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. Collect Sample
   - 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 and insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

3. Process Sample
   - Note: Failure to swab properly may cause false negative results.
   - 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.
   - c. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 3 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 collection procedure for the other nostril. Be sure to brush BOTH nostrils with the SAME SWAB.

4. Add Sample
   - a. 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.
   - b. 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. Wait 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).
   - a. If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.
   - b. If the Control (C) line is visible, and the Test (T) line is visible, the test is positive.

7. Test Interpretation
   - Re-test with a new swab and new test kit. An invalid test result that is incorrect (a false positive).

8. Dispose the Test Kit
   - If the Control (C) line is visible, the test is invalid. Re-test with a new swab and new test kit. An invalid result does not indicate that the individual did or did not have COVID-19 and should be repeated.

9. Report Test Result
   - After test is completed, dispose the kit components in trash.

10. Support ICO3000
    - How to Use This Test
    - 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.
    - How to Use This Test
    - For use with anterior nasal swab specimens. For use in accordance with local health guidelines. 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 (iOS13.0+, 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
- i. 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.
- ii. 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.
- iii. 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.

· 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.
- iv. 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.

Antigen Rapid Test
- Note: Failure to swab properly may cause false negative results.

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 and insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times. You may need to purchase additional tests to perform this serial (repeat) testing.

Antigen Rapid 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 and insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

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

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

Test Set 2
- 1 COVID-18 Test Card in Pouch
- 1 Empty Tube and 1 Sealed Solution
- 1 Swab

Antigen Rapid Test Card in Pouch
- i. The App should be read as positive. 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).
- ii. COVID-19 Positive (+)

Antigen Rapid Test Card
- 1 Swab
- COVID-19 Test Card in Pouch
- the Tube pre-filled with the extraction solution and the Swab.

Antigen Rapid Test Card in Pouch
- 1 COVID-19 Test Card in Pouch
- 1 Pre Filled Tube
- 1 Swab

If the Control (C) line is visible, the test is invalid. Re-test with a new swab and new test kit. An invalid result does not indicate that the individual did or did not have COVID-19 and should be repeated.
**COVID-19 Antigen Rapid Test Instructions for Use**

**Model:** CIO-300/ICO-300/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 this section 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 (nare) swab samples from individuals aged 15 years or older and adult collected anterior nasal (nare) 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 (nare) 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 specific cause of disease. Individuals who test positive with the Health 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 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 LDNC 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 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/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

**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.
- Do not use this product if it 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 § 360b(b)-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 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 test 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 test 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.

- 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 when 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.

- 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 misleading 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 Health COVID-19 Antigen Rapid Test in a dry place between 36-86 °F (18-30 °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-19.

Manufactured for Health Labs, Inc. 880 W. Mauve Ave, Sunnyvale, CA 94085 USA

www.healthlabs.info 1-855-816-7705

Maude: USA

Rev 03/23
COVID-19 Antigen Rapid Test

For Emergency Use Authorization (EUA) only

If you want to use the telehealth testing, please do not open the kit package until instructed to do so.

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 smartphones visit: ihealthlabs.com/pages/support-ICO3000

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.

For in vitro diagnostic use.

Determining a negative result requires multiple tests.

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

DO NOT USE

On anyone under 2 years of age

If you are prone to nose bleeds

If you are concerned that you have been exposed to COVID-19

If you have had a facial or head injury/surgery in the last 6 months

This test can be performed with or without the supervision of a telehealth proctor, to access the telehealth proctor services, please visit: iHealthLabs.com/air

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

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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 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.

For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

Model: ICO-3000

ICO-3001

ICO-3002

For use within 1 hour after opening the foil pouch of COVID-19 Test Card.

Avoid contact of the extraction solution with your skin, eyes, nose or mouth.

Manufactured for iHealth Labs, Inc.

8880 W Maude Ave, Sunnyvale, CA 94085 USA

www.ihealthlabs.com  1-855-816-7705

Contents

1 × COVID-19 Test Card;
1 × Swab;
1 × Pre Filled Tube

Components

COVID-19 Test Card

Swab

Pre Filled Tube

Empty Tube & Sealed Solution

Materials required but are not provided in the kit: Smartphone (iOS12.0+, Android 6.0+) Timer
iHealth COVID-19 Antigen Rapid Test

This test can be performed with or without the supervision of a telehealth provider. Please visit ihealthlabs.com/app/telehealth to download the iHealth COVID-19 Antigen Rapid Test App on your smartphone.

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

For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

Components

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

Contents

- 2 x COVID-19 Test Cards
- 2 x Swabs
- 2 x Pre Filled Tubes

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

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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.

For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

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

Use within 1 hour after opening the foil pouch of COVID-19 Test Card. Avoid contact of the extraction solution with your skin, eyes, nose or mouth.
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.

Materials required but are not provided in the kit: • Smartphone (iOS12.0+, Android 6.0+) • Timer

For Emergency Use Authorization (EUA) only

If you want to use the telehealth testing, please do not open the kit package until instructed to do so.

Components

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

iHealth COVID-19 Antigen Rapid Test

FDA

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.

