**iHealth**

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 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 (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.

**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.

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

   **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.

   **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.

   **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.

   **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.

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   - 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.

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

   **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.

   **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.

5. **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.
   - 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.

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

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.

7. **Dispose the Test Kit**
   - After test is completed, dispose the kit components in trash.
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, for use with anterior nasal swab specimens. For In Vitro Diagnostics (IVD) Use Only.

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 nasal (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.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect SARS-CoV-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-1 and SARS-CoV-2.

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 clinical correlation with patient 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 as the agent may not be the definitive cause of disease. Individuals who test positive with the iHealth COVID-19 Antigen Rapid Test should seek self-isolate and seek 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 infection control decisions. Negative results should be considered in the context of an individual’s recent exposure, 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 SARS-CoV-2 is recommended, such as an in home/self test 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, 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 if you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four 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 itself, while a molecular test (also known as PCR tests) detects genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that 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 infection.

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 guarded collected anterior nasal swab specimens and healthcare provider collected 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 35 out of 35 (95.2%) 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 are more likely to detect cases with less SARS-CoV-2, the virus that causes COVID-19.

What if you test positive?

A positive result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19. There is a small chance that this test can give you a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations and follow-up with your healthcare provider immediately.

What if you test negative?

A negative result indicates 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 SARS-CoV-2 infection and should not be used as the 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.

The iHealth COVID-19 Antigen Rapid 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, it must be performed as indicated in the application (iHealth COVID-19 Antigen Rapid Test) and the instructions for use.

Once the COVID-19 Test Card is removed from the pouch, perform the test as soon as possible. Use the COVID-19 Test Card within 1 hour after opening the foil pouch.

• Do not open the test pouch before and after collecting the sample from the nostril.
• 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. Be sure to read test result after 15 minutes. Do not read results after 30 minutes.
• Do not ingest extraction liquid.
• Keep test kit and components out of the reach of children and pets before and after use.
• Avoid contact with skin and eyes.
• The reagent in the extraction liquid contains ProCIn® 500 which may cause an allergic skin reaction in some people. If the solution makes contact with the skin or eyes, wash flush with copious amounts of water. If skin irritation or eye irritation occurs get medical attention.

STORAGE AND OPERATION CONDITIONS

Store iHealth COVID-19 Antigen Rapid Test in a dry place between 36-86°F (2-30°C) before use. Ensure all test components are at room temperature 65°F (18°C) before use.

The shelf life of the iHealth COVID-19 Antigen Rapid Test is 12 months and it is stable before the expiration date marked on the packaging.

HAZARDOUS INGREDIENTS FOR REAGENT SOLUTION

The Extraction Reagent contains potentially harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice.

https://www.poison.org/contact-us/1-800-222-1222

Manufactured for Health Labs, Inc.
302 San Luzar Cir., Sunnyvale, CA 94086, USA
1-800-770-7779 www.healthlabs.com
Made in China
Rev 07/2022
iHealth®

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 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 (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 or Test Set 2 in the package. Please follow proper steps based on the specific set your received. 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.

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.

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

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

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: Failure to add proper sample may cause false negative results.

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 positive result 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. 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.

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.

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) 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 illness.
(2) This product has not been cleared or approved by the US Food and Drug Administration (FDA). This product has not been cleared or approved by the Health Canada (HC) and is only authorized for the detection of SARS-CoV-2 infection as a supplemental test to molecular diagnostic tests. If used to diagnose COVID-2019 Infection, the results must be confirmed with a supplemental test identified by the FDA or HC.

Note:
- Positive 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 test result is negative, retest the sample after 1-2 days and contact your healthcare provider or local COVID-19 center.
- Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for your patient management may be performed.

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 repeat 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.

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. 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 test result is negative, retest the sample after 1-2 days and contact your healthcare provider or local COVID-19 center.
• Note: A negative result is presumptive and confirmation with a molecular assay, if necessary, for your 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 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 without known exposures to SARS-CoV-2 residing in communities with low prevalence of infection.
COVID-19 Antigen Rapid Test Instructions for Use

Model: ICD-3000 | ICD-1001 | ICD-3002

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

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 HealthCOVID-19 Antigen Rapid Test is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swabs 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) swabs samples from individuals aged 2 years or older with or without symptoms or other epidemiological reasons to suspect 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 (nasal) swabs samples from individuals aged 2 years or older, or adult collected anterior nasal (nasal) swabs samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 within the first seven (7) days of symptom onset.

