Step by Step Instructions

1. Prepare Materials
   - You may have Test Set 1 OR Test Set 2 in the package. Please follow proper steps based on the specific set you received.

   **Test Set 1:** Open the package, take out the COVID-19 Test Card in Pouch, 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.

   **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 go directly 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 into the upper part of the nostril (i.e., potentially resulting in a false negative result).
   - c. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 1-3 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 sample collection procedure for the other nostril. Be sure to brush BOTH nostrils with the SAME SWAB.
   - d. Screw back the large orange cap, put the swab into the empty tube. Then squeeze the sealed solution completely into the empty tube.
   - e. Please confirm the liquid level with or above Edge 2, then go to Step 3 Process Sample.

   **Note:**
   - To be acceptable if the liquid level is above Edge 2. However, please do not proceed with this test, if the liquid level is below Edge 2, as this may result in false or invalid results.

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.
   - d. Screw back the small white cap, put the swab into the empty tube. Then squeeze the sealed solution completely into the empty tube.
   - e. 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.

4. Add Sample
   - a. 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.
   - b. 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).
   - c. Screw back the large orange cap, put the swab into the package. Safely dispose of the swab and the package.

5. Wait 15 Minutes
   - a. 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.
   - b. Look carefully for a C line here. Look carefully for a T line here.

6. Read Result
   - a. A false negative or invalid result may occur if too little solution is added to the test card.
   - b. Results should not be read after 30 minutes (Result shown at X magnification).

7. Test Interpretation
   - a. A negative result is presumptive, meaning it is not definitive.
   - b. If the control (C) line is not visible, the test is invalid.

   **COVID-19 Positive (+)***

   - a. If the Control (C) line and the Test (T) line are visible, the test is positive.
   - b. 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 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).

   **COVID-19 Negative (-)**

   - a. If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.
   - b. To increase the chance that the negative result for COVID-19 is accurate, you should:
   - c. Test again in 48 hours if you have symptoms on the first day of testing.
   - d. Test 2 more times at least 48 hours apart if you do not 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**

   - a. 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 did or did not have COVID-19 and should be repeated.

8. Dispose the Test Kit
   - a. After test is completed, dispose the kit components in trash.

9. Report Test Result
   - a. Report the result following the App instructions or share your test result with your healthcare provider.
COVID-19 Antigen Rapid Test Instructions for Use

Model: iC19-300/ iC19-301 / iC19-302

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 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 (nares) swab samples from individuals 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 ReResult Interpretation sections for more information).

Possible benefits include:

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


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.

For information about current expiration dates for at home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

Chemical Name

Horse (GHS Code for each ingredient)

Concentration

Rabbit anti-SARS-CoV-2 nucleocapsid protein (H09) 0.05%

Horse anti-SARS-CoV-2 nucleocapsid protein (H31)

100 µg/mL

For more information on EUAs please visit:


For the most up to date information on COVID-19, please visit www.cdc.gov/covid19/1

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 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 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. If you have symptoms of a virus that causes COVID-19 because proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.

- This test is real and visually has not been validated for use by those with impaired vision or color-impaired persons.

- Incorrect test results may occur if a specimen is incorrectly collected or handled.

- For more information on EUAs please visit:


- For the most up to date information on COVID-19, please visit www.cdc.gov/covid19/1

- 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.

- 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. If you have symptoms of a virus that causes COVID-19 because proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.

- This test is real and visually has not been validated for use by those with impaired vision or color-impaired persons.

- Incorrect test results may occur if a specimen is incorrectly collected or handled.

- For more information on EUAs please visit:


- For the most up to date information on COVID-19, please visit www.cdc.gov/covid19/1

- 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.
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 DO NOT USE
As an aid in the diagnosis On anyone under 2 years of age
Of 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

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 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.

Components

COVID-19 Test Card

Swab

Pre Filled Tube

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

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131, USA
www.ihealthlabs.com 1-855-816-7705

Model: ICO-3000
ICO-3001
ICO-3002

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

For Emergency Use Authorization(EUA) only

For in vitro diagnostic use only as an independent ancillary device for the iHealth COVID-19 Antigen Rapid Test App as an accessory.

If you are not connected to the internet, visit the website iHealthLabs.com to download the test card and instruction manual.
COVID-19 Antigen Rapid Test
FDA
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

Scan the QR code to access the telehealth testing services. Please visit: ihealthlabs.com

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

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

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

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

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.
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

Components of the kit:
• COVID-19 Test Cards
• Swabs
• 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

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.

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

For more information please visit: iHealthLabs.com

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.

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. 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

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

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

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

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

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.
150C Charcot Ave, San Jose, CA 95131 USA
www.ihealthlabs.com 1-855-816-7705

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

FDA
For Emergency Use Authorization (EUA) only

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

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

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

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

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131 USA
www.ihealthlabs.com 1-855-816-7705

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.

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

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 DO NOT USE

As an aid in the diagnosis of COVID-19 in anyone over 2 years of age.

If you are prone to nose bleeds, do not use.

If you are concerned that you have been exposed to COVID-19, do not use.

If you have had a facial or head injury/surgery in the last 6 months, do not use.

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;

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131, USA
www.ihealthlabs.com 1-855-816-7705

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

Model: ICO-3000
ICO-3001
ICO-3002

4085636200589
211CO21105
2022-05-04
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 NOT USE DO NOT USE

As an aid in the diagnosis of COVID-19 on anyone under 2 years of age or COVID-19 if you are prone to nose bleeds. If you are concerned that you have been exposed to COVID-19 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 viral RNA 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 diagnostic devices 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.

For Emergency Use Authorization (EUA) only

Components

COVID-19 Test Card

Swab

Pre Filled Tube

Empty Tube & Sealed Solution

Manufactured for iHealth Labs, Inc., 150 C. Charcot Ave, San Jose, CA 95131, USA

www.ihealthlabs.com

1-855-816-7705

Made in China
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

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131, USA
www.ihealthlabs.com 1-855-816-7705

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](http://www.fda.gov/covid-tests)

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

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131 USA
www.ihealthlabs.com 1-855-816-7705

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

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

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

FDA
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

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.

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

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

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

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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

Instructions de uso en español ubicadas dentro de la App.

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

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131 USA
www.ihealthlabs.com 1-855-816-7705

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iHealth COVID-19 Antigen Rapid Test

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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

Components

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

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
X On anyone under 2 years of age
X If you are prone to nose bleeds
X If you have had a facial or head injury/surgery in the last 6 months

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

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

UDI

Made in China
Scan the QR code to download the “iHealth COVID-19 Antigen Rapid Test” App on smartphone.

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

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
DO NOT USE
As an aid in the diagnosis On anyone under 2 years of age Of 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.

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

Components

Contents

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

iHealth
COVID-19 Antigen Rapid Test

Model: ICO-3000
ICO-3001
ICO-3002

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131, USA
www.ihealthlabs.com           1-855-816-7705

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Made in China