iHealth® COVID-19 Antigen Rapid Test

Healthcare Provider Instructions for Use

Model: ICO-3000/ICO-3001/ICO-3002

For use with anterior nasal swab specimens
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)

INTENDED USE

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

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older with symptoms of COVID-19 within the first 7 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 7 days of symptom onset.

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

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

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The 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 past medical 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. Individuals who test positive with the iHealth® COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out COVID-19 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 an individual'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 in an individual with as a 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 COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting or by following the mobile application instructions for self-reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The iHealth® COVID-19 Antigen Rapid Test is authorized for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older. The iHealth® COVID-19 Antigen Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

PRODUCT DESCRIPTION

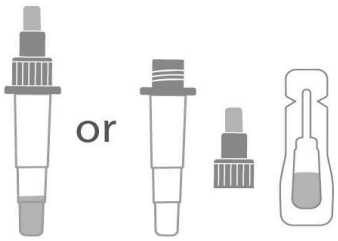
The iHealth® COVID-19 Antigen Rapid Test requires the following elements for operation.

Materials provided in the Test Kit:

Kit components	Quantity			
	1 test Kit	2 tests Kit	5 tests Kit	40 tests Kit
COVID-19 Test Card(s)	1 ea/box	2 ea/box	5 ea/box	40 ea/box
Nasal Swab(s)	1 ea/box	2 ea/box	5 ea/box	40 ea/box
Tube(s)	1 ea/box	2 ea/box	5 ea/box	40 ea/box
Lay User Instruction for Use	1 ea/box	1 ea/box	1 ea/box	1 ea/box

For Healthcare Provider Instructions for Use, please see the company website: https://www.ihealthlabs.com

COVID-19 Test Card(s)



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

Swab(s)

iHealth® COVID-19 Antigen Rapid Test components

Materials required but are not provided in the kit:

- Smartphone (supplied by the user. iOS 12 or above. android 6.0 or above)
- User is required to download the “iHealth COVID-19 Antigen Rapid Test” App for iOS or Android phones. User should follow the step-by-step instructions in-app to complete the test.

PRINCIPLE OF PROCEDURES

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

To begin the test, a self-collected anterior nares swab samples in individuals aged 15 and older or individuals between the age of 2 to 14 with a swab collected by a parent or guardian is inserted into the Tube. The liquid in tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The liquid in 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).
- 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.
- 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.
- Do not use any test component after the expiration date which is printed on the outer packaging.
- Do not use the COVID-19 Test Card if the pouch is damaged or if the seal is broken.
- Do not reuse any test component.
- To obtain accurate results, the test must be performed as indicated in the Instructions for Use.
- Inadequate or inappropriate sample collection may yield false test results.
- Do not touch the tip of the swab before and after collecting the sample from the nostrils.
- Test samples immediately after collection, but no more than 4 hours after specimen collection before placement into extraction buffer or up to 2 hours after placement into extraction buffer, if kept at room temperature.
- Be sure to read test result after 15 minutes. Do not read results after 30 minutes.
- Do not ingest extraction liquid
- Keep test kit and components out of the reach of children and pets before and after use.
- Avoid contact with skin and eyes.
- The reagent in the extraction liquid 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.
- Dispose of used specimens and test components in accordance with Federal, State, and Local requirements.

Important Notes

This test kit is intended to be used as an aid in the clinical diagnosis of a **current COVID-19 infection**. Do not use this test kit as the only guide to manage your illness.

LIMITATIONS

- Do not use on anyone under 2 years old.
- Children aged 2-14 years should be tested by an adult.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The 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.
- Failure to follow the test procedure correctly may results in false negative or false positives results and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- 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.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection 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.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between May, 2021 and October, 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.

