**COVID-19 Antigen Rapid Test Instruction for use**

Model: iCO-1000

This product has not been FDA (Food and Drug Administration) approved, and has not been authorized by the FDA under Emergency Use Authorization (EUA). Please read all the information in this instruction for use before performing the test.

For use with anterior nasopharyngeal for InViro Diagnostics (ID: For Only).

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**Step by Step Instructions**

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

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 future use.
   - b. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.
   - c. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the 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. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.
   - d. Screw back the large orange cap, put the swab back into the package. Safely dispose of the swab and the package.

4. **Add Sample**
   - a. Insert the sample collection device into the Sample Port of the COVID-19 Test Card. Screw back the small white cap.

5. **Wait 15 Minutes**
   - a. Start the timer by clicking the “Start Timer” button, 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-minute timer has completed, as the T-Line may take as long as 15 minutes to appear.

6. **Read Result**
   - a. Results should not be read after 30 minutes. (Result shown at 5x magnification).
   - Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

7. **Disposing of the Test Kit**
   - a. Dispose of the test kit after completing the test as instructed and checking the waste disposal component in the testing area.

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

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**COVID-19 Antigen Rapid Test**

*Download App & Open App*

Scan the QR code to download the “iHealth COVID-19 Antigen Rapid Test” App through your smartphones (iOS 11.0, Android 6.0+).

*Register and Log into App*

Watch Video in App

Each step has a corresponding instructional video in the App. Watch the videos and perform the test according to the instructions.

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**Important Notes**

- Please note that negative results do not rule out COVID-19.
- In case of negative test result, continue to follow social distancing recommendations and take protective measures. If suspicious of infection, please reach out to your healthcare provider or local COVID-19 center.
- Note: A negative test result is presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.

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**COVID-19 Antigen Rapid Test**

**Negative Result**

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.

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**COVID-19 Antigen Rapid Test**

**Positive Result**

A positive test means the viral antigens from COVID-19 were detected and that the individual is presumed positive for COVID-19.

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**Report Test Result**

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

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**COVID-19 Antigen Rapid Test**

**Negative Result**

A negative test result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19.
COVID-19 Antigen Rapid Test Instructions for Use

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

For use by healthcare providers for use before using the test. For use with anterior nasal swab specimens.

INTENDED USE

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. The test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset. The test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset.

What if you test negative?

A negative test result indicates that you are not infected with the virus that causes COVID-19. However, it is possible that you may be infected with the virus and may not test positive because antigen testing is less sensitive than other COVID-19 tests (such as a PCR test). The sensitivity of rapid tests is typically lower than that of other diagnostic tests. If you test negative but still have symptoms, you should get a follow-up test with a healthcare provider.

Storage and operational conditions

Store the COVID-19 Antigen Rapid Test Kit at 2°C to 8°C (36°F to 46°F) before use. It is stable for five (5) years after the expiration date marked on the packaging.

HAZARDOUS INGREDIENTS FOR REAGENT SOLUTION

The extraction reagent contains potentially harmful chemicals. If solution contacts the skin or eye, flush with copious amounts of water. If ingestion occurs, seek medical attention.
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-ICO30000

iHealth
COVID-19
Antigen Rapid Test

Self-Test
At Home
Results In
15 Mins

FDA Emergency Use Authorization

Contents

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

iHealth COVID-19 Antigen Rapid Test is intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens 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 current COVID-19 test
• 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).

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Manufactured for iHealth Labs, Inc., www.ihealthlabs.com
120 San Lacar Ct., Sunnyvale, CA 94086, USA
1-855-816-7765 Made in China Model: ICO30000

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