EN

iHealth®

COVID-19 Antigen Rapid Test

Quick Reference Instruction

Model: ICO-3000

Please read all the information in the full instructions for use before performing the test.
For use with anterior nasal swab specimens from symptomatic individuals.
For In Vitro Diagnostic (IVD) Use Only.

Download App & Open App (OPTIONAL)

Scan the QR code to download the "iHealth Antigen Rapid Test" App through your smartphone (iOS12.0+, Android 9.0+).

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

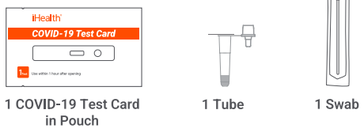
Watch Video in App

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

1 Prepare Materials

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



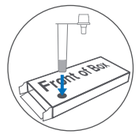
1 COVID-19 Test Card in Pouch

1 Tube

1 Swab

b. Hold the tube upright and tap the tube on the table. After that, gently peel off the foil seal.

c. Place the tube in the front of box labeled "Insert tube here".



2 Collect Sample

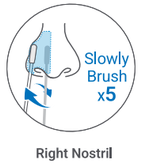
a. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use.

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

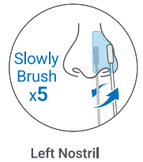
Note:

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

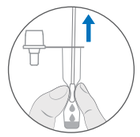
Note:

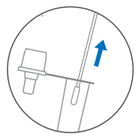
Failure to swab properly in both nostrils may cause false negative results.

3 Process 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.





Note:

If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly and you may obtain a false negative result.

c. Close the tube by pushing the cap firmly into the tube.

d. Put the swab back into the package, safely dispose of the swab and the package.

4 Add Sample

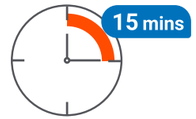
Place the Test Card on a **FLAT** surface and add **3** drops of sample into the Sample Port of the Test Card.

Note:

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

5 Wait 15 Minutes

Immediately after adding sample to the Sample Port, start a 15-minute timer. For users of the App, click the "Start Timer" button on the App. The result will be ready in 15 minutes.



Note:

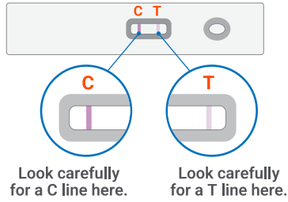
Do NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

6 Read Result

Results should be read between 15 and 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. Any faint T line is positive.

7 Test Interpretation

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

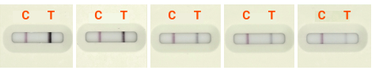
First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
Positive	N/A	N/A	Positive for COVID-19
Negative	Positive	N/A	Positive for COVID-19
Negative	Negative	N/A	Negative for COVID-19

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 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.**

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 does or does not have COVID-19 and the test should be repeated.

8 Dispose the Test Kit

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

You can report your result via "MakeMyTestCount" at the website: https://learn.makemytestcount.org/.

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SERIAL TESTING INFORMATION

If your first test result is negative, you should test again in 48 hours.

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.

All negative results with this test 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.

INTENDED USE

The iHealth COVID-19 Antigen Rapid Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 nucleocapsid protein antigens directly in anterior nasal (nares) swab specimens from individuals with signs and symptoms of COVID-19 within the first 6 days from symptom onset. This test is for non-prescription home use by individuals aged 15 years or older testing themselves, or adults testing individuals aged 2 years or older.

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

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from October 2022 to June 2023 when the COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

FREQUENTLY ASKED QUESTIONS

What does this test do and not do?
The iHealth COVID-19 Antigen Rapid Test is a lateral flow immunoassay device intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 virus. This test is intended to be used as an aid in the clinical diagnosis of active COVID-19. Do not use this test as the only guide to manage your illness. Please consult a healthcare professional to discuss your results and if any additional testing is required.

Who should and should not use this test?
The iHealth COVID-19 Antigen Rapid Test is authorized for use with self- collected anterior nasal (nares) swab samples from individuals 15 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. Do not use this test on anyone under 2 years of age or who is prone to nosebleeds or has had facial injuries or head injuries/ surgery in the past six months.

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. However, due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would. 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 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.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- The test is not a substitute for consultation with a healthcare provider and should not be used to determine treatments without provider supervision. Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are necessary.
- 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.
- 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.
- Improper swab collection may result in incorrectly negative (false negative) results.
- Insert the swab into the tube right after taking the sample.
- 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 the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.

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 October, 2022 and June, 2023. 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.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test is read visually. Individuals with impaired vision or color impaired vision should ensure help in interpretation of their test results.
- The use of oral biotin supplements and use of biotin as a topical application may impact the performance of the test. Exposure to biotin may cause false negative results with this test.

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.

Manufactured for iHealth Labs, Inc.
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