EN

iHealth®

COVID-19 Antigen Rapid Test

Instructions for use

Model: ICO-3000/ ICO-3001/ ICO-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.

Download App & Open App

Scan the QR code to download the "iHealth COVID-19 Antigen Rapid Test" App through your smartphone (iOS12.0+, Android 6.0+).

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

Register and Log into The App

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.

How to Use This Test

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Step by Step Instructions

1 Prepare Materials

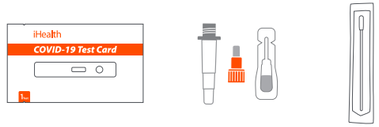
You may have ***Test Set 1*** **OR** ***Test Set 2*** in the package. Please follow proper steps based on the specific set you received.

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

1 COVID-19 Test Card in Pouch | **1 Pre Filled Tube** | **1 Swab**

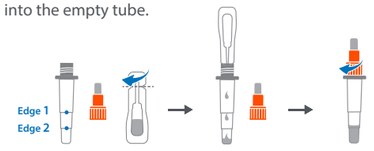
Please go directly to **Step 2 Collect Sample.**

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.

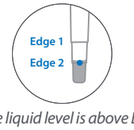


1 COVID-19 Test Card in Pouch | **1 Empty Tube and 1 Sealed Solution** | **1 Swab**

Please look carefully, there are **two Edges** on the empty tube. Then squeeze the sealed solution completely into the empty tube.



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

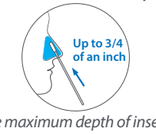


Note:
It is acceptable if the liquid level is above Edge 2. However, please do not proceed with this test, if the liquid level is below Edge 2, as this may result in false or invalid results.

2 Collect Sample

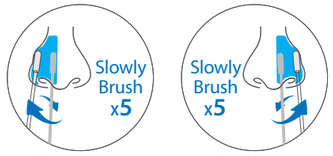
a. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use.

b. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.



Note:
With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person to hold the child's head while swabbing.

c. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 5 times. Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the swab. Using the same swab, repeat the same sample collection procedure for the other nostril. Be sure to brush BOTH nostrils with the **SAME SWAB**.

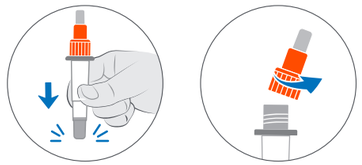


Right Nostril | **Left Nostril**

Note:
Failure to swab properly may cause false negative results.

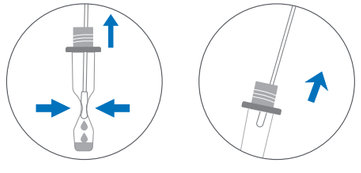
3 Process Sample

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



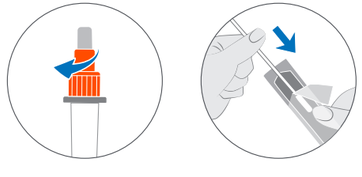
b. Insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

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



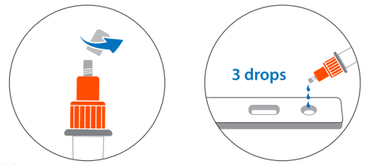
Note:
If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

d. Screw back the large orange cap, put the swab back into the package. Safely dispose of the swab and the package.



4 Add Sample

Twist 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.



Note:
A false negative or invalid result may occur if too little solution is added to the test card.

5 Wait 15 Minutes

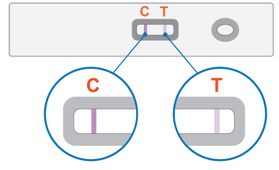
Start the timer by clicking the "Start Timer" button on the App, immediately after adding sample to the Sample Port. The result will be ready in 15 minutes.

Note:
Do NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

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.



Look carefully for a C line here. | **Look carefully for a T line here.**

Note: ***The T line can be extremely faint.***

7 Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive.

Below are photos of actual positive tests. Any faint visible pink-to-purple test (T) line with the control line (C) should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your healthcare provider.

Invalid

If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test kit. 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.

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Please read this instruction for use before using the test.
For use with anterior nasal swab specimens.
For In Vitro Diagnostic (IVD) Use Only.

INTENDED USE

The iHealth COVID-19 Antigen Rapid Test is lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first seven (7) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. This test can be performed with or without the supervision of a telehealth proctor.

The iHealth COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with the iHealth COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures, such as isolating from others and wearing a mask. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/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 or public health reporting and to receive appropriate medical care 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 local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The iHealth COVID-19 Antigen Rapid Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.

The iHealth COVID-19 Antigen Rapid Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

FREQUENTLY ASKED QUESTIONS

What are the known and potential risks and benefits of the test?
Potential risks include:
-- Possible discomfort during sample collection.
-- Possible incorrect test results (see Warnings and Result Interpretation sections for more information).
Potential benefits include:
-- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
-- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here:
https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergencyuse-authorization

What is the difference between an antigen and molecular test?
There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the iHealth COVID-19 Antigen Rapid Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

How accurate is this Test?
Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://www.ihealthlabs.com.

What if I have a positive test result?
A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a negative test result?
A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an invalid test result mean?
An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

For other updated FAQ information, please see the company website: https://www.ihealthlabs.com

Important
Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.
Individuals should provide all results obtained with this product to their healthcare provider.

WARNINGS,PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- An anterior nasal swab sample can be self-collected by an individual age 15 years and older. Children age 2 to 14 years should be tested by an adult.
- If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Do not use on anyone under 2 years of age.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Insert the swab into the tube right after taking the sample.
- Test samples immediately after collection, but no more than 4 hours after specimen collection before placement into extraction buffer or up to 2 hours after placement into extraction buffer, if kept at room temperature.
- Once opened, the test card should be used within 60 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your eyes or mouth. Do not ingest any kit components.
- The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose or mouth, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Triton X-100 / 9002-93-1	Harmful if swallowed (H302) Cause skin irritation (H315) Causes serious eye damage (H318)	0.1%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit:www.cdc.gov/COVID19.
- This test has not been validated for use with a video camera and faint bands may not be visible to a telehealth proctor due to differences between cameras.

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between May, 2021 and October, 2021. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

STORAGE AND OPERATION CONDITIONS

Store iHealth COVID-19 Antigen Rapid Test in a dry place between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. It is stable before the expiration date marked on the packaging.

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

Manufactured for iHealth Labs, Inc.
880 W Maude Ave, Sunnyvale, CA 94085 USA
www.ihealthlabs.com 1-855-816-7705

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