

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 smartphones 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.

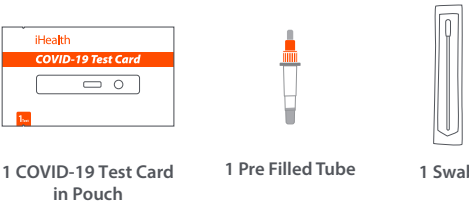
Alternatively, testing can be done by following the step-by-step Testing Instructions below.

Testing Instructions

1 Prepare Materials

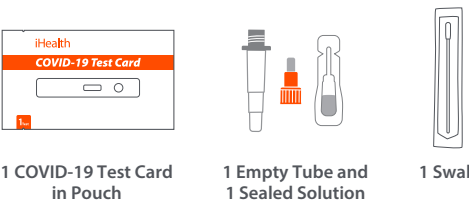
You may have **Test Set 1 OR Test Set 2** in the package. Please follow proper steps based on the specific set you received.

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

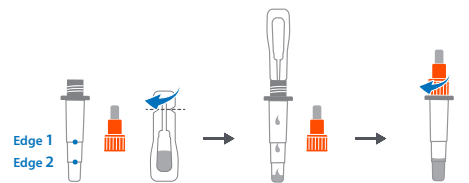


Please go directly to **Step 2 Collect Sample**.

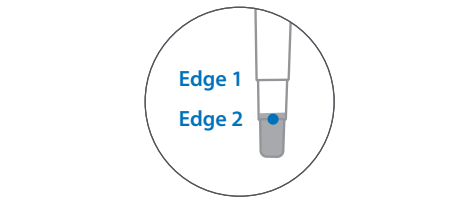
Test Set 2: Open the kit, take out the COVID-19 Test Card in Pouch, Empty Tube, Sealed Solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.



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



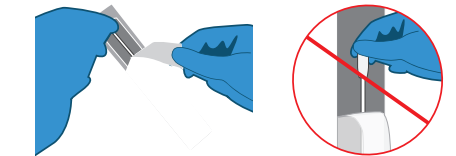
Please confirm the liquid level with or above Edge 2, then go to **Step 2 Collect Sample**.



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

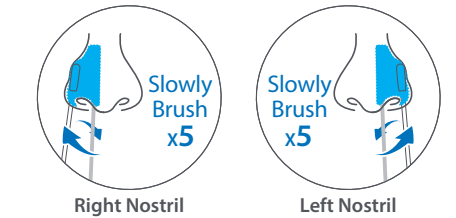
a. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for the disposal of the used swab.



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



c. 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**.

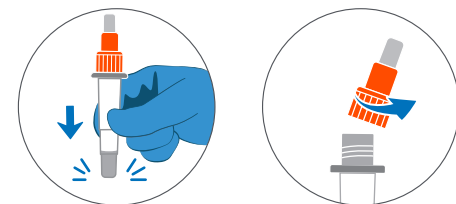


Note:
Failure to swab both nostrils properly may cause false negative results.

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.

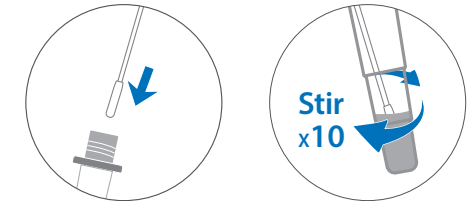
3 Process Sample

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



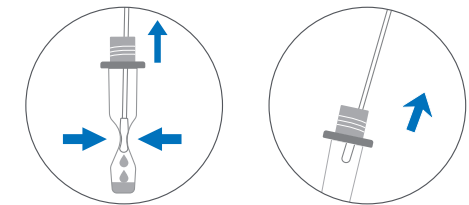
Note:
Invalid results may occur if less than the allotted amount of extraction buffer in the Tube is used. If extraction buffer in the Tube is spilled, discard the Tube and use a new extraction reagent Tube.

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



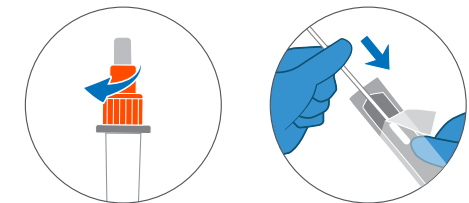
Note:
Failure to stir 10x could result in a false negative result.

