iHealth®

COVID-19 Antigen Rapid Test
Instruction for use

Model: iC2000

This product has not been FDA cleared or approved, but it 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 nasopharyngeal for InViro Diagnostics (ID) for only.

Download App & Open App
Scan the QR code to download the "iHealth COVID-19 Antigen Rapid Test App" through your smartphones (iOS 12.3, Android 6.0+)
For a full list of compatible smartphones: https://ihealthlabs.com/pages/support-iC2000

Register and Log into The App
Watch Video in App
Each step has a corresponding instructional video in the App. Watch the videos and perform the test according to the instructions.

Step by Step Instructions
Prepare Materials
Open the package. take out the COVID-19 Test Card in Pouch, the Tube filed with the extraction buffer and the Swab. When you are ready to proceed with the test, open the full pouch of the COVID-19 Test Card.

Collect Sample
1. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use.
2. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.
3. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.

Note:
- With children, the maximum depth of insertion into the nostril may be less than 1/2 to 3/4 of an inch, and you may need to have a second person hold the child’s head while swabbing.
- 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).

Process Sample
4. Skim and slowly brush against insides of tube in a circular motion against the nasal wall at least 5 times. Take at least 10 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 SAM'S SWAB).
5. Screw back the large orange cap, put the swab back into the package. Slightly dispose of the swab and the package.

Add Sample
6. 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:
- Failure to swab properly may cause false negative results.

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

Test Result Explanation
Positive Result
- A PDD ELISA 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.

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.

Note:
- People note that negative results do not rule out COVID-19.
- In case of negative test result: Continue to follow isolation guidelines and take precautions protective measures. If symptoms of infection persist and/or your test result is negative, repeat the test after 1-2 days and consult your healthcare provider or local COVID-19 center.

In the USA:
- You need to be at least 18 years old to use this kit. You will need to be with a 15-minute timer and have access to a test kit. After testing, the test should be kept in your possession for 90 days following the use of the test kit. If you use a test kit, you will need to be with a 15-minute timer. If you use a test kit, the test should be kept in your possession for 90 days following the use of the test kit.

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

Dispose of the Test Kit
After test is complete, dispose of the kit components in trash.

Note:
- In the USA, the test kit 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 healthcare.
- This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized under the declaration that states that these products are presumptive tests for COVID-19 disease and that no other tests or contraindication to the use of these products. The emergency use of this product is only authorized for the detection of COVID-19 disease in such tests. The declaration includes certain conditions including not releasing the declaration of emergency use of its results diagnosis for detection of SARS-CoV-2 an EUA that is declared by the federal Food and Drug Administration, not the declaration is limited, in authorization is not needed.
COVID-19 Antigen Rapid Test Instructions for Use

Model ECO-1000

This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA).

Please read these instructions 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 a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) 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 self-collected anterior nasal (nares) swab samples from individuals aged 2 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 self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The iHealth COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV-2 and SARS-CoV-1.

Results are for the identification of the SARS-CoV-2 nucleoprotein antigen. The antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but distal correlations with past medical 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. The agent detected may not be the definitive cause of disease. Individuals who test positive with the iHealth COVID-19 Antigen Rapid Test should seek medical follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results are presumptive, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infections and vaccination 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 as an individual with a clinical contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory samples of a negative test for positive results may also be necessary, if there is a high likelihood of SARS-CoV-2 infection, especially when you do not have any symptoms.

Testing for asymptomatic individuals should be performed at least twice over three days with at least 24 hours (and no more than 48 hours) between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

What is the difference between an antigen and molecular test?

An antigen test, such as the iHealth COVID-19 Antigen Rapid Test, detects proteins from the virus. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests are very specific, for the virus, but can also give false positive results. If your test result is positive, it is likely that you are infected with COVID-19. If your test result is negative, you are probably not infected with COVID-19. However, it is not a perfect test. It is possible that you could be infected with COVID-19 even though your test result is negative. If you test negative after a negative result, you should test again in 3-4 days. If you test negative and continue to experience symptoms of fever, cough and shortness 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 you think you may need follow-up testing, please contact your healthcare provider.

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

WASHINGTONS AND PRECAUTIONS

Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform serial (repeat) testing. There is a higher chance of false negative results with home use tests than with laboratory-processed molecular tests. This means that there is a higher chance this test will give you a negative result when you have 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 self-collected nasal swabs. The test performed with 93.7% specificity and 95.9% sensitivity, with 99.1% of the 166 samples tested being correctly classified.

FREQUENTLY ASKED QUESTIONS

Will this test hurt? No, the nasal swab is not sharp and should not hurt. Sometimes the swab can be felt for a couple of seconds only for your comfort 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 increased test results.

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The test results may help limit the spread of COVID-19 to your family and other communities.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once. There may be less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify individuals with 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 and prevent transmission. Testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

What if you test negative?

A negative test result indicates no antigens for COVID-19 were detected in your sample. A negative test result that is incorrect (false negative) in some people with COVID-19 and negative results are presumptive and may be confirmed with a molecular test. This means that you could possibly have COVID-19 even though this test result is negative. If you test negative after a negative result, you should test again in 3-4 days. If you test negative and continue to experience symptoms of fever, cough and shortness 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.

What if you test positive?

Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform serial (repeat) testing. There is a higher chance of false negative results with home use tests than with laboratory-processed molecular tests. This means that there is a higher chance this test will give you a positive result when you have COVID-19.

If you test positive, you should call your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

How do I take the test?

CAUTION: This kit contains small parts. Please use adult supervision. Before solution contact the skin or eye, flush with copious amounts of water. If ingestion occurs, rinse mouth with large amounts of water. If washed or swallowed or inhaled, consult a physician for treatment.