iHealth® COVID-19 Antigen Rapid Test Pro

Instructions for Use

Model: ICO-3000P

For use with anterior nasal swab specimens

For prescription use only

For In Vitro Diagnostic (IVD) use only

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

INTENDED USE

The iHealth® COVID-19 Antigen Rapid Test Pro is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours and no more than 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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 an individual with a close contact with COVID-19 and/or with 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 low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

The iHealth® COVID-19 Antigen Rapid Test Pro is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings.

The iHealth® COVID-19 Antigen Rapid Test Pro is only for use under the Food and Drug Administration's Emergency Use Authorization.

PRODUCT DESCRIPTION

The iHealth® COVID-19 Antigen Rapid Test Pro requires the following elements for operation.

REAGENTS AND MATERIALS

Materials Provided in the iHealth COVID-19 Antigen Rapid Test Pro kit:

- COVID-19 Test Cards - (40/kit)
- Extraction Reagent Tube (Tube) - (40/kit)
- Nasal Swabs - (40/kit)
- Positive Control Swab (Prepared using non-infectious recombinant SARS-CoV-2 nucleocapsid antigen) - (1/kit)

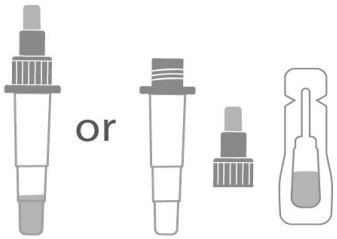
- Negative Control Swab (Blank Swab) - (1/kit)

  Note: Additional iHealth COVID-19 Antigen Rapid Test Pro External Control Swab kits (Cat. No. CS-ICO) are available for purchase if needed. Contact iHealth Customer Care for further information (1-855-816-7705, Monday – Friday 8:30AM – 5:30PM PST).

- Quick Reference Instructions - (1/kit)

iHealth® COVID-19 Antigen Rapid Test Pro Kit Components

COVID-19 Test Card(s)



Tube(s) pre-filled or empty Tube(s) with sealed Solution(s)

Swab(s)

Materials required but not provided in the kit:

- Smartphone (iOS 12 or above, Android 6.0 or above)
- User has the option of downloading the iHealth COVID-19 Test Pro App for iOS or Android phones. The App provides step-by-step instructions regarding how to complete

the test. Alternatively, the test can be performed by following the step-by-step instructions included this Instructions for Use Package Insert below.

- Pair of gloves
- Timer
- Biohazard or sharps container

PRINCIPLE OF THE PROCEDURES

The iHealth® COVID-19 Antigen Rapid Test Pro employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV-2.

To begin the test, an anterior nasal swab sample collected by a health provider or trained operator is inserted into the Extraction Reagent Tube. The liquid in the tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The liquid in the tube now containing the specimen is added to the Sample Port of the COVID-19 Test Card.

If the extracted specimen contains SARS-CoV-2 antigens, a pink-to-purple T Line, along with a pink-to-purple C Line will appear on the COVID-19 Test Card indicating a positive result. If SARS-CoV-2 antigens are not present, or present at very low levels, only a pink-to-purple C Line will appear.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- 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.

- Do not use the iHealth® COVID-19 Antigen Rapid Test Pro test or any kit components after its expiration date printed on the outer packaging, which is 6 months from the date the kit was manufactured.
- Laboratories within the United States and its territories are required to report results to the appropriate public health authorities.
- 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 as an aid in the diagnosis of COVID-19 by detecting viral antigens but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.
- Read the complete iHealth® COVID-19 Antigen Rapid Test Pro Kit Instructions for Use (IFU) before starting the test procedure. The iHealth® COVID-19 Antigen Rapid Test Pro must be performed as indicated in the IFU to obtain accurate results.
- When collecting an anterior nasal swab sample, use only the nasal swab supplied in the test kit.
- Wear appropriate personal protective equipment when performing sample collection and sample testing.
- Do not use the COVID-19 Test Card if the pouch is damaged or if the seal is broken. Once the COVID-19 Test Card is removed from the pouch, perform the test as soon as possible, but no more than one hour after opening the pouch.
- Do not use any of the test components with visible damage.
- Only use the test components provided in a single test kit. Do not mix components from different test kits.
- Do not reuse any test components.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products may result in an incorrect test result.
- The extraction reagent contains ProClin® 300 which may cause skin and eye irritation. If the solution makes contact with the skin or eye, wash/flush with copious amounts of water.

If skin irritation or rash occurs get medical advice/attention.

- Do not touch the tip of the swab before and after collecting the sample from the nostrils.
- If specimen storage is necessary, swabs can be extracted into extraction buffer. The extracted sample in buffer can be stored for up to 2 hours, if kept at room temperature. Alternatively, swab samples can be stored up to 4 hours after sample collection, at room temperature.
- If utilizing the iHealth® COVID-19 Test Pro App, do not exit the App during the testing process.
- Dispose of used components as biohazardous wastes in accordance with federal, state, and local requirements.

LIMITATIONS

- The test detects both viable and nonviable SARS-CoV-2 viral antigens and may yield a positive result in the absence of living microorganisms.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test.
- False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (>10mg per day). Biotin levels above 1μg/mL have been demonstrated to result in false negative test results. However, it is unknown if the concentration of biotin in respiratory specimens may result in false negative results.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- Performance of anterior nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 or for serial screening, when tested twice over two to three days with at least 24 but not more than 48 hours between tests has not yet been determined; a study to support use will be completed.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- The performance of the iHealth® COVID-19 Antigen Rapid Test Pro was established based on the evaluation of a limited number of clinical specimens collected in Provo, Utah, between July and August 2021. The clinical performance has not been established in all

circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Cross-reactivity with respiratory tract organisms other than those tested in the Analytical Specificity study may lead to erroneous results.
- False negative results may occur if a specimen is improperly collected or handled.
- Invalid results may occur if less than the allotted amount of extraction buffer in the Tube is used. If extraction buffer in the Tube is spilled, discard the Tube and use a new extraction reagent Tube.
- False negative results may occur if the specimen swab is not stirred at least 10X in the extraction reagent tube.
- False negative results may occur if swabs are stored in their paper sheath after specimen collection.
- False negative results may occur if the test result is read before the 15 minutes or after the 30 minutes.
- Positive and negative predictive values are dependent on COVID-19 prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low activity when prevalence is moderate to low.
- The iHealth® COVID-19 Antigen Rapid Test Pro does not differentiate between SARS-CoV and SARS-CoV-2.
- The iHealth® COVID-19 Antigen Rapid Test Pro has been evaluated using only human anterior nasal specimens.