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



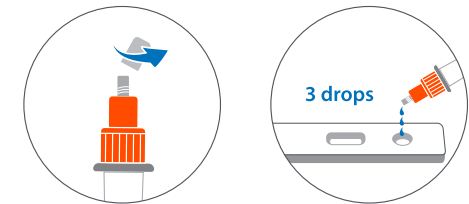
Note:
If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

d. 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

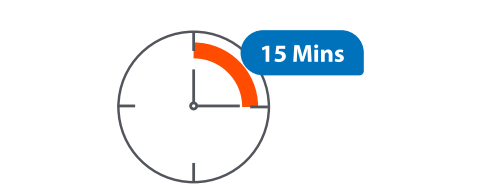
Twist to open the small white cap of the Tube. Add 3 drops of sample to the Sample Port of the COVID-19 Test Card. Replace the small white cap, and twist it into place.



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.

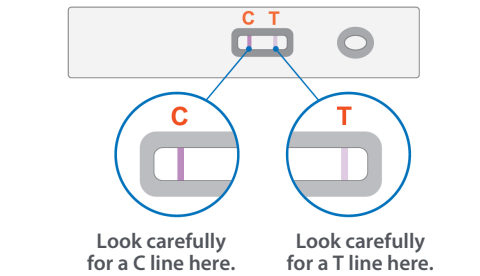


Note:
Do NOT interpret your test result until after your 15-min timer has completed, because the T line may take as long as 15 minutes to appear.

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).



Note: The T line can be extremely faint.

7 Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

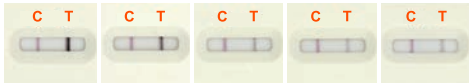
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)



If the Control (C) line and the Test (T) line are visible, the test is positive.

Below are photos of actual positive tests. Any faint visible pink-to-purple test (T) line with the control line (C) should be read as positive.



Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient’s doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive). 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. Individuals who test positive with the iHealth COVID-19 Antigen Rapid Test Pro should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)



If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

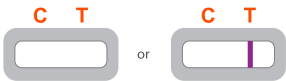
To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek

follow up care with the primary health care provider. All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

Invalid



If the control (C) line is not visible, the test is invalid. **Re-test with a new swab and new test kit.** An invalid result does not indicate if the individual does or does not have COVID-19 and should be repeated.

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 for the qualitative detection of nucleocapsid protein antigen from the

SARS-CoV-2 in direct anterior nasal (nares) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 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 which is generally detectable in anterior nasal (nares) samples 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 and the agent detected may not be the definitive cause of disease.

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

All negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. 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 measures such as isolating from others and wearing masks. 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.

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

The iHealth COVID-19 Antigen Rapid Test Pro is only for in vitro diagnostic use under the Food and Drug Administration’s Emergency Use Authorization. This product has not been FDA cleared or approved.

WARNINGS,PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Wear appropriate personal protective equipment when performing sample collection and sample testing.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- 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.
- Once opened, the test card should be used within 60 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose or mouth, flush with large amounts of water.

If irritation persists, seek medical advice: <https://www.poisonhelp.org> 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%

For more information on EUAs please visit: <https://www.fda.gov/emergency- preparedness-and- response/mcm-legal-regulatory-and-policy- framework/emergency- use-authorization>

For the most up to date information on COVID-19, please visit: "<http://www.cdc.gov/COVID19>" www.cdc.gov/COVID19"

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. It is stable before 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.

Manufactured for iHealth Labs, Inc.
150C Charcot Ave, San Jose, CA 95131, USA
www.ihealthlabs.com 1-855-816-7705

Rev.03/2023

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

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 for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 in direct anterior nasal (nares) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 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 which is generally detectable in anterior nasal (nares) samples 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 and the agent detected may not be the definitive cause of disease.

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

All negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. 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 measures such as isolating from others and wearing masks. 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.

