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.

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.

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.

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

**WARNING!** False negative results can occur when the order of test steps is not correctly followed. Always add the liquid to the sample port, and then add the liquid on top of the swab head in the test cassette.

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

**IMPORTANT!** The swab should cover the sample port completely.

**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.]
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 use your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test will give you a positive result that is not true. If you have a positive result with the SCoV-2 Ag Detect™ Rapid Self-Test you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your symptoms and test results.

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 like symptoms. Negative results do not rule out SARS-CoV-2 infection.

What does the test result mean?
Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the early phase of infection. Positive test results should be interpreted in the context of signs and symptoms correlated with COVID-19. A negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary. Your healthcare provider will consider the test result together with other factors such as your symptoms, possible exposures and epidemiological evidence to determine how best to care for you.

Positive Test 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 SARS-CoV-2 antigen was detected. Please notify your healthcare provider of positive or negative results from the SCoV-2 Ag Detect™ Rapid Self-Test.

Negative Test Result:
The result is negative if a control line ("C") shows in the marked area of the test but no test line ("T") shows. This means that SARS-CoV-2 antigen was not detected.

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

Please notify your healthcare provider or positive or negative results from the SCoV-2 Ag Detect™ Rapid Self-Test.

Warning and Precautions
- This test is a real-time user. Individuals with severe or mild reaction may not be able to read the test.
- Children under 1 year old shall not be left to conduct the test. If children under 1 year old conduct the test, it should be supervised by an adult.
- Failure to follow the test procedure may cause incorrect results.
- Do not use a test kit that has expired.
- Test components are once-use. Do not reuse.
- Do not re-use any dropper bottle of liquid.
- Do not read test results before 20 minutes or after 25 minutes. Results read before 20 minutes or after 25 minutes may lead to false negative or false positive results.
- For best results, read in a well-lit area.

Serial Testing Information and Limitations
If you have symptoms of COVID-19 which are not isolated within the test date, you can have a single test.

- Picking windows should be performed at the time of symptoms, negative results do not rule out the diagnosis. This test is not authorized for use in pregnant women. Antigen detected in the test is not conclusive for infection. A positive result should be confirmed by molecular testing for SARS-CoV-2.
- Individuals who test negative but continue to experience COVID-19 symptoms of fever or cough after 7 days of negative test should seek follow-up care with their healthcare provider. Individuals who test negative should continue to use their healthcare provider to monitor their symptoms.

How to perform the test:
- Remove the test kit from the packaging and place the test kit on a flat surface.
- Gently mix the liquid in the dropper bottle by shaking the bottle. Do not shake vigorously.
- Place the dropper bottle onto the test strip. The dropper bottle should be covered with a dropper cap.
- Place the dropper bottle on the surface to prevent it from slipping.
- In the case of a positive result, if the control line shows ("C") and test line ("T") shows in the marked area of the test, even if a test line ("T") does show up.

Invalid Result:
The test is invalid if no control line shows on the test, even if a test line ("T") does show up.

Where can I find information about Emergency Use Authorizations (EUA) and COVID-19?
For more information on EUAs, please visit: www.fda.gov/coronavirus/landing-page.html

For Emergency Use Authorization (EUA) Only

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA. This product has been authorized or only for the detection of SARS-CoV-2 and not for any other viruses or pathogens. The emergency use of the product is authorized under the declaration that states that the emergency use of the product is authorized for the duration of the declaration. It must follow the instructions and procedures outlined in the EUA. The instructions and procedures outlined in the EUA may differ from the instructions and procedures outlined in the label. Any individual using this product should read the label for instructions and procedures before using the product. The instructions and procedures outlined in the EUA may also change over time. You should follow the instructions and procedures outlined in the EUA.

Uses should consider eye protection.
- You should not drink liquid in dropper bottle.
- You should not march liquid into your eyes or touch your skin, as it may cause irritation and injury. If you use eye drops, rinse carefully with clean water for several minutes. If using contact lenses, remove immediately if irritation or discomfort occurs.
- The test is invalid if no control line shows on the test, even if a test line ("T") does show up.

For more information, please visit www.fda.gov/coronavirus/landing-page.html
COVID-19 ANTIGEN SELF-TEST

Contents:
1 Pouched Test Cassette
1 Single-Use Dropper Bottle
1 Pouched Swab
1 Instructions for Use

FOR IN VITRO DIAGNOSTIC USE

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. § 360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Keep test kit out of reach of children.

For more information, call 1-866-514-9777 or visit www.inbios.com
© InBios. All rights reserved.
Part No. 968916-92

COVID-19
SCoV-2 Ag Detect™ Rapid Self-Test

1 TEST
AGES 2 AND UP

EASY · FAST · TEST AT HOME

SWAB TEST 20 MIN RESULT

FOR EMERGENCY USE AUTHORIZATION (EUA) ONLY

© InBios. All rights reserved.
Part No. 968916-92

www.inbios.com

InBios International, Inc.
307 Westlake Ave. N., #300
Seattle, WA 98109
www.inbios.com
InBios
Covid-19 Antigen Self-Test
2 Test Kit Package Design
Size: 3.1875” x 1.25” x 6.1875”

8-24-22
TWO TESTS PER PACKAGE

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 test does NOT determine if you had COVID-19 in the past or if you have immunity.
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.

Keep test kit out of reach of children.

- 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 test does NOT determine if you had COVID-19 in the past or if you have immunity.