Hazardous Ingredients for Reagent Solution

The Extraction Reagent contains potentially harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: visit https://www.poison.org/contact-us or 1-800-222-1222.

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Triton X-100/9002-93-1	Harmful if swallowed (H302) Cause skin irritation(H315) Causes serious eye damage(H318)	0.1%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%

STORAGE CONDITIONS

Store iHealth® COVID-19 Antigen Rapid Test Pro in a dry location between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. The COVID-19 Test Card inside the foil pouch should be used within 1 hour after opening. Do not use the COVID-19 Test Card after the expiration date marked on the packaging.

QUALITY CONTROL

Internal Quality Control:

A procedural internal control is built in the control “C Line” of the device and is used to ensure that the applied specimen sample has migrated well into the device. It is coated with goat anti-rabbit IgG; a pink-to-purple C Line should appear after the specimen sample is added.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. iHealth® COVID-19 Antigen Rapid Test Pro contains a Positive Control Swab and a Negative Control Swab. These external control swabs serve to monitor the entire assay. External Positive and Negative Control Swabs should be tested once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab’s standard Quality Control

procedures. If the correct external control swab test results are not obtained, do not perform testing of patient samples or report patient sample test results and contact iHealth Labs Inc. support at https://ihealthlabs.com/pages/contact-us .

TEST PROCEDURE

Optional Use of the iHealth COVID-19 Test Pro App:

Download App: Scan the QR code below to download the iHealth COVID-19 Test Pro App through your smartphone (iOS12.0+, Android 6.0+).

For a full list of compatible smartphone visit: **https://ihealthlabs.com/pages/support-ICO3000P**

Register and Log Into The App

Watch Video in App: Each procedural step has a corresponding video instruction. Watch the video and perform the test according to the instructions.

Alternatively, testing can be done by following the step-by-step Testing Instructions below.

Testing 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.

Test Set 1: Open the kit, take out the COVID-19 Test Card in pouch, the Tube pre-filled with the extraction buffer and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.

1 COVID-19 Test Card in Pouch

1 Pre Filled Tube

1 Swab

Please go directly to **Step 2 Collect Sample.**

Test Set 2: Open the kit, 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.

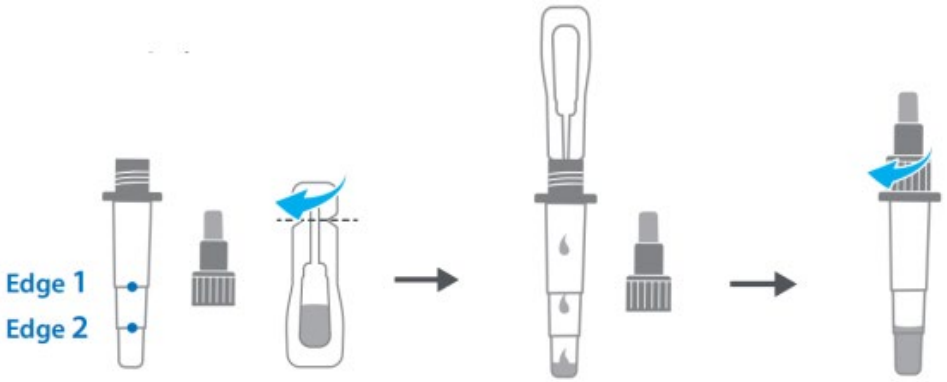
1 COVID-19 Test Card in Pouch

1 Empty Tube and 1 Sealed Solution

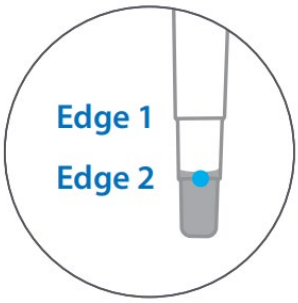
1 Swab

Please look carefully, there are **two Edges** on the empty tube. Then squeeze the sealed

solution completely into the empty tube.



Please confirm that the liquid level is at or above Edge 2, then go to **Step 2 Collect Sample**.

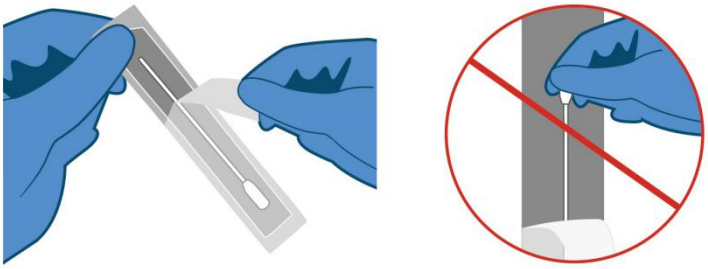


Note:

It is acceptable if the liquid level is above Edge 2. However, please do not proceed with this test, if the liquid level is significantly below Edge 2, as this may result in false or invalid results.

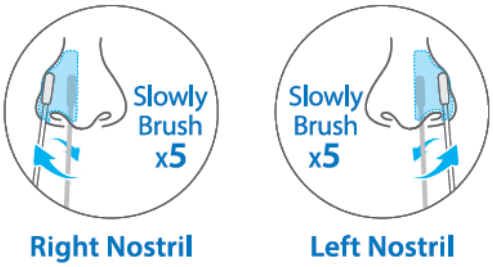
2) Collect Sample

1. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use for the disposal of the used swab.



