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

Please use with in-vitro read out specimens for in-vitro diagnostic (IVD) use only.

**COVID-19**

**Antigen Rapid Test**

**Instruction for use**

**Model:** COV-0002

1. **Prepare Materials**
   - You have Test Kit (10Test Set 12/pk) in the package. Please follow proper steps based on the specific set you received.

2. **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.
   - Please make sure there are two Edges on the empty tube. Then squeeze the sealed solution completely into the empty tube.
   - Please confirm the liquid level with or above Edge 2, then go to **Step 2 Collect Sample.**

3. **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 (up to 1/2 to 3/4 of an inch) into your nasal cavity. (See diagram).
   - c. Firmly and slowly brush against sides of nostril in a circular motion around the nasal walls for 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**.
   - 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**
   - 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.

5. **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 in to express as much liquid as possible from the swab, and then remove the swab.

6. **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.

7. **Read Result**
   - Results should not be read after 30 minutes (Result shown in 2x magnification).
   - A negative result may occur if the test result is read before 15 minutes or after 30 minutes.

8. **Negative Result**
   - **Note:** Do not interpret your test result until after your 15-min timer has completed, as the Time line may take as long as 15 minutes to appear.

9. **Disposal of the Test Kit**
   - After test is complete, dispose the kit components in trash.

10. **Report Test Result**
    - Report the result following the app instructions or share your test result with your healthcare provider.

   **In the USA:**
   - [FDA](https://www.fda.gov/)
   - [IOM](https://www.iom.edu/)
   - [IVD](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=21.308(b)(3))
COVID-19 Antigen Rapid Test Instructions for Use

Model: ICD-1001U / ICD-1001 / ICD-1002

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 not intended for diagnosis of SARS-CoV-2 infection in symptomatic individuals.

For In vitro Diagnostic (IVD) Use Only.

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 a medical setting, use a molecular test. 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 in a medical setting, use a molecular test.

WHEN TO USE THE TEST

The Health® COVID-19 Antigen Rapid Test is a rapid test for the diagnosis of COVID-19 including asymptomatic individuals. The test is intended to be used at the point of care, in healthcare settings, and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.

TEST PERFORMANCE

The Health® COVID-19 Antigen Rapid Test is a rapid test for the diagnosis of COVID-19 including asymptomatic individuals. The test is intended to be used at the point of care, in healthcare settings, and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.

TEST RESULTS

A positive result indicates an active infection with SARS-CoV-2. A negative result indicates no active infection with SARS-CoV-2.

TEST USE

The Health® COVID-19 Antigen Rapid Test is intended for use in healthcare settings and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.

TEST INSTRUCTIONS

1. Read the product label before testing.
2. Read the entire test kit and test instructions before testing.
3. Follow all instructions and use test only as described.

TESTING TIME

The Health® COVID-19 Antigen Rapid Test is a rapid test for the diagnosis of COVID-19 including asymptomatic individuals. The test is intended to be used at the point of care, in healthcare settings, and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.

TEST POSITION

The Health® COVID-19 Antigen Rapid Test is a rapid test for the diagnosis of COVID-19 including asymptomatic individuals. The test is intended to be used at the point of care, in healthcare settings, and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.

TEST STORAGE

The Health® COVID-19 Antigen Rapid Test is a rapid test for the diagnosis of COVID-19 including asymptomatic individuals. The test is intended to be used at the point of care, in healthcare settings, and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.

TEST DISPOSAL

The Health® COVID-19 Antigen Rapid Test is a rapid test for the diagnosis of COVID-19 including asymptomatic individuals. The test is intended to be used at the point of care, in healthcare settings, and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.

TEST RESULTS

A positive result indicates an active infection with SARS-CoV-2. A negative result indicates no active infection with SARS-CoV-2.

TESTING TIME

The Health® COVID-19 Antigen Rapid Test is a rapid test for the diagnosis of COVID-19 including asymptomatic individuals. The test is intended to be used at the point of care, in healthcare settings, and by healthcare providers in the community. The test is not intended to be used in the laboratory. The test is not intended to be used in research. The test is not intended to be used in the diagnosis of SARS-CoV-2 infection in symptomatic individuals.
iHealth COVID-19 Antigen Rapid 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

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.