For in vitro diagnostic use.

DO NOT USE

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

DO 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.

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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.
- For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

Contents

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

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

Manufactured by iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

Use within 1 hour after opening the foil pouch of COVID-19 Test Card.
Avoid contact of the extraction solution with your skin, eyes, nose or mouth.
**COVID-19 Antigen Rapid Test**

For Emergency Use Authorization (EUA) only

If you want to use the telehealth testing, please do not open the kit package until instructed to do so.

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

Materials required but are not provided in the kit: • Smartphone (iOS12.0+, Android 6.0+) • Timer

**Components**

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

**Instructions 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 (nare) swab samples.

- For in vitro diagnostic use.
- Determining a negative result requires multiple tests.
- 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.

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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. § 360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

**Contents**

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

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

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706

Use within 1 hour after opening the foil pouch of COVID-19 Test Card.
Avoid contact of the extraction solution with your skin, eyes, nose or mouth.
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

Materials required but are not provided in the kit: • Smartphone (iOS12.0+, Android 6.0+) • Timer

For Emergency Use Authorization(EUA) only

If you want to use the telehealth testing, please do not open the kit package until instructed to do so.

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

Please visit: iHealthLabs elehealth prt CTS this to VID-19 A on swab can be per ac the QR code rapid or do elehealth pr the smarA on swat phone.

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.

• For in vitro diagnostic use.
• Determining a negative result requires multiple tests.
• 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.

• In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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.
• For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

Components

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

Contents
6 x COVID-19 Test Cards; 6 x Swabs; 6 x Pre Filled Tubes

Swab COVID-19 Test Card Pre Filled Tube

Materials required but are not provided in the kit:    Smartphone (iOS12.0+, Android 6.0+)     Timer

Use within 1 hour after opening the foil pouch of COVID-19 Test Card.
Avoid contact of the extraction solution with your skin, eyes, nose or mouth.

For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

iHealth
COID-19
Antigen Rapid Test

Self-Test
At Home
Results In
15 Mins

FDA

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880 W Maude Ave, Sunnyvale, CA 94085, USA
www.ihealthlabs.com 1-855-816-7705

iHealth Manufacturing Inc.
19715 Arrow Hwy, Irwindale, CA 91706

Use within 1 hour after opening the foil pouch of COVID-19 Test Card.
Avoid contact of the extraction solution with your skin, eyes, nose or mouth.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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.

For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests
Scan the QR code to download the “iHealth COVID-19 Antigen Rapid Test” App on smartphone.

For in vitro diagnostic use. Determining a negative result requires multiple tests. 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

DO NOT USE

As an aid in the diagnosis of anyone under 2 years of age with COVID-19

If you are prone to nose bleeds

If you are concerned that you have been exposed

If you have had a facial or head injury/surgery in the last 6 months

Use within 1 hour after opening the foil pouch of COVID-19 Test Card.

Avoid contact of the extraction solution with your skin, eyes, nose or mouth.

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

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an 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.

For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

Components

40 × COVID-19 Test Cards;
40 × Swabs;
40 × Pre Filled Tubes

Swab COVID-19 Test Card Pre Filled Tube

Empty Tube & Sealed Solution

Model: ICO-3000
ICO-3001
ICO-3002

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

2022-05-04
iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706
COVID-19 Antigen Rapid Test

If you want to use the telehealth testing, please do not open the kit package until instructed to do so.

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

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.

For in vitro diagnostic use. Determining a negative result requires multiple tests. 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 a confirmed COVID-19 patient
If you are a healthcare provider or public health official

DO NOT USE
On anyone under 2 years of age
If you are prone to nose bleeds
If you are concerned that you have been exposed
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.

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA. This product has been authorized only for the detection of 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.

For more information on expiration dating for COVID-19 antigen tests, please refer to: http://www.fda.gov/covid-tests

Use within 1 hour after opening the foil pouch of COVID-19 Test Card.

Avoid contact of the extraction solution with your skin, eyes, nose or mouth.

Manufactured by iHealth Labs, Inc.

4001 Hilton Drive Sunnyvale, CA 94085 USA
www.ihealthlabs.com 1-855-816-7705

Contents
1 × iHealth COVID-19 Test Card; 1 × Swab; 1 × Pre Filled Tube

Made in China
COVID-19 Antigen Rapid Test

For Emergency Use Authorization (EUA) only

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Materials required but are not provided in the kit:
- Smartphone (iOS12.0+, Android 6.0+)
- Timer

iHealth COVID-19 Antigen Rapid Test

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

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Contents
- 2 × COVID-19 Test Cards
- 2 × Swabs
- 2 × Pre Filled Tubes

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880 W Maude Ave, Sunnyvale, CA 94085 USA
www.ihealthlabs.com 1-855-816-7705

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

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This test can be performed with or without the supervision of a telehealth proctor, to access the telehealth proctor services, please visit: iHealthLabs.com/air

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Components

Contents

40 × COVID-19 Test Cards;
40 × Swabs;
40 × Pre Filled Tubes

ICO-3000
ICO-3001
ICO-3002

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