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

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

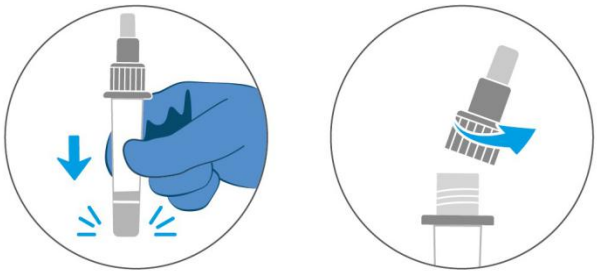


Note: Failure to swab both nostrils properly may cause false negative results.

Note: Swab samples should be tested within 4 hours after sample collection, if kept at room temperature. Alternatively, for swabs that been extracted into the buffer, the extracted sample should be tested within 2 hours, if kept at room temperature.

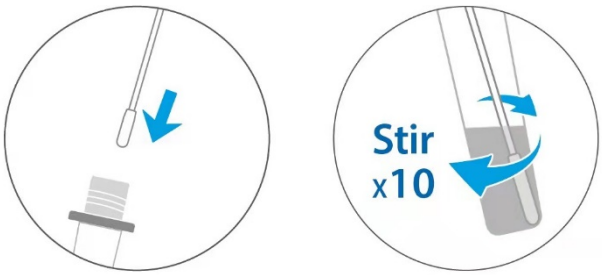
3) Process Sample

1. Tap the Tube vertically on the table, twist the large orange cap to open the Tube.



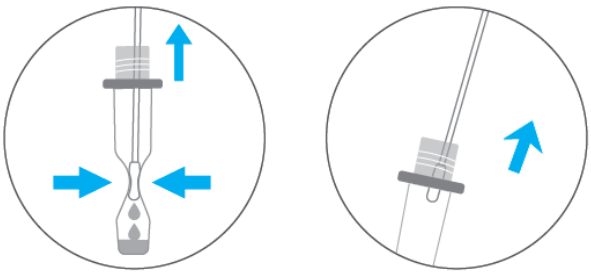
Note: Invalid results may occur if less than the allotted amount of extraction buffer in the Tube is used. If extraction buffer in the Tube is spilled, discard the Tube and use a new extraction reagent Tube.

2. Insert the swab into the Tube, touch the bottom of the Tube with the swab tip, and stir 10 times.



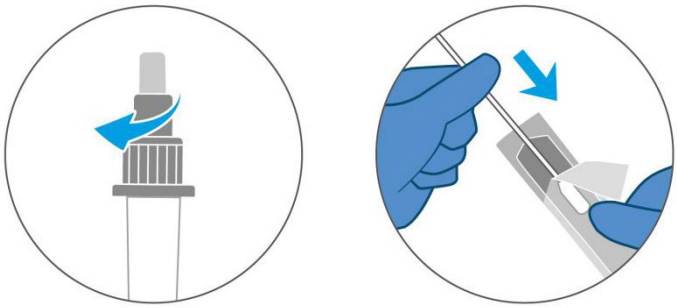
Note: Failure to stir 10X could result in a false negative result.

3. Squeeze the sides of the Tube to express as much liquid as possible from the swab, and remove the swab.



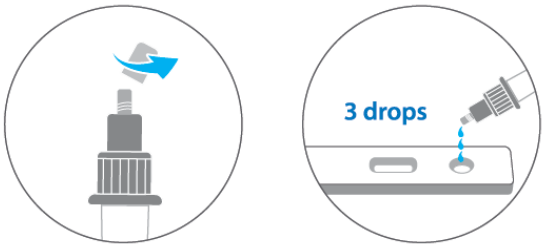
Note: If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

4. Replace the large orange cap onto the Tube and twist it to close. Put the swab back into the package. Safely dispose of the swab and the package in biohazardous waste.



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. Replace the small white cap, and twist it into place.



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

5) Wait 15 minutes

Start timing immediately after adding the sample to the Sample Port. The result will be ready in 15-30 minutes.

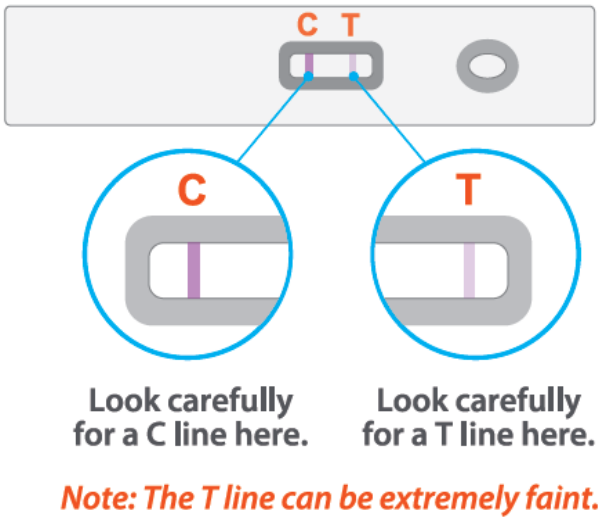
Note: Do NOT interpret the result until after your 15-minute timer has completed, because the T Line may take as long as 15 minutes to appear.

Note: False results may occur if the test is read before 15 minutes or after 30 minutes.

6) Read Result

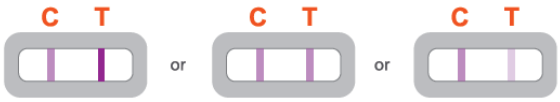
Results should not be read after 30 minutes.

Results shown below at 2x.



7) Test Result Explanation

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.

