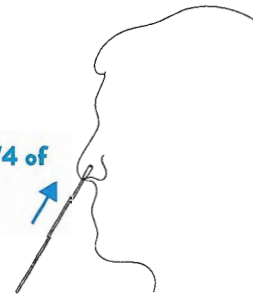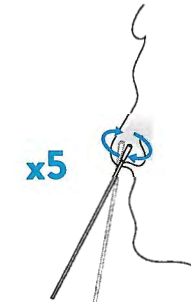**A.** Open swab package at stick end.

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.
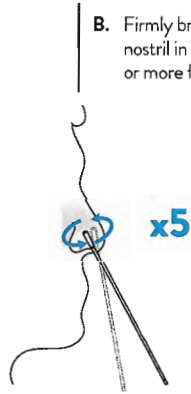
Up to 3/4 of an inch.

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

x5

7 Swab Right Nostril

A. Remove swab and insert it into right nostril.

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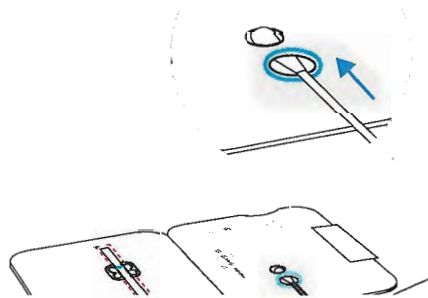

x5

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.

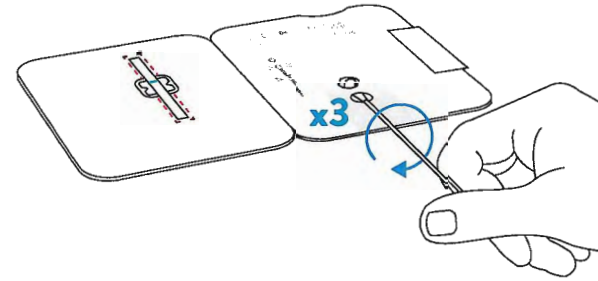Insert swab tip into BOTTOM HOLE and firmly push up until tip fills TOP HOLE.

9 Turn Swab 3 Times

⊘ Keep card FLAT on table.

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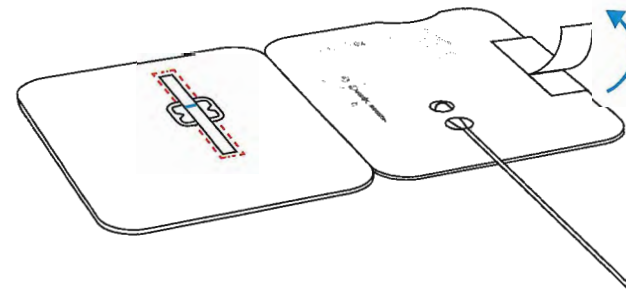

x3

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.
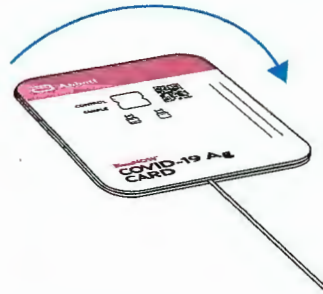
12 Wait 15 Minutes

⊙ **DO NOT** disturb card during this time.

15:00
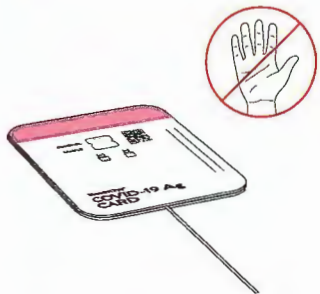
Note: *False results can occur if the card is disturbed/moved or test results are read before 15 minutes.*

13 Scan QR Code

If using a mobile device:

If using a computer:

14 Show Result to Your Proctor

CONTROL
SAMPLE
(+)   (−)

