

USING THE AT-HOME COVID-19 RAPID ANTIGEN TEST KITS

Requirements

- a) Windows or Mac/Apple laptop with a webcam (or a desktop computer with an adjustable/moveable webcam), microphone, and speaker – **OR** –
An Apple phone/tablet or an Android phone/tablet.
- c) An email address.
- d) An internet connection.

Process

<If you have already downloaded the app and created an account, proceed to #5.
If you need assistance downloading the app, call 330-364-4474 ext. 231.>

1. **Download the NAVICA app from the [Apple App Store](#) or the [Google Play App Store](#) from your smartphone/tablet.**
2. **Open the NAVICA app on your smartphone/tablet.**
3. **Create a NAVICA account from the app on your smartphone/tablet and remember your credentials (username and password). If the patient to be tested is a minor (age 17 or younger), tap the TEST SITE icon at the bottom of the NAVICA app and then tap the profile icon at the upper right of the screen to add a MANAGED PROFILE for the minor to be tested.**
4. **Follow the prompts to input your name, date of birth, and email address or scan your ID to upload the data.**
5. Take the test kit home. Do not open your test kit until instructed to do so by the eMed test proctor.
6. Open a web browser (Chrome, Firefox, or Safari) on your laptop or desktop or phone and go to ohio.emed.com
7. Click the START TESTING button on the page.
8. Click the LOGIN WITH NAVICA button on the page and use your NAVICA account credentials you created in Step 2 above.
9. Confirm your account and personal information.
10. Answer the series of questions to prepare for the visit with the eMed proctor and click CONTINUE. This will begin the testing session with the eMed proctor.
11. Provide your name and date of birth to the eMed proctor.
12. Follow all directions from the eMed proctor to take the test.
13. Review your results.

(continued)

Results

1. After you complete the test, you will receive a “pass” on your NAVICA smartphone/tablet app, which will contain your test results. Tap PASS on the NAVICA app to view your results and pass.
2. If you test negative, you can show your pass to your school or employer from your smartphone/tablet. Your school or employer will verify the validity of this pass using the NAVICA app on their own smartphone/tablet by scanning the patient’s QR code as displayed on their smartphone/tablet. Make sure your school or employer can view you actually opening the NAVICA app and accessing the pass in real-time.

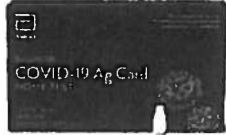
Helpful Hints

- View this 2-minute video to see the test taking process: <https://tinyurl.com/4j8nxf6c>.
- If you need assistance downloading the app, you can contact the library at (330) 364-4474 ext. 231.
- The eMed proctor is not a healthcare provider, but is qualified to administer the test and to read the results.
- Ensure that you have plenty of space in front of you to use the test kit. The test card must lay flat on a hard surface.
- The eMed proctor will have you adjust your webcam, tablet, or phone camera at various times during the testing. If you have a desktop webcam it needs to be re-positionable. The proctor will need to view the test kit on the surface in front of you at certain times and will need to view you (the patient) at other times. For the test to be valid, follow all of the proctor’s instructions. For example, the proctor must be able to view the test card during the 15 minutes the test runs or it will be invalidated.
- You will need to scan the QR code on the test card with your webcam at two separate times. Make sure you hold the QR code up to the webcam when instructed. Keep the QR code in the center of the camera and hold it as still as possible.
- If a telehealth session is interrupted, the individual should immediately return to ohio.emed.com and select the option to begin a test and explain to a proctor that the prior session was interrupted. If the proctor determines that the session is unable to proceed, contact eMed support at (844) 943-0753 for assistance.
- eMed is responsible for reporting results. For the individual being tested, results are returned through the NAVICA app, and the NAVICA pass can be used to demonstrate a test result to an employer, school, or other party.
- If your results are not available within the Navica app or you have specific questions related to the testing, call eMed Customer Support at (844) 943-0061.

Updated 4/9/2021

Abbott BinaxNOW COVID-19 Ag CARD HOME TEST KIT

Ohio User Guide



Getting Started

DO NOT OPEN ITEMS UNTIL INSTRUCTED TO DO SO

A. Download the NAVICA app from the Apple App Store or Google Play Store on your smartphone or tablet



B. Login or create a NAVICA account - create a managed profile for any children or other dependents you plan to get tested under the "Account and Settings" icon at the top of the screen.