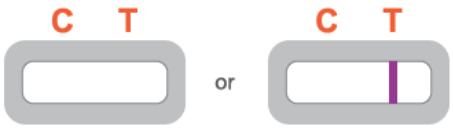
Below are photos of actual positive tests. **Please note that the T Line may be faint.**

Negative Result

A **NEGATIVE** result will show ONLY a C Line. A negative result means viral antigens from COVID-19 were not detected.

- **Please note that negative results do not rule out COVID-19.**
- **A negative result is presumptive and confirmation with a molecular assay, if 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 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 or residing in communities with low prevalence of infection**

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. A retest using a new test should be conducted.

8) Dispose of the Test Kit

After the test is completed, dispose of all kit components in biohazardous waste.

9) Report Test Result

Report the test results to the appropriate healthcare providers and relevant public health authorities, in accordance with the standard procedures of your institution.

Test Instructions for iHealth COVID-19 Antigen Rapid Test Pro External Control Swab

The external positive control swab should result in a positive iHealth COVID-19 Antigen Rapid Test Pro test result. Similarly, the external negative control swab should result in a negative iHealth COVID-19 Antigen Rapid Test Pro test result. All test control result should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

1. Open the iHealth COVID-19 Antigen Rapid Test Pro Test Card just prior to use, lay it on flat surface, and perform assay as follows.
2. Remove the External Positive Control swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for swab disposal after use.
3. Follow Step 3 (*Process Sample*) through Step 8 (*Dispose of the Test Kit*) of the ***Test Instructions*** above.
4. Remove the External Negative Control swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for swab disposal after use.
5. Follow Step 3 (*Process Sample*) through Step 8 (*Dispose of the Test Kit*) of the ***Test Instructions*** above.
6. If the expected external control swab results are not achieved, conduct repeat testing

with new external control swabs and a new test card. If repeat testing is still inconsistent with expected results, contact iHealth Labs Inc. support at https://ihealthlabs.com/pages/contact-us

CONDITIONS OF AUTNORIZATION FOR LABORATORIES

The iHealth® COVID-19 Antigen Rapid Test Pro Test Letter of Authorization,[1] along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling will be available on the FDA website post authorization: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist clinical laboratories in using the iHealth® COVID-19 Antigen Rapid Test Pro, the relevant Conditions of Intended Authorization are listed below:

A. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

B. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov), and you (via frr.covid19@ihealthlabs.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

You, authorized distributor(s), and authorized laboratories using your product must

ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets the requirements to perform high, moderate, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation." as "authorized laboratories."

CLINICAL PERFORMANCE

Clinical performance characteristics of iHealth® COVID-19 Antigen Rapid Test Pro were evaluated Provo, Utah, between July and August 2021. iHealth® COVID-19 Antigen Rapid Test Pro testing was performed by seven operators with no laboratory experience, at a CLIA waived testing site, consistent with the intended users of the device. To be enrolled in the study, subjects had to present at the participating study center with suspected COVID-19. Subjects who presented within 7 days of symptom onset were included in the initial primary analysis. Study subjects ranged in age from 6 to 74 years of age. Two anterior nasal swab (ANS) samples were collected from each subject. One swab was used for testing using the iHealth® COVID-19 Antigen Rapid Test Pro at the study site. The other swab was placed in viral transport media, frozen at -70℃, and transported to an independent laboratory for testing using a highly sensitive FDA EUA-authorized SARS-CoV-2 RT-PCR assay.

A total of 64 subjects with signs and symptoms of COVID-19 were enrolled in the study and yielded a valid result. The iHealth COVID-19 Antigen Rapid Test Pro correctly identified 88.2% (30/34) of the positive ANS samples and correctly identified 100% (30/30) of negative ANS samples. The performance is shown in the following tables.

iHealth® COVID-19 Antigen Rapid Test Pro	**Comparator Method**		
	Positive	**Negative**	**Total**
Positive	**30**	**0**	**30**
Negative	**4†**	**30**	**34**
Total	**34**	**30**	**64**
Positive Agreement (PPA): 30/34 88.2% （95%CI: 73.4% - 95.3%）			
Negative Agreement (NPA): 30/30 100% （95%CI: 88.6% - 100%）			

[†]All 4 false negative ANS samples, yielded a positive result when further testing, using a second FDA EUA-authorized RT-PCR assay was employed.

Study Subjects Stratified by Age Group

Age Group	Number of Subjects
<14 years of age	2
14-24 years of age	14
25-35 years of age	17
36-46 years of age	19
47-74 years of age	12
Total	64

Study Summary Results Stratified by Days from Symptom Onset

iHealth COVID-19 Antigen Rapid Test Pro Results						
Days from Symptom Onset	RT-PCR Positive		iHealth test Positive		%PPA 95% CI	
1	1		1		100% (1/1) 20.6 – 100%	
2	0		0		-	
3	6		6		100% (6/6) 60.9 – 100%	
4	6		6		100% (6/6) 60.9 -100%	
5	7		6		85.7% (6/7) 48.7 – 97.4%	

iHealth COVID-19 Antigen Rapid Test Pro Results						
Days from Symptom Onset	**RT-PCR Positive**		**iHealth test Positive**		**%PPA 95% CI**	
6	**8**		**6**		**75.0% (6/8) 40.9 – 92.9%**	
7	**6**		**5**	**1**	**83.3% (5/6) 43.6 – 97.0%**	
Total	**34**		**30**	**30**	**88.2% (30/34) 73.4 - 95.3%**	

* All ANS samples were confirmed by a highly sensitive FDA EUA-authorized SARS-CoV-2 RT-PCR test.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

Limit of Detection (LoD)

The LoD of iHealth® COVID-19 Antigen Rapid Test Pro was established by using limiting dilutions of heat inactivated SARS-CoV-2 virus (USA-WA1/2020) sample. The strain was spiked into clinical matrix prepared by mixing raw nasal fluid in saline and confirmed again as SARS-CoV-2 negative by RT-PCR.

