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iHealth ICO-3000

iHealth COVID-19 Antigen Rapid Test (Model ICO-3000) Instruction Manual

Your guide to safe and effective at-home COVID-19 testing.

1. PRODUCT OVERVIEW

The iHealth COVID-19 Antigen Rapid Test is an FDA EUA authorized over-the-counter (OTC) at-home self-test designed to detect the presence of SARS-CoV-2 viral antigens. This test provides results in 15 minutes using a non-invasive nasal swab.

The test is designed to detect multiple COVID-19 variants, helping users stay informed as the virus evolves. It is suitable for individuals aged 2 years and above. For children aged 2-14 years, adult collection of the sample is required.



Image: The iHealth COVID-19 Test card displaying a positive result after 15 minutes, alongside information regarding FDA-granted shelf-life extensions for specific lot numbers. This highlights the quick result time and updated product validity.

2. WHAT'S INCLUDED

Each iHealth COVID-19 Antigen Rapid Test kit contains the following components:

- 2 x COVID-19 Test Cards (individually sealed in pouches)
- 2 x Swabs (individually sealed)
- 2 x Pre-filled Tubes with extraction solution

- Instruction for Use leaflet



Image: A visual representation of the kit contents, showing two individually packaged test cards, two nasal swabs, and two pre-filled solution tubes, along with the instruction manual.

3. IMPORTANT SAFETY INFORMATION

This test is intended for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen from anterior nasal (nares) swab specimens. This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA).

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

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

4. SETUP AND PREPARATION

Before starting the test, ensure you have a clean, flat surface. Wash or sanitize your hands thoroughly and make sure they are dry.

4.1. Prepare Materials

Open the package and carefully remove one COVID-19 Test Card in its pouch, one pre-filled tube with solution, and one swab. Keep the remaining test kit components sealed for later use.

4.2. Prepare the Solution Tube

Tap the pre-filled tube vertically on a table to ensure all liquid is at the bottom. Twist the large orange cap to open the tube. Confirm the liquid level is at or above Edge 2 as indicated on the tube. If the liquid level is below Edge 2, do not proceed with the test as this may result in false or invalid results.

5. OPERATING INSTRUCTIONS

5.1. Collect Nasal Sample

Remove the swab from its package, being careful not to touch the tip of the swab. Keep the swab package for later use.

Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril. Do not go deeper than 3/4 of an inch. For children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need a second person to hold the child's head while swabbing.

Firmly and slowly brush against the insides of the nostril in a circular motion against the nasal wall at least 5 times. Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the swab. Using the same swab, repeat the same sample collection procedure for the other nostril. Be sure to brush BOTH nostrils with the SAME SWAB.

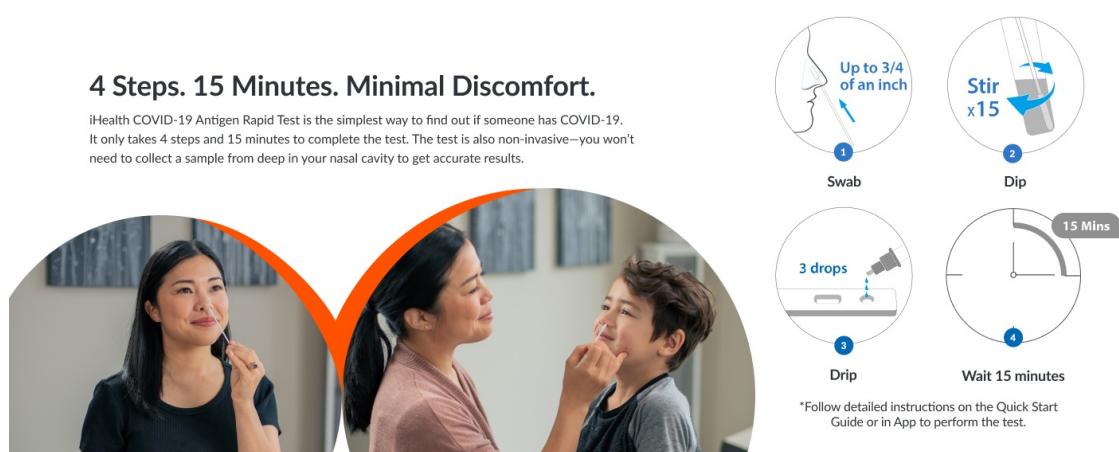


Image: Visual guide illustrating the four simple steps for using the iHealth COVID-19 test: Swabbing the nostril, dipping the swab into the solution, dripping the solution onto the test card, and waiting 15 minutes for results.

5.2. Process Sample

Insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab. If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly, potentially resulting in a false negative result.

Screw back the large orange cap, put the swab back into the package. Safely dispose of the swab and the package.