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

The iHealth® COVID-19 Antigen Rapid Test Pro is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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)

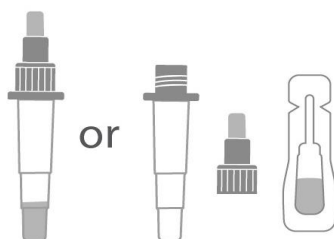
Note: Additional iHealth COVID-19 Antigen Rapid Test Pro External Control Swab kits (Cat. No. CS-ICO) are available for purchase if needed. Contact iHealth Customer Care for further information (1-855-816-7705, Monday – Friday 8:30AM – 5:30PM PST).

- 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, PRECAUTIONS AND SAFETY INFORMATION

- For in vitro diagnostic use.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. 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.
- 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.

- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Wear appropriate personal protective equipment when performing sample collection and sample testing.
- Do not use if any of the test kit contents or packaging is damaged..
- Test components are single-use. Do not re-use. Do not mix components from different test kits.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- When collecting an anterior nasal swab sample, use only the nasal swab supplied in the test kit.
- 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.
- Once foil pouch is opened, the test card should be used within 60 minutes.
- 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.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Laboratories within the United States and its territories are required to report results to the appropriate public health authorities.
- 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.
- The reagent solution contains harmful chemicals (see table below). If the solution

contacts your skin, eyes, nose or mouth, flush with large amounts of water. **If irritation persists, seek medical advice: <https://www.poisonhelp.org> 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) Cause 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%

- For more information on EUAs please visit:
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between July and August 2021. The clinical performance has not been established for 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.

- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- Ensure that there is sufficient lighting for testing and interpretation.
- These test results are shown as lines of color. Because these lines can be very faint, users with conditions affecting their vision - such as far-sightedness, glaucoma, or color blindness - are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- 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.
- 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.
- 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.
- 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.

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. It is stable before 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 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 the 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



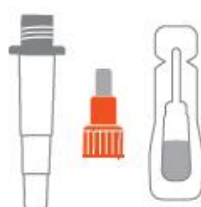
1 Swab

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

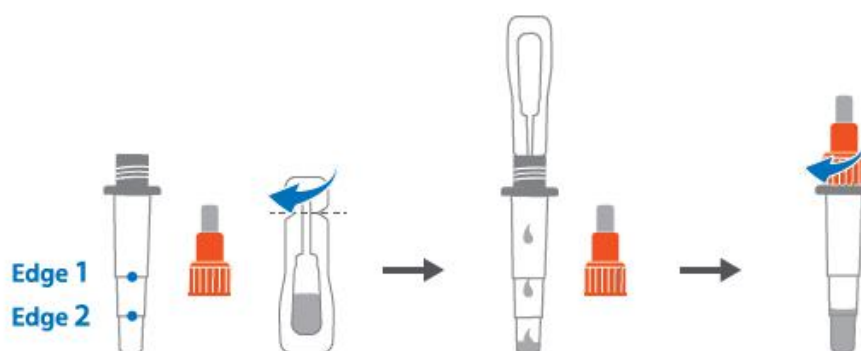


1 Empty Tube and
1 Sealed Solution

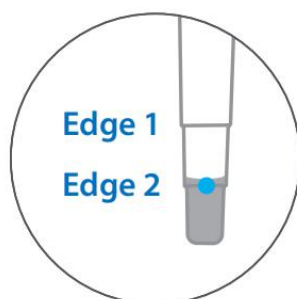


1 Swab

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



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

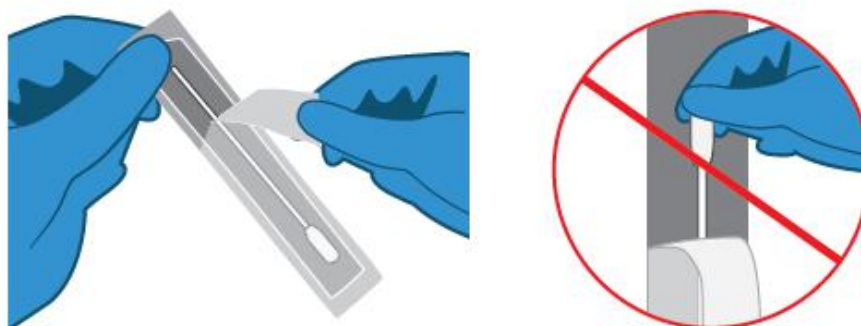


Note:

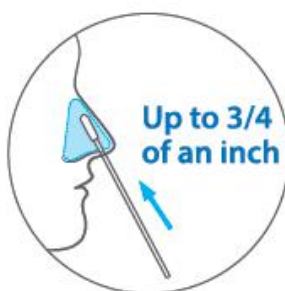
It is acceptable if the liquid level is above Edge 2. However, please do not proceed with this test, if the liquid level is significantly below Edge 2, as this may result in false or invalid results.