- The iHealth® COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.
- False negative results may occur in individuals who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin. Biotin levels of 1 µg/mL and greater have been demonstrated to result in false negative test results

Hazardous Ingredients for Reagent Solution

The Extraction Reagent contains potentially harmful chemicals (see table below). If the test 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 call 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%

STORAGE CONDITIONS

Store iHealth® COVID-19 Antigen Rapid Test 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. The shelf-life of the iHealth® COVID-19 Antigen Rapid Test is 9 months and it is stable until the expiration date marked on the packaging.

QUALITY CONTROL

A procedural internal control is built in the “control line (c)” of the device and is used to ensure that the applied specimen has migrated well into the device. It is coated with goat anti-rabbit IgG and a red colored line should appear after sample was added.

TEST PROCEDURE

Download App: Scan the QR code (below) to download the “iHealth COVID-19 Antigen Rapid Test” App through your Smartphone (iOS12.0+, Android 6.0+). For a full list of compatible smartphone visit: https://ihealthlabs.com/pages/support-ICO3000

Register and Log Into The App

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

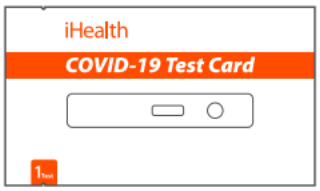
Instructions

The instructions provided here include all the steps of the test. Specific, detailed video instructions on how to perform this test are in the "iHealth COVID-19 Antigen Rapid Test" App.

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 package, take out the COVID-19 Test Card in Pouch, the Tube pre-filled with the extraction solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.



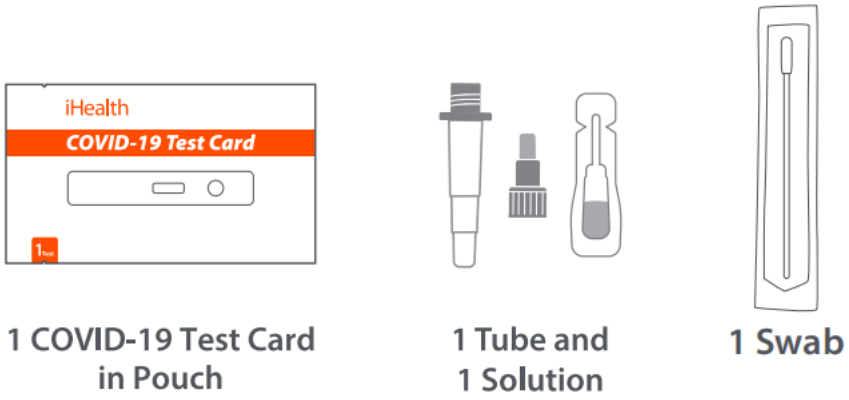
1 COVID-19 Test Card in Pouch

1 Tube

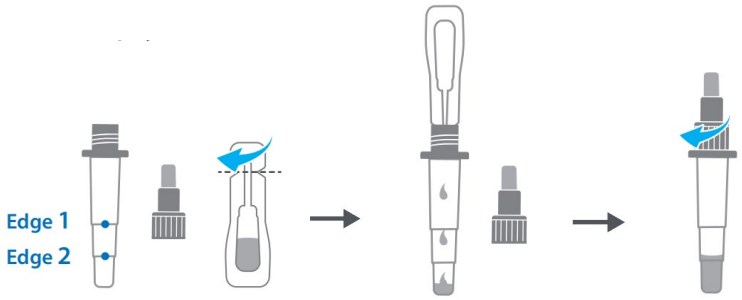
1 Swab

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

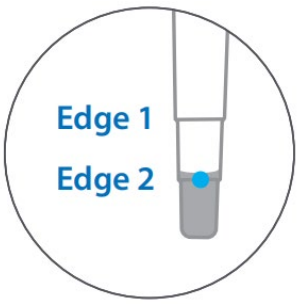
- ***Test Set 2:*** Open the package, take out the COVID-19 Test Card in Pouch, empty Tube, sealed Solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.



