

CareStart™ COVID-19 Antigen Home Test

USER INSTRUCTIONS



You must follow the test directions carefully to get an accurate result.
Visit accessbile.net to obtain the complete instructions for use.

FOR USE UNDER EMERGENCY USE AUTHORIZATION (EUA) ONLY.

IMPORTANT: Swabbing the nostrils is critical for obtaining an accurate result. If you do not swab your nose, the device will produce a false negative result.

- 1 Wash your hands thoroughly for at least 20 seconds before the test.



- 2 Unpack the test components from the tray.



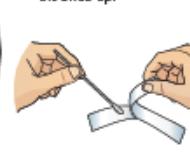
- 3 Remove the test cassette and place it on a flat, clean surface.



- 4 Locate the extraction vial and gently peel off the aluminum foil seal, being sure to keep the vial upright and place it in the packaging tray.



- 5 Locate a nasal swab and remove from the pouch. Be careful not to touch the swab tip.



- 6 Gently insert the swab no more than 3/4 inch into the LEFT nostril. Then, slowly rotate the swab at least 5 times in a circular path for a total of 15 seconds. If you have questions, see the CDC Guidelines.



- 8 Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



- 9 Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Discard the swab in trash.



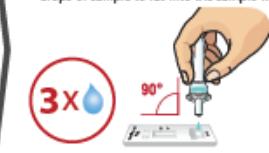
- 10 Close the vial by pushing the cap firmly onto the vial.



- 11 With your finger, mix thoroughly by flicking the bottom of the vial.



- 12 Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow THREE (3) drops of sample to fall into the sample well.



13 Start a timer.

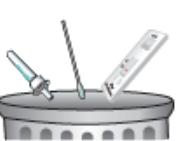
Read the result at 10 minutes. The test result should not be read after 15 minutes.



IMPORTANT
Do not move or lift the test cassette during this time.
Do not exit the mobile app during this process.

Disposal

Dispose of all used test kit components and swab samples in household trash.



Using Mobile Application

- Ensure you have an Internet connection and download the App prior to starting the test
- Ensure you are using a compatible smartphone. (For a list of compatible smartphone OS systems, visit www.accessbile.net/app)
- Only open the foil pouch packaging of test cassette when the App instructed to do so.

Please start the test and follow the in-app self-paced, step-by-step test instructions.

1. Download and open App, On/Go™ Mobile Application
2. Answer a few questions in the App
3. Watch the instructional video.
4. Follow step-by-step instructions for your test.

5. Test result

The App will assist in your visual result interpretation. Please follow the instructions provided in the App. You will be required to take a picture of the test device, and then look at the test cassette and answer questions about the result interpretation.



Results Interpretation

Make sure you wait the full 10 minutes.

You will be able to interpret your test results by following the in-app interpretation instructions or those provided below.

NOTE: The test results should be read by visual and interpreted at 10 minutes after the sample application and interpretation of the results should not exceed 15 minutes as it may yield inaccurate results.

COVID-19 Detected (Positive)

One purple-colored line next to "C" and one blue-colored line next to "T" indicates COVID-19 positive result.



IMPORTANT Look very closely! The color intensity in the test region will vary. Any colored line in the test region should be considered as positive.

A positive test result 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 in making a final diagnosis and patient management decisions. You should self-isolate at home and avoid contact with others as per CDC recommendations to avoid spreading the virus to others.

Invalid

Invalid barcode or absence of a purple-colored line next to "C".



Re-test with a COVID-19 test may be needed.

An invalid test result indicates that your test has experienced an error and is unable to interpret the result of the test. You will need to re-test with a new test or consult a healthcare professional. If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the re-test.

COVID-19 Not Detected (Negative)

One purple-colored line only next to "C" indicates a negative result.



Re-test in 24-48 hours if your first test result is negative. A negative test result indicates that antigens from SARS-CoV-2 were not detected from the specimen. 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. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and confirmed with a molecular assay, if necessary, for patient management.