2) Collect Sample

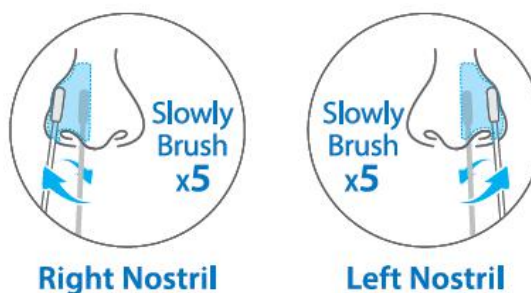
a. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for the disposal of the used swab.



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



- c. 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**.

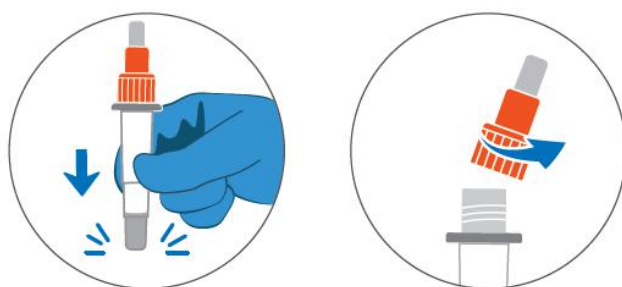


Note: Failure to swab both nostrils properly may cause false negative results.

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.

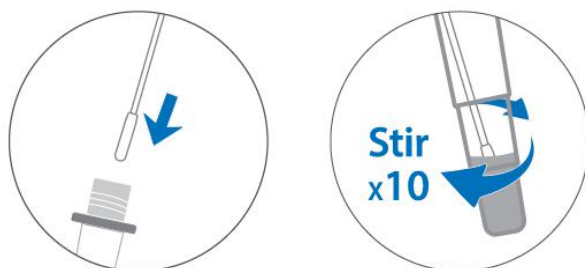
3) Process Sample

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



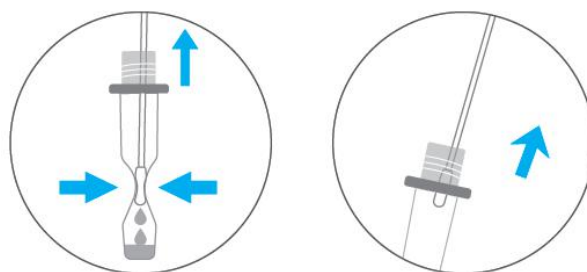
Note: Invalid results may occur if less than the allotted amount of extraction buffer in the Tube is used. If extraction buffer in the Tube is spilled, discard the Tube and use a new extraction reagent Tube.

b. 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.

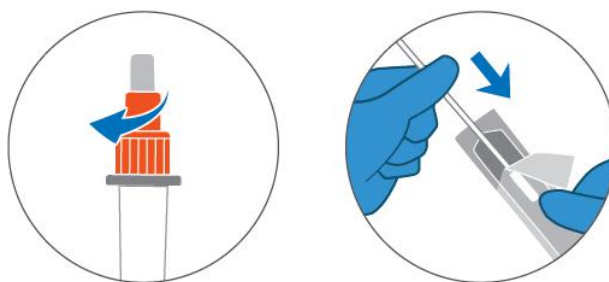
c. Squeeze the sides of the Tube to express as much liquid as possible from the swab, and remove the swab.



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).