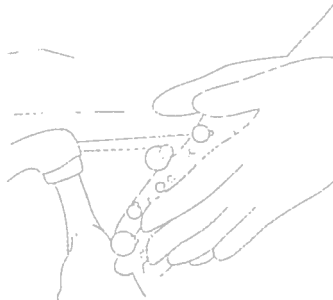
C. Find available test pickup sites on ohio.emed.com

D. Select "Test Site" in the NAVICA app and display the NAVICA ID to pick up a test for anyone on your account

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Wash Your Hands

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

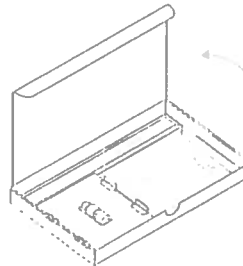


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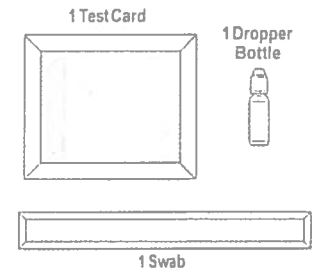
1 Set Up

DO NOT open items until instructed.

A. Open your test kit.

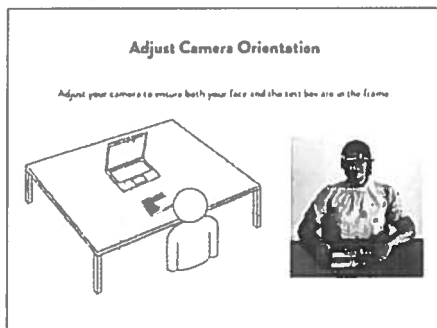


B. You should have:



BinaxNOW COVID-19 Ag CARD HOME TEST KIT

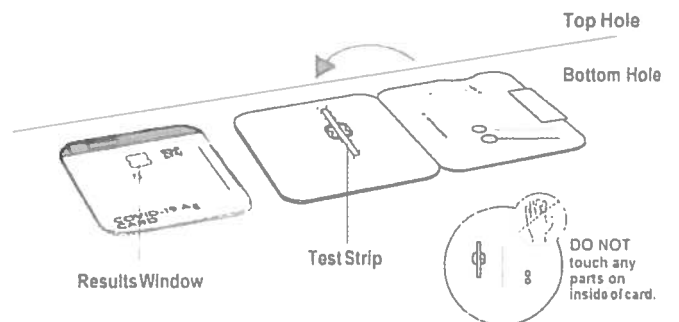
2 Go to ohio.emed.com and select "Start Test"



BinaxNOW COVID-19 Ag CARD HOME TEST KIT

3 Open Card

Card must stay FLAT on table for entire test.



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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.

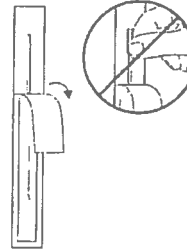


Bluebird COVID-19 Ag CARD HOME TEST KIT

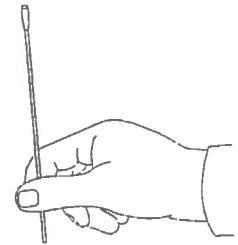
5 Open Swab

ⓘ Keep fingers away from swab end.

A. Open swab package at stick end.



B. Take swab out.

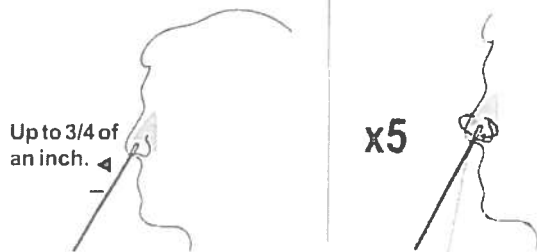


Bluebird COVID-19 Ag CARD HOME TEST KIT

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

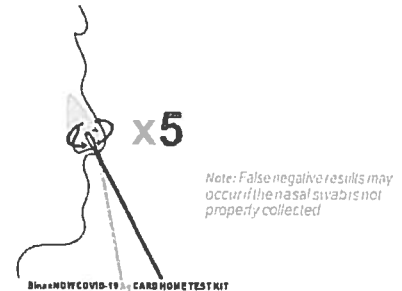


Bluebird COVID-19 Ag CARD HOME TEST KIT

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.

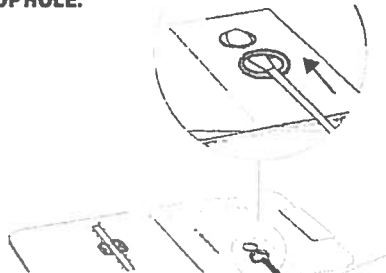


Bluebird COVID-19 Ag CARD HOME TEST KIT

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.