RESULT INTERPRETATION

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
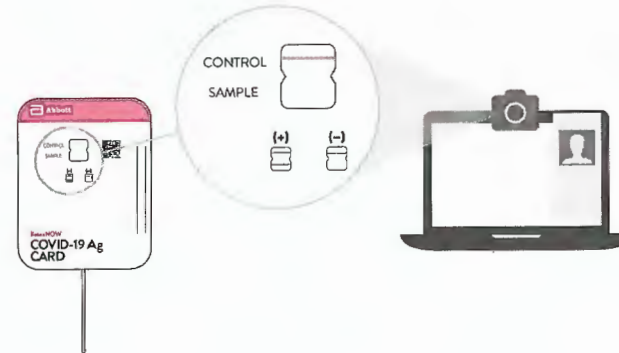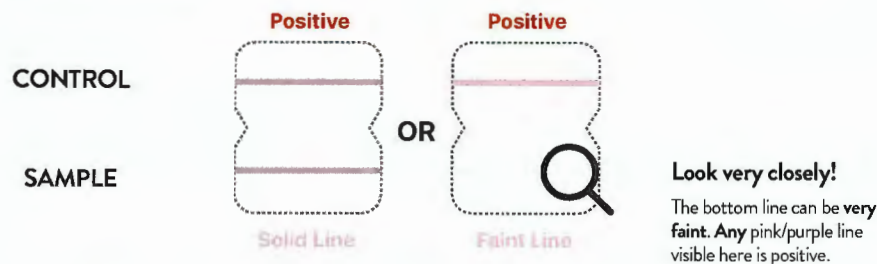3. Check for an Invalid Result

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**.

Look very closely!

The bottom line can be **very faint. Any** pink/purple line visible here is positive.

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


A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

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**.
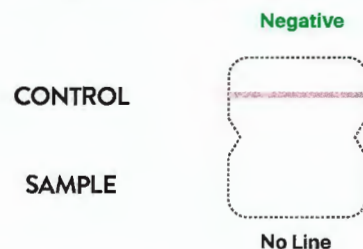
A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

Check for Invalid Result

If you see any of these, the test is invalid.
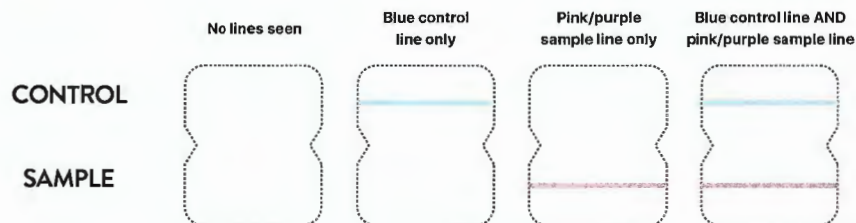
Dispose In Trash
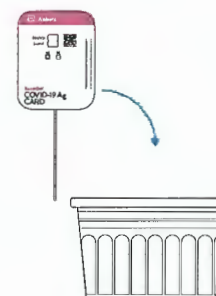
COVID TEST INFORMATION AND INSTRUCTIONS

Instructions for Rapid At-home Antigen Testing

Last updated December 29, 2021

Before you begin:

- If you or someone in your care is experiencing a medical emergency, call 911.
- Read all included box instructions on how to properly perform the test.
- Make sure your test is ready to use. This may include checking that there is a visible control line on the test. Make sure everything looks right on the test before you use it, otherwise your results may not be accurate.
- Once you've completed the test as instructed, follow the box instructions on how to read and interpret your results. Your test should include pictures and diagrams showing what is considered a positive or negative test result.

My test is positive: Now what?

Step 1: Isolate

If you get a positive result, stay away from others for at least 5 days. The beginning of your isolation period is the day of your positive test result or the day your symptoms began, whichever happened last. You can find instructions on how to isolate here: https://covid19.colorado.gov/how-to-isolate.

Step 2: Contact your health care provider.

Contact your health care provider to discuss your symptoms, positive test results, and any next steps they may recommend, including whether you may be a candidate for monoclonal antibody therapy. If you do not have a primary care provider or health insurance, consider a telehealth or nurseline option.

Monoclonal antibody therapy:

Monoclonal antibody therapy is available for all adults and children of all ages, including newborns, if they:

A. Have tested positive for COVID-19, and
B. Have mild to moderate symptoms of the disease for 10 days or less, and
C. Are at high risk of becoming seriously ill.

See the [How Do I Know If I'm High Risk, and What Do I Do Next?](#) page on CombatCOVID.hhs.gov to learn more.

People at risk of getting very sick from COVID-19 include:

- People who are 65 years old or older.
- Babies who are fewer than 1 year old.
- People who are obese or overweight. This includes adults with a [BMI](#) of 25 or more. It also includes children under age 18 years old whose providers determine they meet the criteria.
- Pregnant people.
- People with [certain underlying medical conditions](#).

