SCoV-2 Ag Detect™ Rapid Self – Test Instructions

For Emergency Use Authorization (EUA) only. In vitro diagnostic use only.

Carefully read these instructions before starting the test.

Materials Needed for Testing
1. Test in pouch (Do not open until use)
2. Single use dropper bottle
3. Swab
4. Timing device (not included)

It is recommended that gloves are used during testing. A face mask should be worn if swabbing someone else. Gloves and a face mask are not provided.

Prepare for the Test
1. Wash hands or use hand sanitizer before starting the test.
2. Remove one test from the packaging. Place the test on a flat surface, like a counter or tabletop, in an area with good lighting.

Step 1: Swab Nostrils
1. Remove one swab from the packaging. Be careful not to touch the swab tip (soft end) with hand.
2. Carefully insert the swab at least 0.5 inch (1 cm) inside on nostril.
3. Slowly rotate the swab using medium pressure at least four times, rubbing the insides of nostril for 15 seconds. The swab tip should be touching the inside wall of the nostril through each rotation. Using the same swab, repeat sample collection in the other nostril.

Only use the swab provided in the kit. • Improper swabbing may lead to false results. • Be sure to swab both nostrils with the same swab.
If swabbing another person, you should wear a face mask. • The swab may not need to be inserted as far into the nostrils if swabbing a child.

Step 2: Run the Test
1. Hold the top of the test firmly with one hand and place the swab tip (soft end) into the sample port. Gently push the swab tip into the sample port while pressing the swab handle down. The swab should be firmly in the test.
2. The swab should be flat in the test and cover the sample port.
3. Remove top of dropper bottle by twisting the top plastic piece. Do not use mouth or teeth to open bottle.
4. Hold the dropper bottle above the swab head. Slowly add all of the liquid on top of the swab head. Add 1 drop at a time until dropper is empty. Do not add the liquid all at once.

IMPORTANT!
Invalid or incorrect results can occur when less than the whole bottle is added to the test. Make sure to add all of the liquid slowly holding the bottle vertically 0.5 inches above the swab head. False negative results can occur when the order of test steps is not correctly followed. Always add the swab to the sample port, and then add the liquid on top of the swab head in the test cassette.

5. Leave test untouched on a flat surface. Check the test results after TWENTY (20) to TWENTY-FIVE (25) minutes.

Wait 20 TO 25 MINUTES

IMPORTANT!
Incorrect results may occur if tests are read before 20 minutes or after 25 minutes.

Turn over for instructions how to read and understand the results.
Step 3: Check Test Results

Positive Results: The test is positive if a control line (“C”) and test line (“T”) both show in the marked areas on the test. This means that COVID-19 antigen was detected. Look at test line closely! A very light pink test line is still considered a positive result.

Negative Results: The test is negative if a control line (“C”) shows in the marked area of the test but no test line (“T”) shows. This means that COVID-19 antigen was not detected.

Invalid Results: The Test is invalid if no control line shows on the test, even if a test line (“T”) does show up.

Understanding Your Results

What does a positive test result mean?
A positive test result means that proteins from the virus that causes COVID-19 were found in your sample. It is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. The chance of something else causing this test to give you a positive test result is that false positive). If you test positive with the SCoV-2 Ag Detect ™ Rapid Self-Test you should self-isolate and seek follow-up care with your 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.

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

What does an invalid test result mean?
If no control line shows up on the test, the result is invalid (even if any test line shows up). An invalid test result means the test was not able to tell you if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and the test should be run again, using a new test and dropper bottle.