The estimated LoD found from the initial 4 different concentrations test by testing 5 replicates. At each dilution, samples were added to swabs and then tested through the full assay workflow, from processing in the extraction reagent to read test result.

A concentration was chosen between the last dilution to give five positive results and the first to give five negative results. Using this concentration, the LoD was further refined with a 2-fold dilution series. The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time (concentration at which at least 19 out of 20 replicates tested positive).

The iHealth® COVID-19 Antigen Rapid Test Pro LOD in natural nasal swab matrix is 20×10^3 $TCID_{50}$/mL.

Analytical Specificity

Cross Reactivity and Microbial Interference

The potential cross-reactivity (exclusivity) of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using the iHealth® COVID-19 Antigen Rapid Test Pro. Potential microbial interference was evaluated with samples containing heat inactivated SARS-CoV-2 virus(USA-WA1/2020) sample at approximately 3 x LoD.

A total of 36 commensal and pathogenic microorganisms (10 bacteria, 1 yeast, and 25 viruses) that may be present in the nasal cavity, and pooled human nasal wash, were evaluated in this study. Each of the organism and viruses were tested in five replicates in the absence or presence of heat inactivated SARS-CoV-2 virus.

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below.

Organism		Concentration		Cross-reactivity	Microbial Interference
Other high priority pathogens from the same genetic family	Human coronavirus 229E	3.74×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus OC43	2.51×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus NL63	1.36×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	MERS-coronavirus	1.36×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
High priority organisms likely in the circulating area	Adenovirus Type 1	2.04×10^7	$TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 4	2.09×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 7A	2.04×10^7	$TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 8	1.13×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 31	1.13×10^5	U/mL	No cross-reactivity	No interference
	Adenovirus Type 41	9.36×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Human Metapneumovirus 3(hMPV-3) Type B1	3.11×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Human Metapneumovirus 4(hMPV-4) Type B2	5.25×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference

	Human Metapneumovirus 9(hMPV-9) Type A1	9.36×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 1	6.30×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 2	7.55×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 3	2.29×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4A	4.50×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4B	1.36×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Influenza A H3N2 Virus	1.13×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Influenza B Virus	3.74×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Enterovirus Type 68	7.55×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
	Enterovirus Type 71	2.29×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type A (RSV-A)	1.90×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type B (RSV-B)	3.74×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Rhinovirus Type 1A	9.36×10^4	$TCID_{50}$/mL	No cross-reactivity	No interference
	Haemophilus influenzae	6.75×10^8	CFU/mL	No cross-reactivity	No interference
	Streptococcus pneumoniae	1.80×10^8	CFU/mL	No cross-reactivity	No interference
	Streptococcus pyogenes	2.04×10^9	CFU/mL	No cross-reactivity	No interference
	Candida albicans	3.15×10^8	CFU/mL	No cross-reactivity	No interference
	Pooled human nasal wash – representative of normal respiratory microbial flora	-		No cross-reactivity	No interference
	Bordetella pertussis	3.22×10^9	CFU/mL	No cross-reactivity	No interference
	Mycoplasma pneumoniae	1.35×10^8	CFU/mL	No cross-reactivity	No interference
	Chlamydia pneumoniae	8.65×10^7	IFU/mL	No cross-reactivity	No interference
	Legionella pneumophila	7.10×10^9	CFU/mL	No cross-reactivity	No interference
	Staphylococcus aureus	3.23×10^9	CFU/mL	No cross-reactivity	No interference

	Staphylococcus epidermidis	1.24×10^9	CFU/mL	No cross-reactivity	No interference
	Mycobacterium tuberculosis	1.15×10^8	CFU/mL	No cross-reactivity	No interference

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for Human Coronavirus HKU1, SARS-CoV-1, *Mycobacterium tuberculosis* and *Pneumocystis jirovecii*.

- Human Coronavirus HKU1 showed 36.74% homology across 82% of the nucleocapsid sequence, which is relatively low. However, cross-reactivity cannot be ruled out.
- SARS-CoV-1 showed 90.52% homology across 100% of the nucleocapsid sequence and therefore cross-reactivity is likely.
- *Pneumocystis jirovecii* shows no protein sequence homology with nucleocapsid sequen ce. However, cross-reactivity cannot be ruled out.
- *Mycobacterium tuberculosis* showed no protein sequence homology with nucleocapsid sequence.

Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the iHealth® COVID-19 Antigen Rapid Test Pro.

The SARS-CoV-2 analyte concentration in the positive samples was approximately 3 x LoD. All samples tested in 5 replicates produced expected results, demonstrating that the iHealth® COVID-19 Antigen Rapid Test Pro performance was not affected by any of the 26 potentially interfering substances listed in the table below at the concentrations tested.

Substance	Concentration	Cross-reactivity	Interference
Whole Blood	4%	No cross-reactivity	No interference
Mucin	0.5%	No cross-reactivity	No interference
Chloraseptic (Menthol)	1.5 mg/mL	No cross-reactivity	No interference
Chloraseptic (Benzocaine)	1.5 mg/mL	No cross-reactivity	No interference
Naso GEL (NeilMed)	5% v/v	No cross-reactivity	No interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No cross-reactivity	No interference
Afrin (Oxymetazoline)	15% v/v	No cross-reactivity	No interference

