ABBOTT BINAXNOW™ COVID-19 AG CARD TEST HELPFUL TESTING TIPS

This document is a supplement to the manufacturer's instructions and is intended to provide helpful testing tips when using the Abbott BinaxNOW™ COVID-19 Ag Card test.

To ensure accurate performance of this test, please refer to the package insert or Instructions for Use for complete details on how to perform the test. Additional instructions can be found at **www.fda.gov/media/141570/download**.

For information on the Abbott BinaxNOW™ COVID-19 Ag Card Test, please view the manufacturer's website at **https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html.**

* Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

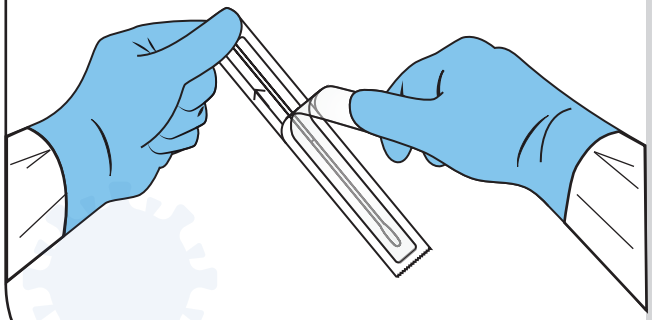
Before the Test

Store kit at 2-30°C (35.6-86° F).
Do not freeze kits.

Test kit reagents/cards must be at room temperature before use. If stored in a refrigerator, allow time to warm up to room temperature.

Only the swabs provided with the kit are approved for use with test. Do not use other swabs.

Acceptable specimens include nasal swabs obtained by collection from both nostrils. Do not return specimen to original paper packaging once it has been opened.



It is important for new operators to receive adequate training on how to successfully test the system with the controls before beginning specimen processing.

In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position. Do not use the card if the blue line is not present.

Quality control testing should also be performed after receiving new shipments of test kits.

Training should include successfully testing one positive and one negative control. For supervisors managing the testing process, additional quality control kits, including 10 positive swabs, are available from the manufacturer.

Positive Result

Pink/Purple Control Line

Pink/Purple Sample Line

Negative Result

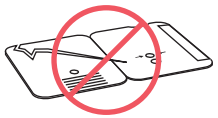
Pink/Purple Control Line

Make sure to label specimen or test card correctly to avoid record-keeping issues.

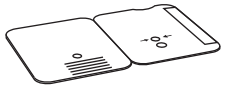
Gloves should be changed immediately after collecting, handling, and processing a new specimen. Discard used gloves in a biohazardous waste container.

Specimens should be tested right away, or within 1 hour after collection with proper storage in a sealed, clean, unused transport tube. If specimens are not tested within 1 hour of collection, testing is not recommended because false negative results can occur. If greater than a 1 hour delay occurs, dispose of the sample swab in a biohazardous waste container and collect a new specimen for testing. Do not use viral transport media for specimen storage.

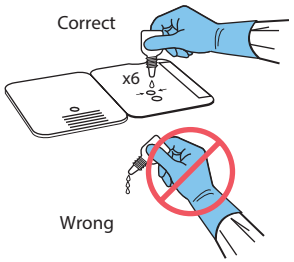
During the Test



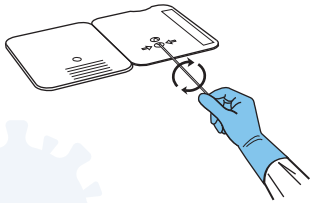
Leave the card sealed in its foil pouch until just before use and do not use the card if the card or foil pouch is open, damaged, expired or if the blue line is not present.



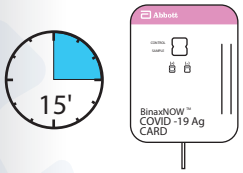
The card must remain flat when performing the test. Carefully flex the card as needed to ensure it lays flat on the table. Do not change the position of the card while the test is being processed.



Use only the correct volume of extraction reagent: no more, no less. When adding the reagent, hold the bottle vertically (not at an angle) ½ inch above the card and slowly add 6 drops directly to the top hole of the swab well using the dropper bottle provided with the kit. Do not touch anything including the card with the tip of the bottle.



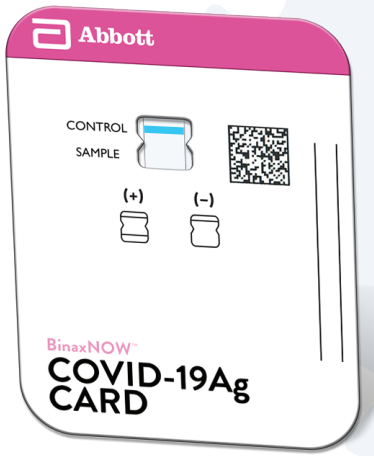
Insert sample or control swab into bottom hole and firmly push upwards so that the swab tip is visible in the top hole. Rotate the swab 3 times "clockwise" once inserted into the card, remove the adhesive liner, close the card, and turn on a timer. Do not close the card before rotating the swab.



Visually read test results 15 to 30 minutes after the swab is inserted and the card is closed for processing. Results may be invalid if read before 15 minutes or after 30 minutes. Using a timer will assist with ensuring proper time is given for specimen processing.

Avoid cross-contamination between specimens, which includes decontaminating surfaces before processing another specimen.

When processing multiple specimens successively, ensure proper timing for each specimen during processing and before reading results.



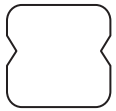
After the Test

Record test results and safely dispose of the card in a biohazardous waste container.

Repeat the test if the test's internal control does not meet the expected result (please review Invalid and Valid Result examples to the right for additional details).

Multiple sequential specimens with unexpected results inconsistent with clinical indications may indicate errors have occurred and the individuals should be retested.

Invalid Results


No Control Line


Blue Control Line Only


Sample Line Only


Blue Control Line
Sample Line

If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.

Valid Results

Negative Result


Pink/Purple Control Line

The single Pink/Purple Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

Positive Result


Pink/Purple Control Line
Pink/Purple Sample Line

The Pink/Purple Control Line together with a Sample Line means that the detection part of the test was done correctly and the COVID-19 antigen was detected.