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



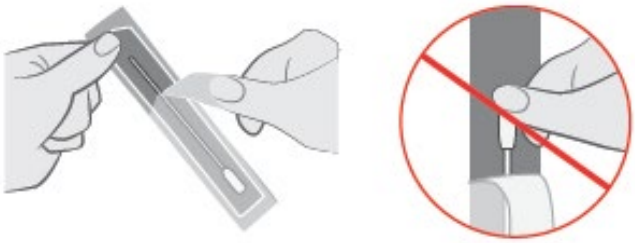
Please confirm the liquid level with or above Edge 2, then go to **Step 2 Collect Sample**.



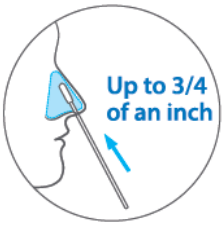
NOTE:
It is acceptable if the liquid level is above Edge 2. However, please do not proceed with this test, if the liquid level is below Edge 2, as this may result in false or invalid results.

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.

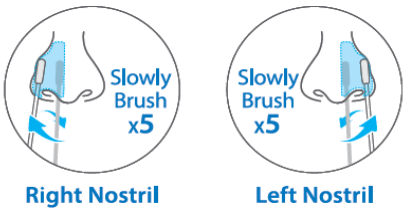


2. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.



Note: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

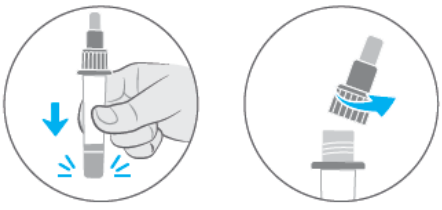
3. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 5 times. Using the same swab, repeat the same sample collection procedure for the other nostril. Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the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



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

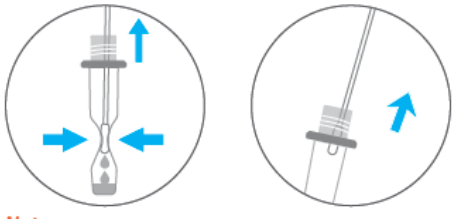
3) Process Sample

1. Tap the tube vertically on the table and twist the large orange cap to open the tube.



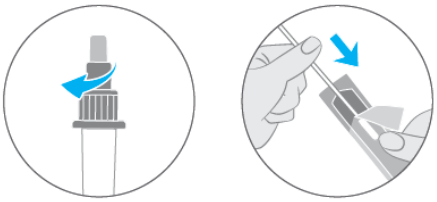
2. Insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

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



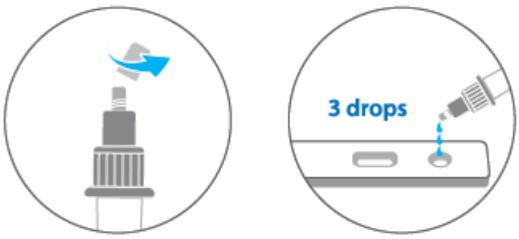
Note: If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

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



4) Add Sample

Twist to open the small white cap of the tube. Add 3 drops of sample to the Sample Port of the COVID-19 Test Card. Screw back the small white cap.



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

5) Wait 15 minutes

Start the timer by clicking the “Start Timer” button on the App, immediately after adding sample to the Sample Port. The result will be ready in 15 minutes.

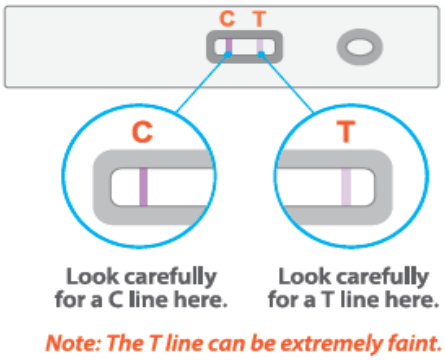
Note: DO NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

6) Read Result

Results should not be read after 30 minutes.

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes

Result shown 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 and the individual is positive for COVID-19.

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

- Persons who test positive should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.

Negative Result

A **NEGATIVE** result will show ONLY a C line. A negative result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19.

