iHealth®

COVID-19 Antigen Rapid Test
Instruction for use

Model ICO-3000ICO-3001ICO-3002

This product has not been FDA cleared or approved, but has been authorized by FDA under an emergency Use Authorization (EUA). Please read all the information in this instruction for use before performing the test.

For use with anterior nasal swab specimens. For In vitro Diagnostic (IVD) Use Only.

Download App & Open App

Scan the QR code to download the “iHealth COVID-19 Antigen Rapid Test” App through your smartphone (iOS 12.0+, Android 6.0+).

Register and Log into The App

For a full list of compatible smartphones visit: https://ihealthlabs.com/pages/support-ICO3000

Watch Video in App

Each step has a corresponding instructional video in the App. Watch the video and perform the test according to the instructions.

Step by Step Instructions

Prepare Materials

You may have Test Set 1 or Test Set 2 in the package. Please follow proper steps based on the specific set you received.

Test Set 1: Open the package, take out the COVID-19 Test Card in Pouch, empty Tube, sealed Solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.

Test Set 2: Open the package, take out the COVID-19 Test Card in Pouch, empty Tube, sealed Solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.

1 Collect Sample

a. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab-package for later use.

b. Gently insert the entire absorbent tip of the swab into a nostril.

c. Firmly and slowly brush against insides of nostril until the liquid level is above Edge 2. As you are brushing, squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.

2 Collect Sample

a. Insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

b. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.

3 Process Sample

a. Tap the tube vertically on the table and twist the large orange cap.

b. Screw back the large orange cap, put the swab and the package.

c. Please confirm the liquid level with above or below Edge 2, then go to Step 2 Collect Sample.

4 Add Sample

Test to open the small white cap of the tube. Add 3 drops of sample to the Sample Port of the COVID-19 Test Card. Screw back the small white cap.

5 Wait 15 Minutes

Start the timer by clicking the “Start Timer” button on the App, immediately after adding sample to the Sample Port. The result will be ready in 15 minutes.

6 Read Result

Results should not be read after 30 minutes (Result shown at 2x magnification).

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

7 Test Result Explanation

A POSITIVE result must show BOTH a C line and a T line. A positive result means that viral antigens from COVID-19 were detected and the individual is positive for COVID-19.

Below are photos of actual positive tests. Please note that the T line may be faint.

Persons who test positive should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.

Negative Result

A NEGATIVE result will show ONLY a C line. A negative result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19.

• Please note that negative results do not rule out COVID-19.

• In case of negative test result: Continue to follow all social distancing recommendations and take protective measures. If suspicions of infection persist and/or your first test is negative, repeat the test after 1-2 days and consult your healthcare provider or local COVID-19 center.

• Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. Additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with as close contact with COVID-19 or with suspected exposure to COVID-19 in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Invalid Result

If there is NO LINE, or if there is ONLY a T line, the test is INVALID. Invalid result means that the test did not function correctly. You will need to retest with a new test kit. If upon retesting, the test result is still invalid, contact your doctor or local COVID-19 center. An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.

8 Dispose the Test Kit

After test is completed, dispose the kit components in trash.

9 Report Test Result

Report the result following the App instructions or share your test result with your healthcare provider.

In the USA:

1) The test is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use the test as the only guide to manage your care. (2021 USA: This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). The product has been authorized only for the detection of proteins from SARS-CoV-2 not for any other virus or pathogen). The emergency use of the 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 Sec. 566(b)(2)(B) of the Federal Food, Drug and Cosmetic Act, 21 USC § 360bb-3(a)(2), unless the declaration is terminated or authorization is revoked sooner.

2) Before using the product, please read this instruction for use carefully.

3) Please follow all instructions as directed.

4) Each test kit contains 6 test devices. Keep the kit after the first test is completed. Please do not use expired test kits.

5) This test is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use the test as the only guide to manage your care.

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19) This product is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use the test as the only guide to manage your care.
For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual in close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals with known exposures to SARS-CoV-2 residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19-like symptoms of fever, cough or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or healthcare provider. Individuals should provide all results obtained with this product to their healthcare provider for public health reporting or by following the mobile application instructions for self-reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with state, local, and federal requirements using appropriate Lorain County and Smoked Cod names, as described by the Laboratory in Vitro Diagnostics (LVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The iHealth COVID-19 Antigen Rapid Test is authorized for non-prescription self-use and/or, as applicable for an adult user, by an adult user testing another person aged 2 years or older. The iHealth COVID-19 Antigen Rapid Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

FREQUENTLY ASKED QUESTIONS

Will this test hurt? No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. 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.
Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others 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 and false results may occur, repeated testing may be necessary to detect SARS-CoV-2 more reliably than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce the spread of infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. It is important that you work with your healthcare provider to help you understand the next steps you should take. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19 earlier, especially if you do not have any symptoms.

Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms. Typically, you should still have COVID-19 negative test results even though the test is negative. If you receive a negative result, you should test again in 24-48 hours. If your test result is negative but continue to experience symptoms of fever, cough, shortness of breath or breathlessness you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 lab test result, or think you may need follow up testing, please contact your healthcare provider.


WARNINGS AND PRECAUTIONS

Test results are not a substitute for a test that is performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to perform additional tests to perform a serial (repeat) testing.

There is a higher chance of false negative results with home test than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have a COVID-19 infection by detecting COVID-19 antigen but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This test is intended for diagnosis of coronavirus infection by detecting COVID-19 antigen but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.

Do not use the COVID-19 Test Card if the pouch is damaged or if the seal is broken.

Do not reuse any test component.

To obtain accurate test results, the test must be performed as indicated in the application (Health COVID-19 Antigen Rapid Test) and/or Instructions for Use. Follow the COVID-19 Test Card within 1 hour after opening the foil pouch. Use the COVID-19 Test Card for at least 1 hour after opening the foil pouch, the perform the test as soon as possible. Use the COVID-19 Test Card within 1 hour after opening the foil pouch. It is important that you work with your healthcare provider to help you understand the next steps you should take. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19 earlier, especially if you do not have any symptoms.

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