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 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 one nostril.
3. Slowly rotate the swab using medium pressure at least four times, rubbing it along the insides of the 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.
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 the swab is not covered by the sample.

To

20:00

25:00
Tests are read before 20 minutes or after 25 minutes.

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.

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

Positive Result: 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.

Negative Result: The test is negative if a control line (C) shows 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 (C) shows on the test, even if a test line (T) shows up.

Understanding Your Test 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. Read the serial testing section if you test negative and are experiencing COVID-19 like symptoms. Negative results do not rule out SARS-CoV-2 infection.

What does a negative test result mean?
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. Read the serial testing section if you test negative and are not experiencing COVID-19 like symptoms. Negative results do not rule out SARS-CoV-2 infection.

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 result means the test was not able to test if you have COVID-19. If the test is invalid, a new sample should be collected to collect a new nasal swab and the test should be run again, using a new test and a new kit.

Frequently Asked Questions Concerning

What are the harms and potential benefits of this test?
Potential risks include:
- Possible discomfort during sample collection.
- Possible normal test results seen (understanding Your Test Results section).

Potential benefits include:
- The result will help you to limit the spread of COVID-19 to your family and others in your community.

What is a negative test result?
A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. Read the serial testing section if you test negative and are not experiencing COVID-19 like symptoms. Negative results do not rule out SARS-CoV-2 infection.

What is a positive test result?
A positive test result means that proteins from the virus that causes COVID-19 were found in your sample. Read the serial testing section if you test negative and are experiencing COVID-19 like symptoms. Negative results do not rule out SARS-CoV-2 infection.
- Do not let dropper bottle liquid enter your eyes or touch your skin, as discomfort and irritation may occur.

- If dropper bottle liquid gets in your eyes, rinse carefully with clean water for several minutes. If wearing contact lenses, remove immediately if able, continue rinsing, and seek medical help.

- If dropper bottle liquid gets on your skin, wash area immediately with a lot of soap and clean water or wash liquid from skin.
If you have symptoms of COVID-19, you can use a single test.
If you do not have symptoms of COVID-19, you will need at least two tests per person.
You may need to purchase additional tests to perform serial (repeat) testing.
This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

This product has not been FDA cleared or approved, but has been authorized under an EUA.
This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
The emergency use of this product 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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For more information, call xxx-xxx-xxxx or visit www.inbios.com

Part No. XXXXXXXXXXXXXXXX

Contents:
5 Pouched Test Cassettes
5 Single-Use Dropper Bottles
5 Pouched Swabs
1 Instructions for Use

FAST RESULTS 20 MINUTES

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Contents required to perform one test:
- Cassette device
- Sterile swab
- Single use buffer
- Instructions for Use

See instructions for use for complete contents. Content will vary depending on number of tests shown on front of box.

FAST RESULTS 20 MINUTES

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Sticker - 43mm x 22 mm
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