COVID-19 Antigen Rapid Test Instruction 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 (DIY) Use only.

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, pre-filled 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.

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+).

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.

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, 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, pre-filled 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. 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.

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.
   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.

3. 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.

4. 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.

5. Read Result
   Results should not be read after 30 minutes (Result shown at 2x magnification).
   a. A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.
   b. Note: The T line can be extremely faint.

6. Test Result Explanation
   Positive Result
   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.
   Positive Result
   A positive result means that viral antigens from COVID-19 were detected and the individual is positive for COVID-19.
   Negative Result
   A negative result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19.

7. Dispose the Test Kit
   After test is completed, dispose the kit components in trash.

8. Report Test Result
   Report the result following the App instructions or show your test result with your healthcare provider.

For a full list of compatible smartphones visit: https://ihelthlabs.com/pages/support/IQ1000

Notes:
- Please go directly to Step 2 Collect Sample.
- Please confirm the liquid level with or above Edge 2, then go to Step 3 Collect Sample.
- 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).
- Stir back the large orange cap, put the swab back into the package. Safely dispose of the swab and the package.
- 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.
- 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.
- A false negative or invalid result may occur if too little solution is added to the test card.

In the USA:
(1) The test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. Do not use the test as the only guide to manage your care.
(2) 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 and 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 anoro Diagnostic test 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.

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

**INTENDED USE**
The iHealth COVID-19 Antigen Rapid Test is a lateral flow assay intended for the qualitative detection of nucleoprotein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nares (nasal) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nasal) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset.

The iHealth COVID-19 Antigen Rapid Test does not replace medical assessment, including infection control decisions, including infection control decisions. 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.

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The iHealth COVID-19 Antigen Rapid Test does not replace medical assessment, including infection control decisions. 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.

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 with a positive COVID-19 test and/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 an individual with no known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

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 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 local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined 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 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 (LVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The iHealth COVID-19 Antigen Rapid Test is intended for use under the Food and Drug Administration’s Emergency Use Authorization.

**FREQUENTLY ASKED QUESTIONS**

**What is this test?**

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 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 identify COVID-19 more reliably than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce 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 is (i.e., testing every day or every other day) is more likely to detect COVID-19 especially when 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. Serial testing may test a positive result is highly accurate, but 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 and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests 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.

How accurate is this test?

The iHealth COVID-19 Antigen Rapid Test was compared to an FDA authorized molecular SARS-CoV-2 test using fresh self-collected or patient/ guardian collected anterior nasal (nasal) swab samples. The molecular test performed NP swab specimens. Subjects 2 years or older with or without symptoms participated in this study. The iHealth COVID-19 Antigen Rapid Test correctly identified 33 out of 35 (94.3%) of symptomatic positive samples and correctly identified 102 out of 104 (98.1%) of symptomatic negative samples in this study.

Please note that the accuracy of this test may decrease the longer you have had symptoms of infection, as the amount of virus in the sample decreases. In general, molecular RT-PCR tests are more sensitive than antigen tests and may be more likely to detect cases with less SARS-CoV-2, the virus that causes COVID-19.

What if you test positive?

A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC guidance. Refer to your local guidelines for identification of COVID-19 more reliably than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce 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 is (i.e., testing every day or every other day) is more likely to detect COVID-19 especially when you do not have any symptoms.

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for treatment or patient management decisions, along with your medical history, and your symptoms.

What if you test negative?

A negative test result means that no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 but clinical correlation with other symptoms may need to be confirmed with a molecular test. This product is a diagnostic test and may not be adequate to exclude COVID-19. The test is not intended for 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. 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. Serial testing may test a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should test again in 24-48 hours. If you test positive and continue to experience symptoms of fever, cough, and/or breathlessness of breath 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 status after testing or think you may need follow-up care, please contact your healthcare provider.

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


For up-to-date information on COVID-19, please visit the CDC COVID-19 website: https://www.cdc.gov/coronavirus/2019-ncov/index.html

**WARNINGS AND PRECAUTIONS**

• Test samples immediately after collection, but no more than 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repet) testing.

• There is a higher chance of false negative results with home use tests with 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.

• 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.

• 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 diagnostic of coronovirus 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 this product on anyone under 2 years old.

• Children aged 2-14 years should be tested by an adult.

• Do not use on anyone who is prone to naso-sinus or has had nasal, facial, or head/may not be allergic to the Laboratory In Vitro Diagnostics (LVD) Test Code Mapping for SARS-CoV-2.

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Self-Test At Home Results In 15 Mins
**iHealth COVID-19 Antigen Rapid Test**

**Self-Test At Home Results In 15 Mins**

**FDA Emergency Use Authorization**

**Contents**
- 2 x COVID-19 Test Cards
- 2 x Swabs
- 2 x Pre Filled Tubes
- 2 x Empty Tubes & 2 x Sealed Solutions

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**iHealth**

*Instrucciones de uso en español ubicadas dentro de la App.*

The iHealth COVID-19 Antigen Rapid Test is intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.

- 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.

**DO USE**
- As an aid in the diagnosis of COVID-19
- If you are concerned that you have been exposed to COVID-19

**DO NOT USE**
- On anyone under 2 years of age
- If you are prone to nose bleeds
- If you have had a facial or head injury/surgery in the last 6 months

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

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Manufactured for iHealth Labs, Inc.
120 San Luca Ct., Sunnyvale, CA 94086, USA
1-855-816-7705 Made in China www.ihealthlabs.com

Use within 1 hour after opening the foil pouch. Avoid contact of the extraction liquid in Tube with skin and eyes.
iHealth® COVID-19 Antigen Rapid Test

Self-Test At Home Results In 15 Mins

Contents

5 x COVID-19 Test Cards
5 x Swabs
5 x Pre-filled Tubes
5 x Empty Tubes & 5 x Sealed Solutions

FDA Emergency Use Authorization

Sales and Service Contact:
reachsupport@ihealthlabs.com

Packaging may vary. 5 Tests per box. Retail: $49.00

iHealth®

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