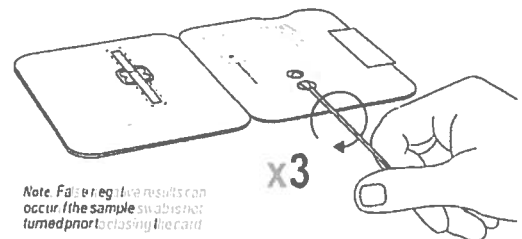


Bluebird COVID-19 Ag CARD HOME TEST KIT

9 Turn Swab 3 Times

ⓘ Keep card FLAT on table.

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



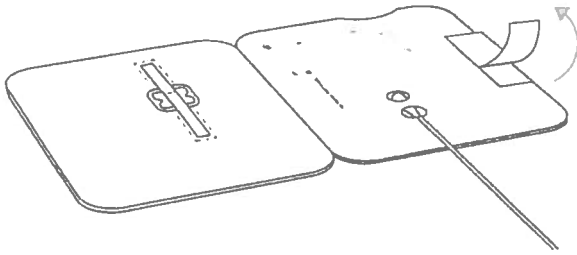
Bluebird COVID-19 Ag CARD HOME TEST KIT

10 Peel Strip

DO NOT remove swab.

Keep card FLAT on table.

Keep swab in place. Peel adhesive liner off.



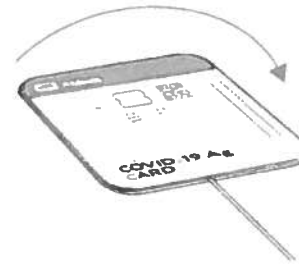
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11 Close Card And Seal

DO NOT remove swab.

Keep card FLAT on table.

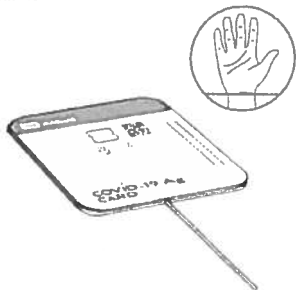
Close left side of card over swab to seal it. Keep card face up on table.



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12 Wait 15 Minutes

DO NOT disturb card during this time.

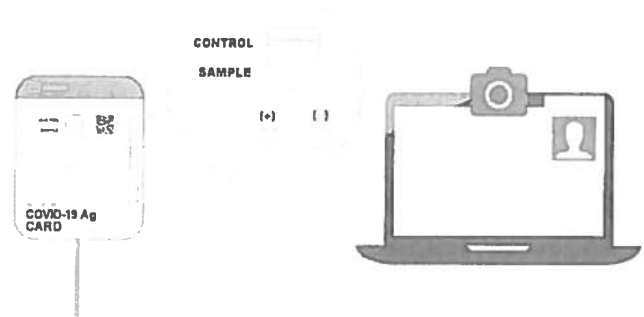


15:00

DO NOT TOUCH THE CARD OR SWAB DURING THIS TIME. WAITING FOR RESULTS TO APPEAR.

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13 Show Result to Your Proctor



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14 Steps To Check Your Results

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:

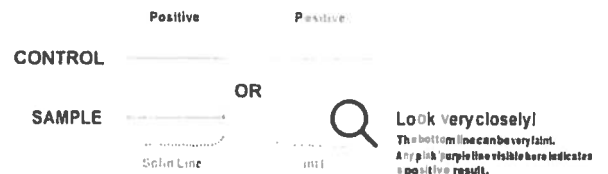
1. Check for a Positive Result
2. Check for a Negative Result
3. Check for an Invalid Result

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15 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.

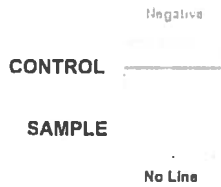


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Check for Negative COVID-19 Result

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.



B1000-NDHW COVID-19 Ag CARD HOME TEST KIT

Check for Invalid Result

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



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Interpreting Test Results

Antigen tests are generally less sensitive than PCR-based methods and their clinical performance depends on the circumstances in which they are used. The Centers for Disease Control and Prevention (CDC) have released guidance for rapid antigen testing for SARS-CoV-2. FDA and CDC guidance suggest that antigen test results should be considered in the context of clinical observation, patient history, and epidemiological information.

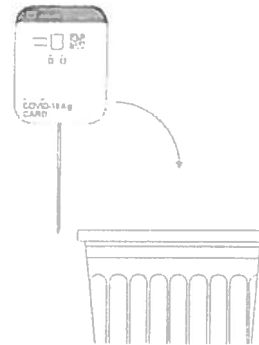
A positive test result when the person is symptomatic or has been exposed to COVID-19 indicates that SARS-CoV-2 antigen was detected and that the individual is very likely infected and considered a COVID-19 case. Positive individuals should be isolated per Ohio Department of Health guidance.