How to get treatment: There are three ways to get treatment in Colorado.

1. Make an appointment at a state-led clinic. **You do not need a prescription to make an appointment at a state-led clinic. However, you must have an appointment in order to receive treatment.** Call the COVID-19 vaccine hotline at 1-877-CO VAX CO (1-877-268-2926) for help making an appointment. The hotline is available Monday through Friday, 8 a.m. to 8 p.m.; Saturday and Sunday, 9 a.m. to 6 p.m. MT. The call center will be closed on Nov. 25, Dec. 25, and Jan. 1 for the holidays. You can also [find a list of upcoming available appointments at COMassVax.org](#).
2. Talk with your doctor or health care provider. Let them know you have tested positive for COVID-19 and want to get monoclonal antibody treatment. If you are eligible, your health care provider may be able to help you find a place to get treatment.
3. Reach out to a health care provider who is offering treatment in Colorado. [Click here for a map of places where you can get treatment](#). You can also find places to get treatment at [The National Infusion Center Association](#) or the [HHS Protect Locator](#)

Step 3: Report your test results to public health.
Report your positive results and recent close contacts to public health to ensure you and your contacts receive the most up-to-date recommendations and resources, like testing and [monoclonal antibody therapy](#).

- To report your positive test result to public health, go to [covidbinax.colorado.gov/login](#). Create an account, then select test type "At-home antigen - self reported" (see image below) to report your positive test result.

Lab Test Info

O At-home antigen - self reported

O BinaxNOW antigen test

O Cue Health Test

- If you are unable to report your positive result on the website, you can also report your positive results to your local public health agency (LPHA). Find the contact information for your LPHA here: https://cdphe.colorado.gov/public-information/find-your-local-public-health-agency

Step 4: Inform your close contacts

In general, close contact means you were within six feet of someone for 15 minutes or more in a 24-hour period.

- If you have had close contact with any unvaccinated people in the two days before you took the test or two days before your symptoms started (whichever happened first), those people will need to quarantine immediately.
    - Close contacts who got their second dose of Pfizer or Moderna more than six months ago who have not received a third dose will also need to quarantine.
    - Close contacts who got the Johnson & Johnson vaccine more than two months ago who have not received a second dose will also need to quarantine.
- If you have been in close contact with people who have been vaccinated with all recommended doses, those people do not need to quarantine, but they should get tested 5 days after your contact with them. They should also wear a mask in all indoor public spaces for the 10 days after exposure.
- Additional quarantine guidelines for students and people who work in school settings can be found here: https://covid19.colorado.gov/practical-guide-for-operationalizing-cdc-school-guidance
- More information about quarantine is available at: https://covid19.colorado.gov/how-to-quarantine.

Step 5: Update your status in CO Exposure Notifications

People can use the CO Exposure Notifications service to anonymously alert some of their close contacts, including people they do not know but with whom they were in close contact. If you have CO Exposure Notifications installed or enabled on your phone, you can upload your positive test directly using the self-report feature.

- To self-report, users have the option within the Exposure Notifications service to request a verification code for their positive tests. Once a user's phone is validated, the state sends an SMS with a verification code to submit their positive case within

Exposure Notifications. The user can tap the included link to alert others of a potential exposure.
- Only other people with CO Exposure Notifications installed on their phone can receive an exposure notification, so not all of your close contacts will be notified this way. When possible, alert your close contacts about their exposure as soon as you are able, so they know to quarantine and get tested.
- You can find more information on the CO Exposure Notifications service here: https://www.addyourphone.com/

My test is negative: Now what?

Depending on your situation, you may require additional testing. You should get a laboratory-based PCR test if you have symptoms of COVID-19 but tested negative on the antigen test because antigen tests may miss some positive cases.
- Find a free PCR testing site here: https://covid19.colorado.gov/testing. All of the community testing sites listed use PCR testing. Some pharmacies may offer PCR as well.
- For people who need a test result in order to return to school and lab-based PCR is not available, find out what you need to do next with the Return to Learn tool here.
- You should also contact your health care provider to discuss your symptoms, whether any additional testing may be necessary to determine the cause of your symptoms, and whether you may benefit from any treatments. If you do not have a primary care provider or health insurance, consider a telehealth or nurseline option.

You do not need to report your negative result, as public health action will not be taken on negative unproctored, self reported rapid tests.