CVS Nasal Spray (Cromolyn)	15% v/v	No cross-reactivity	No interference
Zicam	5% v/v	No cross-reactivity	No interference
Homeopathic (Alkalol)	1:10 dilution	No cross-reactivity	No interference
Sore Throat Phenol Spray	15% v/v	No cross-reactivity	No interference
Tobramycin	4 μg/mL	No cross-reactivity	No interference
Mupirocin	10 mg/mL	No cross-reactivity	No interference
Fluticasone Propionate	5% v/v	No cross-reactivity	No interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No cross-reactivity	No interference
Nasocort Allergy 24 hour (Triamcinolone)	15% v/v	No cross-reactivity	No interference
NeilMed SinuFlow Ready Rinse (Sodium Chloride, Sodium bicarbonate)	15% v/v	No cross-reactivity	No interference
NeilMed SinuFrin Plus (Oyxmetazoline HCl)	15% v/v	No cross-reactivity	No interference
Neo-Synephrine (Phenylephrine ,hydrochloride)	15% v/v	No cross-reactivity	No interference
Rhinocort (Budesonide /Glucocorticoid)	15% v/v	No cross-reactivity	No interference
Saline nasal spray (Saline)	15% v/v	No cross-reactivity	No interference
Zanamivir	282.0 ng/mL	No cross-reactivity	No interference
Biotin	1.0 μg/mL	No cross-reactivity	No interference
Laundry Detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% v/v	No cross-reactivity	No interference
Dish-washing Liquid (Sodium lauryl sulfate)	1% v/v	No cross-reactivity	No interference
Bleach (Sodium Hypochlorite)	1%v/v	No cross-reactivity	No interference

Hook Effect

No high dose hook effect was observed when tested with a concentration of 1.15x 10^7 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with the iHealth® COVID-19 Antigen Rapid Test Pro.

Flex Study

The robust use of iHealth® COVID-19 Antigen Rapid Test Pro was demonstrated by the following flex studies: delay in result reading, extraction liquid volume variability, swab mixing expression variability, temperature and humidity, impact of light sources, test device held at different orientation and disturbance during analysis.

CUSTOMER HELPLINE

If you have any questions about the iHealth® COVID-19 Antigen Rapid Test Pro or your test result, please contact our toll-free Customer Helpline on 1-855-816-7705.

SYMBOLS IN USE


Caution


Do not Reuse


Consult Instructions for Use

In Vitro Diagnostic Medical Device


Storage Temperature Limitation


Keep in a dry place

Keep away from direct sunlight

Do not use if package is damaged

Manufacturer

Manufactured for iHealth Labs, Inc.

120 San Lucar Ct , Sunnyvale, CA 94086, USA

1-855-816-7705 www.iHealthlabs.com

Made in China

Rev.01/2022

iHealth® COVID-19 Antigen Rapid Test Pro

QUICK REFERENCE INSTRUCTIONS

Model: ICO-3000P

For use with anterior nasal swab specimens

For prescription use only.

For In Vitro Diagnostic(IVD) use only

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

Please refer to the iHealth® COVID-19 Antigen Rapid Test Pro Instructions for Use for detailed assay instructions, cautions, limitations and warnings on the website: www.iHealthlabs.com.

You can request a free paper copy by contacting our Technical Support on policy@ihealthlabs.com.

Failure to follow the test procedure may result in erroneous results, or invalidate the test result.

You can follow the instructions in the 'iHealth COVID-19 Test Pro" App when performing the test.

TEST PROCEDURE

Optional Use of the iHealth COVID-19 Test Pro App:

Download App: Scan the QR code below to download the iHealth COVID-19 Test Pro App through your smartphone (iOS12.0+, Android 6.0+).

For a full list of compatible smartphone visit:
https://ihealthlabs.com/pages/support-ICO3000P

Register and Log Into The App

Watch Video in App: Each procedural step has a corresponding instructional video instruction. Watch the video and perform the test according to the instructions.

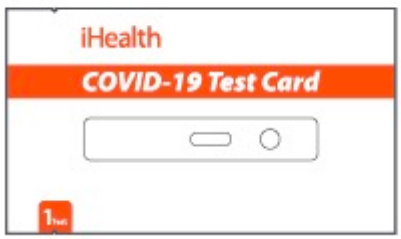
Alternatively, testing can be done by following the step-by-step Testing Instructions below.

Testing 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.

Test Set 1: Open the kit, take out the COVID-19 Test Card in pouch, the Tube filled with extraction buffer, and the Swab. When you are ready to proceed with testing, open the foil pouch and remove the COVID-19 Test Card.



1 COVID-19 Test Card in Pouch

1 Pre Filled Tube

1 Swab

Please go directly to **Step 2 Collect Sample.**

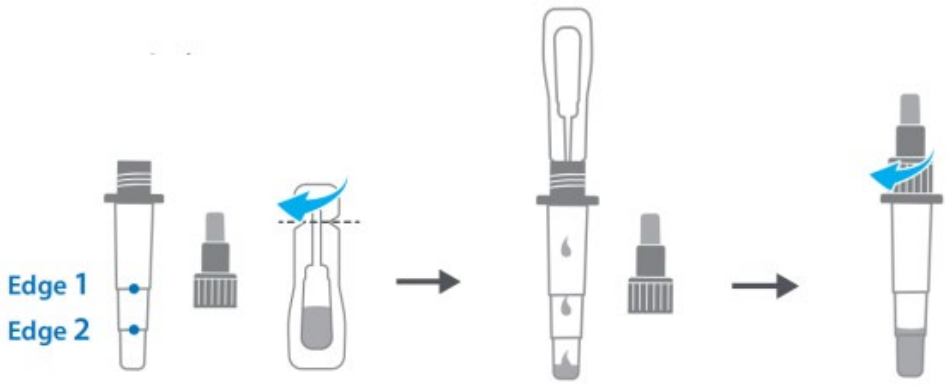
Test Set 2: Open the kit, take out the COVID-19 Test Card in Pouch, empty Tube, sealed Solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.

1 COVID-19 Test Card in Pouch

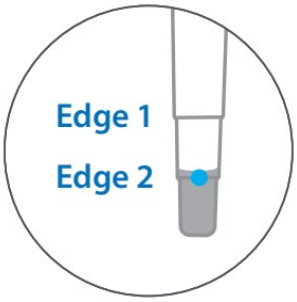
1 Empty Tube and 1 Sealed Solution

1 Swab

Please look carefully, there are **two Edges** on the empty tube. Then squeeze the sealed solution completely into the empty tube.



Please confirm that the liquid level is at or above Edge 2, then go to **Step 2 Collect Sample**.