5.3. Add Sample to Test Card

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. A false negative or invalid result may occur if too little solution is added to the test card.

6. INTERPRETING RESULTS

Wait 15 minutes. Read the result at 15 minutes. Do not read the result before 15 minutes or after 30 minutes. 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. Results should not be read after 30 minutes (Result shown at 2x magnification). A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

6.1. Positive Result

A positive result must show BOTH a C line and a T line. A positive result means that viral antigens from COVID-19 were detected and the individual is positive for COVID-19. Note that the T line can be extremely faint. 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.

6.2. Negative Result

A negative result will show ONLY a C line. A negative result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19. Please note that negative results do not rule out COVID-19. In case of negative test result, continue to follow all social distancing recommendations and take protective measures. If suspicions of infection persist and/or your first test is negative, repeat the test after 1-2 days and consult your healthcare provider or local COVID-19 center.

6.3. Invalid Result

If there is NO LINE, or if there is ONLY a T line, the test is INVALID. An invalid result means that the test did not function correctly. You will need to retest with a new test kit. If upon retesting, the test result is still invalid, contact your doctor or local COVID-19 center. An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.

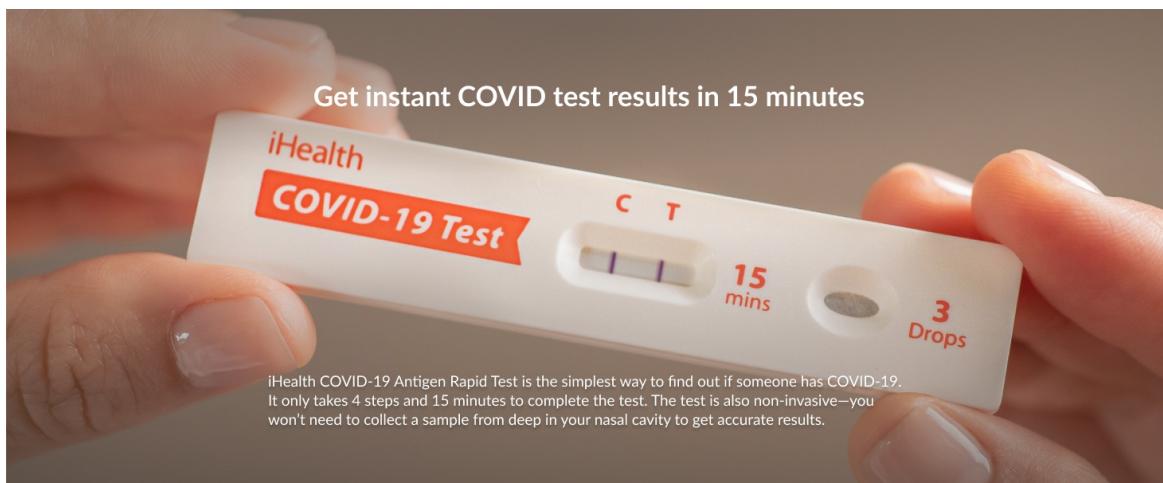


Image: A close-up of the iHealth COVID-19 Test card displaying a positive result (two lines) after 15 minutes, indicating the presence of viral antigens.

7. DISPOSAL

After the test is completed, dispose of all kit components in the trash according to local regulations.

8. REPORTING TEST RESULTS

Report the result following the App instructions or share your test result with your healthcare provider. The iHealth Test app (optional) can be used to guide you through the testing process and report results.

An in-home test designed to get results in 15 min.

Not only is the iHealth COVID-19 Antigen Rapid Test easy and non-invasive, it's a small engineering beauty. The test has a highly-absorbent swab that is individually sealed to help prevent contamination so you can view the results of your in-home test with confidence.



Highly Absorbent Swab

Made of PU foam, the absorbent tip of the swab makes sample collection more efficient than a regular swab.



Double-Cap Security Design

The double-cap design allows you to safely store the liquid and then precisely drip the mixed sample to the test card.



Easy-to-understand Results

The unique test card shortens the time to get your results and makes the results easy to read. If only the C line shows up, the test is negative. If both C and T lines show up, the test is positive.

Image: Screenshots from the iHealth Test app demonstrating features for group management, iHealth Pass generation for digital proof of negative results, and vaccination record storage.

9. SPECIFICATIONS

- Model Number:** ICO-3000
- Product Dimensions:** 3.46 x 0.71 x 0.16 inches
- Item Weight:** 0.1 ounces
- Manufacturer:** iHealth
- Date First Available:** November 4, 2021

10. WARRANTY AND SUPPORT

- Limited Warranty:** This product comes with a 1-year limited warranty.
- Customer Support:** US-based customer support is available for assistance. Refer to the product packaging or official iHealth website for contact details.