Please confirm the liquid level with or above Edge 2, then go to Step 2 Collect Sample.

**Collect Sample**

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

2. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your mouth.

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.

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

5. Wait 15 Minutes
   - Start the timer by clicking the “Start Time” button on the app, 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 Test Time may take as long as 15 minutes to appear.

6. Read Result
   - Results should not be read after 30 minutes (Result shown as 2x magnification)
   - Note: A false negative or positive result may occur if the test result is read before 15 minutes or after 30 minutes.

7. Test Result Explanation
   - Positive Result
     - A positive result means that viral antigens from SARS-CoV-2 were detected and the individual is positive for COVID-19.
   - Negative Result
     - A negative result means that viral antigens from SARS-CoV-2 were not detected and the individual is presumed negative for COVID-19.

**Invalid Result**

If there is no LINES, 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. Upon retouching, 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.

8. Dispose of the Test Kit
   - After test is complete, 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:**
- The test is limited to be used by or at the direction of a healthcare professional for the in vitro diagnostic use to detect viral antigens from SARS-CoV-2 in whole blood,uffy coat, plasma, and serum.
- The test is limited to be used by or at the direction of a healthcare professional for the in vitro diagnostic use to detect viral antigens from SARS-CoV-2 in whole blood,uffy coat, plasma, and serum.
- Before use, carefully read the accompanying Instruction for Use and the WARNINGS/ PRECAUTIONS information before use. Read the information before use. The test is intended to be used as an aid to help healthcare providers diagnose SARS-CoV-2 infection. The test is not a substitute for other clinical considerations and does not affect the need for seeking medical advice.
- The test is not intended for use as a rapid test for COVID-19.
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COVID-19 Antigen Rapid Test Instructions for Use

Model: ICD-1001/ ICD-1001/ ICD-1001

INTENDED USE

The Health® COVID-19 Antigen Rapid Test is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2.

This test is for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 18 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset. This test is also authorized for non-prescription home use with adult-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.

This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older, or adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (no more than 48 hours) between tests.

The Health® COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

RESULTS

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary. If there is a high clinical probability of COVID-19 in an individual with a close contact with COVID-19 with no suspected 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 high likelihood of SARS-CoV-2 infection, such as with individuals known exposure to SARS-CoV-2 or residing in communities with high prevalence of infection.

Individuals who test negative and continue to experience COVID-19-like symptoms of fever, cough 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 for public health reporting or by following the mobile application instructions for self-reporting. This product detects SARS-CoV-2 and does not report other viral or bacterial infections.

The Health® COVID-19 Antigen Rapid Test is not for use by the general public, including but not limited to patients treated in a facility, unless under the direct supervision of a licensed healthcare professional.

The Health® COVID-19 Antigen Rapid Test is not for use under the Food and Drug Administration Emergency Use Authorization.

FREQUENTLY ASKED QUESTIONS

Will this test hurt? No. No pain, no pricking. There should not be any discomfort.

Can I test my child? Yes. SARS-CoV-2 does not affect children. However, children should be monitored for symptoms. As with all testing, parents should supervise and assist when necessary.

What is the known and potential risks and benefits of this test? This test has not been evaluated by the U.S. Food and Drug Administration (FDA). As with all testing, there are potential risks and benefits:

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results.

Potential benefits include:

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

What is serial testing? Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may be necessary. Serial testing is more reliable than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. It is important that you work with your healthcare provider to help you understand the next steps you should take. Serial testing may be testing every day or every other day. If you are more symptomatic, you should test daily until you have no symptoms for three days, with at least 24 hours between tests. You may need to purchase additional tests to perform serial testing.

What is the difference between an antigen and molecular test? An antigen test, such as the Health® COVID-19 Antigen Rapid Test, detects proteins from the virus. Molecular tests, such as the PCR test, detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. Your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with hospital-based molecular tests. This means there is a higher chance this test will give you a negative result when you have COVID-19.

How accurate is this test? The Health® COVID-19 Antigen Rapid Test was compared to a laboratory-confirmed molecular test using self-collected nasopharyngeal swabs and found to have a sensitivity of 92% and a specificity of 99.7%.

WAVINGS AND PRECAUTIONS

Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours between tests. If you have symptoms of COVID-19 or have a positive result on a previous test, you may need to purchase additional tests to perform serial testing.

Testing at home is important for those who are asymptomatic and cannot easily access care. However, this test is not intended for use in high-risk settings such as schools, nursing homes, or other congregate care facilities.

This test is intended for use by individuals who are asymptomatic for COVID-19 and do not have symptoms of COVID-19.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

This test is intended for diagnosis of coronavirus infection by detecting COVID-19 antigen but should not be used as a sole criterion for the determination of infection.

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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

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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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.
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

iHealth®

FDA Emergency Use Authorization

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Manufactured for iHealth Labs, Inc. Made in China
Model: ICO-3000
ICO-3001
ICO-3002
120 San Lucas Ct., Sunnyvale, CA 94086, USA
1-855-816-7705 www.ihealthlabs.com

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