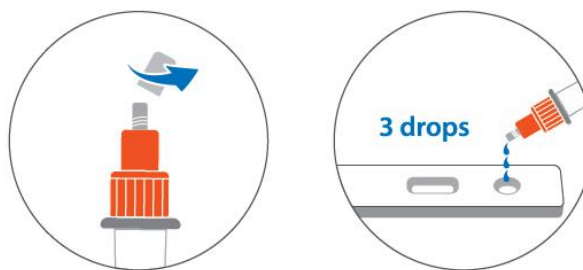
d. Replace the large orange cap onto the Tube and twist to close. Put the swab back into the

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.

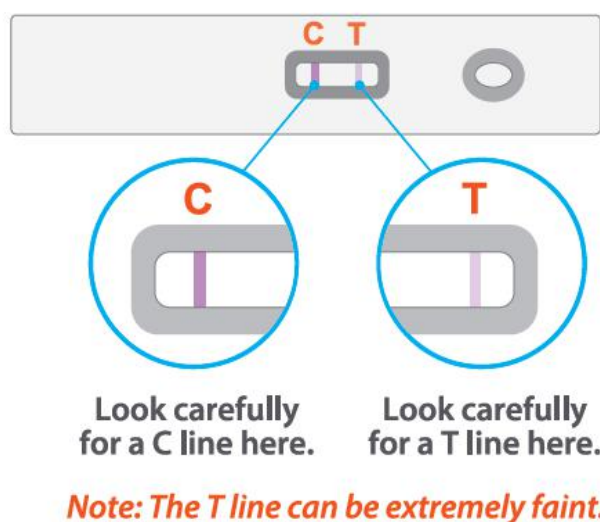


Note: Do NOT interpret the result until after your 15-minute timer has completed, because the T Line may take as long as 15 minutes to appear.

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 magnification).



7) Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)



If the Control (C) line and the Test (T) line are visible, the test is positive.

Below are photos of actual positive tests. Any faint visible pink-to-purple test (T) line with the control line (C) should be read as positive..

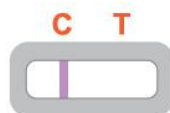


Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the iHealth® COVID-19 Antigen Rapid Test Pro should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)



If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

Invalid



If the control (C) line is not visible, the test is invalid. **Re-test with a new swab and new test kit.** An invalid result does not indicate if the individual does or does not have COVID-19 and should be repeated.

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.

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 AUTORIZATION 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-use-authorizations-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

COVID-19 Serial Screening

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in the following Table.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC			SYMPTOMATIC		
	ON FIRST DAY OF TESTING			ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive					
	(Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	
1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.						
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.						
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.						

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°C, 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%
6	8	6	75.0% (6/8)	40.9 – 92.9%
7	6	5	83.3% (5/6)	43.6 – 97.0%
Total	34	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, 17.5 µL 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 $\geq 95\%$ 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 TCID₅₀/mL. Based upon the testing procedure for this study the LoD of 20×10^3 TCID₅₀/mL equates to 3.5×10^2 TCID₅₀/swab.

NIH/RADx Variant Testing

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx) initiative. Specimen pools were prepared by the RADx team using clinical pooled samples from currently circulating Omicron strains and tested by RADx to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, this test detected 100% of live virus Omicron samples at a Ct-value of 26.7 (n=5). Testing was also compared to two additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 26.7) were not detected by this test in this study.

Omicron Pool 1 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Ihealth COVID-19 Antigen Rapid Test Pro Percent Positive (n=5)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)
Dilution 1	18.0	100	100	100
Dilution 2	19.4	100	100	100
Dilution 3	20.0	100	100	100
Dilution 4	21.5	100	100	100

Dilution 5	23.0	100	100	100
Dilution 6	24.4	100	100	100
Dilution 7	25.4	100	0	0
Dilution 8	26.7	100	0	0
Dilution 9	27.7	0	0	0
Dilution 10	28.7	0	0	0
Dilution 11	29.8	0	0	0
Dilution 12	30.6	0	0	0

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	No interference

				cross-reactivity	
	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 sequence. 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 (Oxymetazoline HCl)	15% v/v	No cross-reactivity	No interference
Neo-Syneprine (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 1.15×10^7 TCID₅₀/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.

150 Charcot Ave, San Jose, CA 95131, USA

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

Rev.04/2023

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.

120 San Lucar Ct , Sunnyvale, CA 94086, USA

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

Made in China