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

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
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<tbody>
<tr>
<td>1. Test in pouch (Do not open until use)</td>
<td>SCoV-2 Ag Detect™ Rapid Test Cassette</td>
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<tr>
<td>2. Single-use dropper bottle</td>
<td>InBios</td>
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<td>3. Swab</td>
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<td>4. Timing device (not included)</td>
<td>20.00</td>
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</tbody>
</table>

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 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.

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.

IMPORTANT! Hold swab close to the tip so it does not break when putting in the test.

WANT 20 TO 25 MINUTES

IMPORTANT! Improper 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.
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. It is very likely you have COVID-19 and it is important to be under the care of your healthcare provider.

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 below if you test negative and are not experiencing COVID-19 symptoms.

Warnings and Precautions

- If you feel pain, please stop the test and seek advice from a healthcare provider.
- Do not let dropper bottle liquid enter your eyes or touch your skin, as discomfort and irritation may occur.
- Keep test kit out of reach of children.

Serial Testing Information and Limitations

- If you have symptoms of COVID-19 that start within the last five days, you may test a single time.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests.
- The SCoV-2 Ag Rapid Test should not be used to test individuals without symptoms.
- Testing for individuals with symptoms of COVID-19 should be performed earlier than 3 days after symptom onset.
- The test is invalid if no control line shows up. This means that COVID-19 antigen was detected.
- The test is invalid if a test line (“T”) does not show up. This means that COVID-19 antigen was not detected.

FDA 510(k) Clearance

The SCoV-2 Ag Rapid Test is aleared for use by authorized laboratories under the federal Emergency Use Authorization (EUA) for COVID-19.

FDA EUA

The SCoV-2 Ag Rapid Test is a rapid test for the detection of antigens of the SARS-CoV-2 virus. It is cleared by the FDA under the federal Emergency Use Authorization (EUA) for COVID-19. This test is not intended to be used as a public health screening tool. It should be used by healthcare providers for point-of-care testing in high-risk settings, such as in individuals without known exposure to COVID-19 in testing communities with low prevalence of infection.

Hazards

- Acute toxicity, Oral (H302)
- Skin irritation (H315)
- Skin corrosion (H314)
- Serious eye damage (H318)

Hazardous Ingredients

- Sodium hydroxide
- Hydrochloric acid
- Sodium chloride

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For questions or to learn more about this product, visit www.inbios.com/v19 or call 206-344-8621 or 866-482-4681 (toll free).

Frequently Asked Questions

Will this test hurt?
No, the nasal swab is not sharp and it should not hurt. Sometimes it can lead to slightly uncomfortable sensations. If you feel pain, please stop the test and seek advice from a healthcare provider.

What are the known and potential risks and benefits of this test?
Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Understanding Your Test Results section).

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- A single test may limit the spread of COVID-19 in your family and in your community.

What is Serial Testing?
Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests, serial testing is often recommended for individuals with symptoms of COVID-19 who test negative on their first test.

What is the difference between an antigen and a molecular test?

Antigen tests, such as the SCoV-2 Ag Rapid Test, detect proteins from the virus. Molecular tests detect genetic material from the virus. Antigen tests are very specific for the virus, but they are less sensitive than molecular tests. This means that an antigen test is likely negative, but a molecular test can be negative. If your test result is negative in an antigen test, you should follow your healthcare provider's advice for whether to have additional testing or to continue isolating at home. If you test positive on an antigen test, you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with molecular-based diagnostic tests.

In a clinical setting, results from the SCoV-2 Ag Rapid Test were compared to an FDA EUA authorized molecular SARS-CoV-2 test (ProC Lin™ 300) with excellent performance and 100% negative predictive value. The performance of this test in a high-risk setting will be different from other settings.

When can I find information about Emergency Use Authorizations (EAUs) and COVID-19?
For more information on the SCoV-2 Ag Rapid Test, please visit
www.inbios.com/v19

For the most up-to-date information on COVID-19, please visit www.cdc.gov/coronavirus.
COVID-19 ANTIGEN SELF-TEST

This product has not been FDA cleared or approved and has been authorized under an EUA.

The product has been authorized only for the detection of protein from SARS-CoV-2, not for any other viruses or pathogens.

This emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the in vitro diagnostic for detection of SARS-CoV-2 RNA in respiratory specimens from individuals with symptoms consistent with COVID-19.

For more information, call 1-888-783-4671 or visit www.inbios.com
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EASY • FAST • TEST AT HOME

FOR EMERGENCY USE AUTHORIZATION (EUA) ONLY

SCoV-2 Ag Detect™ Rapid Self-Test

5 TESTS

AGES 2 AND UP

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