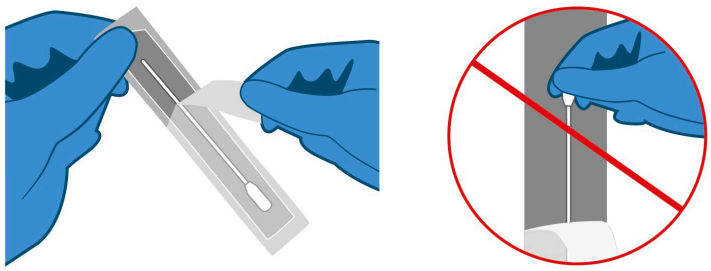


Note:

It is acceptable if the liquid level is above Edge 2. However, please do not proceed with this test, if the liquid level is significantly below Edge 2, as this may result in false or invalid results.

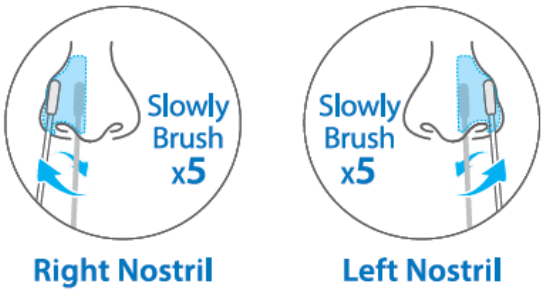
2) Collect Sample

1. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use for the disposal of the used swab.



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

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

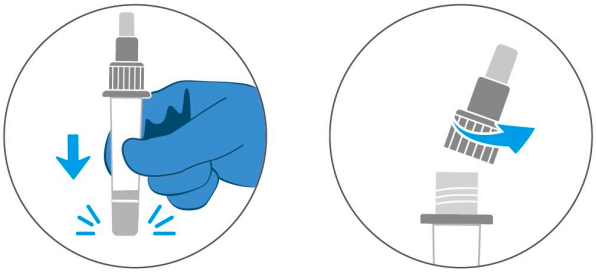


Note: Failure to swab both nostrils properly may cause false negative results.

Note: Swab samples should be tested within 4 hours after sample collection, if kept at room temperature. Alternatively, for swabs that been extracted into the buffer, the extracted sample should be tested within 2 hours, if kept at room temperature.

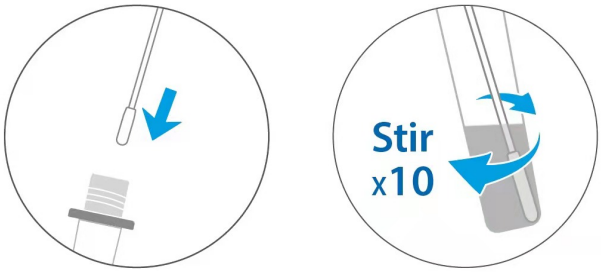
3) Process Sample

1. Tap the Tube vertically on the table, twist the large orange cap to open the Tube.



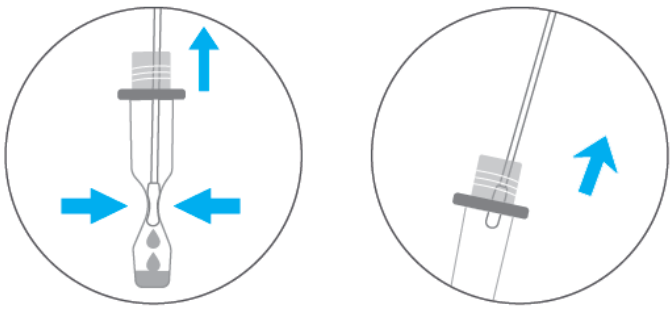
Note: Invalid results may occur if less than the allotted amount of extraction buffer in the Tube is used. If extraction buffer in the Tube is spilled, discard the Tube and use a new extraction reagent Tube.

2. Insert the swab into the Tube, touch the bottom of the Tube with the swab tip, and stir 10 times.



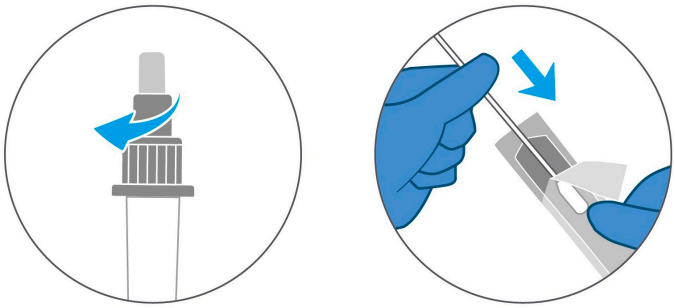
Note: Failure to stir 10X could result in a false negative result.

3. Squeeze the sides of the Tube to express as much liquid as possible from the swab, and remove the swab.



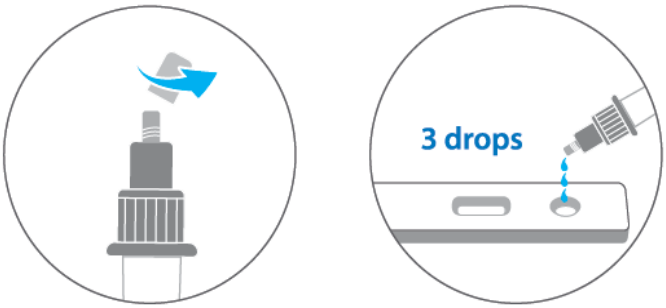
Note: If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

4. Replace the large orange cap onto the Tube and twist to close. Put the swab back into the package. Safely dispose of the swab and the package in biohazardous waste.



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. Replace the small white cap, and twist it into place.



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

5) Wait 15 minutes

Start timing immediately after adding sample to the Sample Port. The result will be ready in 15-30 minutes.

