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! The swab should cover the sample port completely

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

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.

- You may light pink test line is still considered a positive result.

Negative Result: The test results are negative if 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 Result: 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 not found in your sample. Read the testing section shown below if you test negative and are not experiencing COVID-19-like symptoms. Negative results do not rule out SARS-CoV-2 infection.

What is the difference between an antigen and molecular test?

An antigen test, such as the SCoV-2 Ag Detect™ Rapid Self-Test, detects proteins from the virus. Molecular tests detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means there is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that this test may not detect the virus in all individuals who test negative.