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 an individual with a close contact with COVID-19 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 unknown exposure 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.

For use with anterior nasal swab specimens and healthcare provider collected nasal swab specimens. Subjects 2 years old or with/without symptoms participated in this study. The HealthCOVID-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.

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

WARNINGs AND PRECAUTIONS

• Testing for symptomatic 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.

• There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance 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.

The 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 detection. Other laboratory tests and clinical information (signs and symptoms) should be considered for diagnosis.

• Do not use on anyone under 2 years old.
• Do not use in patients who are prone to nosocomial or has had head or injury surgery in the last 6 months.
• Do not reuse any test component after the expiration date which is printed on the outer packaging.

STORAGE AND OPERATION CONDITIONS

Store iHealth COVID-19 Antigen Rapid Test in a dry place between 36-86 °F (3–30 °C). Test all components are at room temperature 65-85 °F (18–30 °C) before use. Store the shelf life of the HealthCOVID-19 Antigen Rapid Test is 12 months and it is stable before the expiration date marked on the packaging.

IHAB Laboratories Inc.
15715 Arrow Hwy, Irwindale, CA 91706
https://www.healthlabs.com | 855-816-7705

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

What if your test negative?

A negative result indicates 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 and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you receive a negative result test again in 24-48 hours. If you test negative and continue to experience symptoms of fever, cough and/or 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 think you may need follow up testing, please contact your healthcare provider.

Potential benefits include:

• Possible incorrect test results.

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 knownt and potential risks and benefits of this test?

Potential risks include:

• Possible incorrect test results.

Potential benefits include:

• The results, along with other information, can help your healthcare provider make informed recommendations about your care.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 multiple times. Because antigen tests are 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 of infection. Additional confirmatory 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 a 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, 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. 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 HealthCOVID-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 not as sensitive as molecular tests. This means that 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 parent/guardian collected anterior nasal swab specimens and healthcare provider collected NP swab specimens. Subjects 2 years old or with/without symptoms participated in this study. The HealthCOVID-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 able to more correctly identify test cases with less SARS-CoV-2, the virus that causes COVID-19.

If you test positive?

A positive 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 recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result along with your medical history and your symptoms.

What is the difference between an antigen and molecular test?

An antigen test, such as the HealthCOVID-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 not as sensitive as molecular tests. This means that 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.

Causes severe skin burns (H311)

0.1%

Causes serious skin damage (H315)

0.1%

Causes skin irritation (H315)

0.1%

Causes eye irritation (H318)

0.1%

May cause an allergic skin reaction in people with sensitization (H319)

0.1%

May cause eye irritation (H318)

0.1%

May cause skin irritation (H315)
iHealth® COVID-19 Antigen Rapid Test

Self-Test At Home Results In 15 Mins

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

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 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.
- 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 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.

Manufactured for iHealth Labs, Inc.
120 San Lucas 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.
Scan the QR code to download the “iHealth COVID-19 Antigen Rapid Test” App on smartphone.

Follow the instructional video in “iHealth COVID-19 Antigen Rapid Test” App to quickly start the test.

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

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

iHealth®

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.

- 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 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.

Manufacturer for IHealth Labs, Inc. Made in China
Model: ICO-3000
120 San Lucas Ct., Sunnyvale, CA 94086, USA
1-855-816-7705 www.ihealthlabs.com

Use within 1 hour after opening the foil pouch.
Avoid contact of the extraction liquid in Tube with skin and eyes.
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.

Scan the QR code to download the “iHealth COVID-19 Antigen Rapid Test” App on smartphone.
Follow the instructional video in “iHealth COVID-19 Antigen Rapid Test” App to quickly start the test.
For a full list of compatible smartphone visit: ihealthlabs.com/pages/support-ICO3000

Components

COVID-19 Test Card
Swab
Pre Filled Tube
Empty Tube & Sealed Solution

Instructions de uso en español ubicadas dentro de la App.

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Contents

5 x COVID-19 Test Cards; 5 x Swabs; 5 x Pre Filled Tubes

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