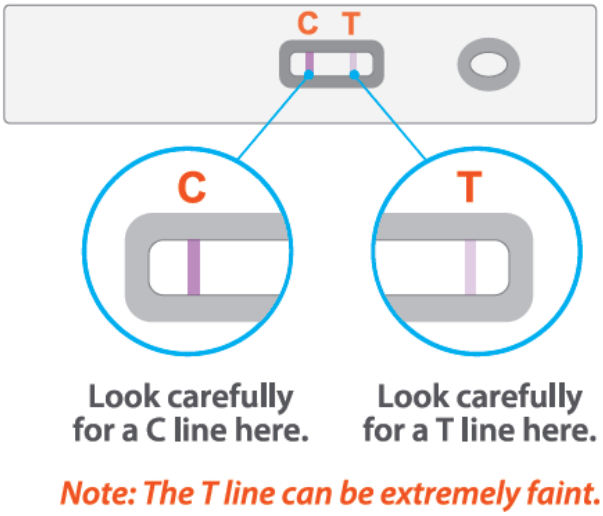
Note: Do NOT interpret your test result until after your 15-minute timer has completed, because the T line may take as long as 15 minutes to appear.

Note: False results may occur if the test result is read before 15 minutes or after 30 minutes.

6) Read Result

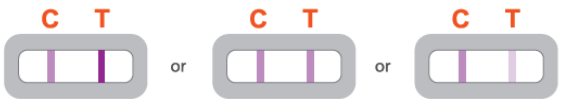
Results should not be read after 30 minutes.

(Result shown at 2x magnification).



7) Test Result Explanation

Positive Result



A POSITIVE result must show BOTH a C line and a T line. A positive result means viral antigens from COVID-19 were detected.

Below are photos of actual positive tests. **Please note that the T line may be faint.**

Negative Result

A **NEGATIVE** result will show ONLY a C line. A negative result means viral antigens from COVID-19 were not detected.

- **Please note that negative results do not rule out COVID-19.**
- **A negative result is presumptive and confirmation with a molecular assay, if 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 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 or residing in communities with low prevalence of infection**

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. A retest using a new test should be conducted.

8) Dispose of the Test Kit

After the test is completed, dispose of all kit components in biohazardous waste.

9) Reporting the Test Result

Report the test results to the appropriate healthcare providers and relevant public health authorities, in accordance with the standard procedures of your institution.

EXTERNAL QUALITY CONTROL

iHealth® COVID-19 Antigen Rapid Test Pro contains a Positive Control Swab and a Negative Control Swab. These external control swabs serve to monitor the entire assay. External Positive and Negative Control Swabs should be tested once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

If the correct control swab test results are not obtained, do not perform testing of patient samples or report patient sample test results.
Contact iHealth Labs Inc. support at https://ihealthlabs.com/pages/contact-us .

INTENDED USE

The iHealth® COVID-19 Antigen Rapid Test Pro is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens from direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over

three days with at least 24 hours and no more than 48 hours between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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 an individual with a close contact with COVID-19 and/or with 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 low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

The iHealth® COVID-19 Antigen Rapid Test Pro is intended for use by healthcare professionals or operators who are proficient in performing tests in point of care settings.

The iHealth® COVID-19 Antigen Rapid Test Pro is only for use under the Food and Drug Administration's Emergency Use Authorization.

STORAGE AND OPERATION CONDITIONS

Store iHealth® COVID-19 Antigen Rapid Test Pro in a dry location between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. The COVID-19 Test Card inside the foil pouch should be used within 1 hour after opening. Do not use the COVID-19 Test Card after the expiration date marked on the packaging.

CUSTOMER HELPLINE

If you have any questions about the iHealth® COVID-19 Antigen Rapid Test Pro or your test result, please contact our toll-free Customer Helpline on 1-855-816-7705.

In the USA,

- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- 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 www.iHealthlabs.com

Made in China

Rev.01/2022

Control name: iHealth® COVID-19 Antigen Rapid Test Pro External Control Swabs

Model: CS-ICO

For use under Emergency Use Authorization (EUA) only.

For in vitro diagnostic use only.

For prescription use only

This iHealth® COVID-19 Antigen Rapid Test Pro External Control Swabs are only for use with iHealth® COVID-19 Antigen Rapid Test Pro.

Package contents:

The iHealth® COVID-19 Antigen Rapid Test Pro External Control Swabs contain (1) Antigen Positive Control Swab and (1) Antigen Negative Control Swab. The Positive Control Swab is prepared by spiking a sterile swab with a solution of non-infectious recombinant SARS-CoV-2 nucleocapsid antigen diluted phosphate buffered saline. The Negative Control Swab is a sterile blank swab.

Summary and Explanation of the Test

iHealth Labs, Inc provides an external positive and negative assayed quality control kit, the iHealth® COVID-19 Antigen Rapid Test Pro External Control Swabs to monitor the performance of the iHealth® COVID-19 Antigen Rapid Test Pro.

Good laboratory practice suggests the use of positive and negative external controls to ensure that test reagents are working and that the test is correctly performed. iHealth® COVID-19 Antigen Rapid Test Pro External Control Swabs serve to monitor the entire assay.

The positive and negative control swabs should be tested once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

Storage Instructions:

Store in a dry place between 36-86 °F (2-30 °C).
Controls should not be used past the expiration date on the package.

Procedure / Interpretation / Limitations

Users should refer to the iHealth® COVID-19 Antigen Rapid Test Pro Instructions for Use available on the website: www.iHealthlabs.com

See section ***Test Instructions for iHealth COVID-19 Antigen Rapid Test Pro External Control Swabs*** for external control testing procedures and results interpretation in "***iHealth® COVID-19 Antigen Rapid Test Pro Instructions for Use***"

In the USA:

• This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;

• This product has been authorized only for the detection of proteins from SARSCoV-2, not for any other viruses or pathogens; and,

• 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner

Manufactured for iHealth Labs, Inc.

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Made in China