**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). This product has been authorized only for the detection of SARS-CoV-2 and its associated viral RNA. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use 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 authorized emergency use is revoked sooner.

**Preparation**

- **Prepare Materials**
  - You may have a 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, 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.

**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**
   - a. Remove the swab from its package, being careful not to touch the tip of the swab.
   - b. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.
   - c. Firmly and slowly brush against the 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 specimen collection procedure for the other nostril. Be sure to brush BOTH nostrils with the SAME SWAB.

3. **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. **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.

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.

6. **Read Result**
   - Results should not be read after 30 minutes (Result shown as 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.

7. **Test Result Explanation**
   - Positive Result
     - Both C and T lines are present.
   - Negative Result
     - No C or T line is present.
   - Invalid Result
     - 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 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.

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 care.

(2) In USA - This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). The product has been authorized only for the detection of SARS-CoV-2 and its associated viral RNA. 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 this product 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 authorized emergency use is revoked sooner.

**False Negative or False Positive Result**

- Failure to肿 swamp properly may cause false negative results.

**Important Notes**

- **Note:** A negative result does 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 first test result was negative, repeat the test after 1-2 days and consult your healthcare provider or local COVID-19 center.
- **Note:** A negative result is presumptive and confirmation with a molecular assay is necessary, for 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 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 positive likelihood of SARS-CoV-2 infection, as such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.
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 in an individual with known 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.

Individuals who test negative and continue to experience COVID-19 symptoms, such as fever, cough, and/ or shortness of breath may still have COVID-19 infection and should seek follow-up care with their physician or healthcare provider.

Testing for asymptomatic individuals who were exposed to COVID-19 is more likely to detect COVID-19, especially when you do not have any symptoms. Testing serially (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 serially (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 serially (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 serially (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 serially (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 serially (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
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 testing (testing on subsequent days).
• 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**

- 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.

Avoid contact of the extraction liquid in Tube with skin and eyes.

**Manufactured for iHealth Labs, Inc. Made in China**

For articles of medical equipment, visit health.com/p/apps/com/1.png

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

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

**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.
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**
- 2 x COVID-19 Test Cards
- 2 x Swabs
- 2 x Pre Filled Tubes
- 2 x Empty Tubes & 2 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

Manufactured for iHealth Labs, Inc.
120 San Lucar 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.

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.

**UDI**
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

Instrucciones de uso en espanol 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 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. § 360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Manufactured for iHealth Labs, Inc. Made in China
Model: ICO-3000

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