A positive test result for an asymptomatic person who has not been exposed has the potential to be a false positive result. In these situations, the individual with the positive test result should be isolated until confirmatory PCR testing can be performed and results returned.

For negative results, FDA guidelines suggest "it is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen tests if they are obtained during routine screening or surveillance." However, symptomatic individuals with presumptive negative tests should be isolated until confirmatory PCR testing can be performed and results returned.

B1000-NDHW COVID-19 Ag CARD HOME TEST KIT

Dispose in Trash



B1000-NDHW COVID-19 Ag CARD HOME TEST KIT

Results Returned to NAVICA App

You can find result details under "Results" and display a NAVICA pass for seven days under "Passes"



B1000-NDHW COVID-19 Ag CARD HOME TEST KIT

BinaxNOW™ COVID-19 Ag Card
Product Expiry Update

Abbott

May 2021

Dear Valued Customer:

Since the launch of the BinaxNOW™ COVID-19 Ag Card Home Test, Abbott has continued testing for product stability to extend the expiration date and have shared these results with the FDA. Testing has been completed to support a shelf-life (expiration date) of up to 12 months. This letter is to notify you the BinaxNOW™ COVID-19 Ag Card Home Test, part number 195-200, in your possession may now have a longer than labeled product expiry date.

A listing of BinaxNOW™ COVID-19 Ag Card Home Test lots which qualify for this expiry extension, can be found in Attachment 1. These lots were originally dated with an expiry of 9 months. The attachment lists the lot number, currently labeled kit expiry and new kit expiry date.

The device housing has a 2D barcode for use with NAVICA. For customers using the NAVICA app, an update to the NAVICA app will be implemented to recognize the extended expiry date in May 2021.

Please be aware that the product Unique Device Identifier (UDI) barcode on the kit box will display the original expiry date when scanned. This barcode is not used in conjunction with NAVICA.

We are pleased to offer our customers this additional dating in support of their COVID-19 testing efforts. Future extensions may be communicated, as more data becomes available.

If you have further questions, please contact Abbott Technical Services at:

- o Telephone: 1 800 257 9525
- o Email: ts.scr@abbott.com

Sincerely,

Emily Deane
Divisional Vice President, Quality Assurance

The BinaxNOW™ COVID-19 Ag Test Card has not been FDA cleared or approved; has been authorized by the FDA under an emergency use authorization. The emergency use of this product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens, and 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.

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Attachment 1 - BinaxNOW™ COVID-19 Ag Home Test lots with extended expiry

Lot Number	Original Expiry	New Expiry
134260	9/6/2021	12/6/2021
134260A	9/6/2021	12/6/2021
134260B	9/6/2021	12/6/2021
134260C	9/6/2021	12/6/2021
134260D	9/6/2021	12/6/2021
134260E	9/6/2021	12/6/2021
134260F	9/6/2021	12/6/2021
134260G	9/6/2021	12/6/2021
134260H	9/6/2021	12/6/2021
134260I	9/6/2021	12/6/2021
134260J	9/6/2021	12/6/2021
136102	9/1/2021	12/1/2021
136102A	9/1/2021	12/1/2021
136102B	9/1/2021	12/1/2021
136102C	9/1/2021	12/1/2021
136102D	9/1/2021	12/1/2021
136102E	9/1/2021	12/1/2021
136102F	9/1/2021	12/1/2021
136102G	9/1/2021	12/1/2021
136102H	9/1/2021	12/1/2021
136102I	9/1/2021	12/1/2021
136102J	9/1/2021	12/1/2021
136103	9/1/2021	12/1/2021
136103A	9/1/2021	12/1/2021
136103B	9/1/2021	12/1/2021
136103C	9/1/2021	12/1/2021
136103D	9/1/2021	12/1/2021
136103E	9/1/2021	12/1/2021
136103F	9/1/2021	12/1/2021
136103G	9/1/2021	12/1/2021
136103H	9/1/2021	12/1/2021
136103I	9/1/2021	12/1/2021
136103J	9/1/2021	12/1/2021
136103K	9/1/2021	12/1/2021
136903A	9/6/2021	12/6/2021
136903B	9/6/2021	12/6/2021
136903C	9/6/2021	12/6/2021
136903D	9/6/2021	12/6/2021
136903E	9/6/2021	12/6/2021
136903F	9/6/2021	12/6/2021
136903G	9/6/2021	12/6/2021
136903H	9/6/2021	12/6/2021
136903J	9/6/2021	12/6/2021
136903K	9/6/2021	12/6/2021
137133A	9/6/2021	12/6/2021
137133B	9/6/2021	12/6/2021
137133C	9/6/2021	12/6/2021
137133D	9/6/2021	12/6/2021