- Please note that negative results do not rule out COVID-19.
- In case of negative test result: Continue to follow all social distancing recommendations and take protective measures. If suspicions of infection persist and/or your first test is negative, repeat the test after 1 - 2 days and consult your healthcare provider or local COVID-19 center.
- Note: 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**. Invalid result means that the test did not function correctly. **You will need to retest with a new test kit.** If upon retesting, the test result is still invalid, contact your doctor or local COVID-19 center. An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.

8) Dispose the Test Kit

After test is completed, dispose of all kit components in trash.

9) Report Test Result

Report the result following the App instructions or share your test result with your healthcare provider.

CLINICAL PERFORMANCE

Clinical performance characteristics of iHealth® COVID-19 Antigen Rapid Test was evaluated in a total of five (5) investigational sites throughout the U.S. A total of 139 individuals with signs and symptoms of COVID-19 within the first seven (7) days of symptom onset completed the study and obtained a valid result. Each Subject was provided a iHealth® COVID-19 Antigen Rapid Test. Under the observation of a clinical site staff member trained as a proctor, subjects fifteen (15) years and older independently collected an anterior nasal sample, conducted the test, interpreted and reported their self-test result. The parents of subjects two (2) to fourteen (14) years of age collected the anterior nasal sample, conducted the test, interpreted and recorded the test result for the child. The iHealth® COVID-19 Antigen Rapid Test results were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. The iHealth® COVID-19 Antigen Rapid Test when conducted by a lay user correctly identified 94.3% of positive samples. Additionally, the iHealth® COVID-19 Antigen Rapid Test correctly identified 98.1% of negative samples. The performance is shown in the following table.

iHealth® COVID-19 Antigen Rapid Test	Comparator Method		
	Positive	Negative	Total
Positive	33	2[b]	35
Negative	2[a]	102	104
Total	35	104	139
Positive Agreement: (33/35) 94.3%; 95% Confidence Interval: 81.4% to 98.4%			
Negative Agreement: (102/104) 98.1%; 95% Confidence Interval: 93.3% to 99.5%			
[a] Of the 2 false negative samples, one was positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, the other one was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay. [b] Of the 2 false positive samples, one was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, the other was inconclusive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.			

2 samples generated an invalid COVID-19 Antigen Rapid Test result.

Age and gender distribution and positive rate of symptomatic subjects within first 7 days of symptom onset				
Age Group (years)	Female	Male	Positive	Positivity Rate % (total positive/total tested)
2 to 13	6	8	3	21.4% (3/14)
14 to 24	15	12	3	11.1% (3/27)
25 to 64	46	44	28	31.1% (28/90)
≥65	5	3	1	12.5% (1/8)
Total	72	67	35	25.2% (35/139)

Positive results broken down by days since symptom onset				
Days Since Symptom Onset	RT-PCR Positive (+)	iHealth test Positive (+)	PPA	95 % Confidence Interval
1	1	1	100.0%	20.7% - 100.0%
2	3	3	100.0%	43.8% - 100.0%
3	3	2	66.7%	20.8% - 93.9%
4	5	5	100.0%	56.6% -100.0%
5	12	12	100.0%	75.7% - 100.0%
6	6	6	100.0%	61% - 100.0%
7	5	4	80.0%	37.6% - 96.4%
All specimens	35	33	94.3%	81.4% - 98.4%

Additional asymptomatic individuals and individuals beyond the seven days of symptom onset were tested, but excluded from the primary performance calculations because they were not included in the intended use. A higher proportion of low positive specimens were observed in these populations, resulting in PPAs between of 85-88% in these individuals.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LOD)

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

Cross Reactivity (Analytical Specificity) 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. 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 38 commensal and pathogenic microorganisms (13 bacteria and 25 viruses) that may be present in the nasal cavity 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.

List of Organism		Concentration tested	Cross-reactivity results	Microbial Interference results
Other high priority pathogens from the same genetic family	Human coronavirus 229E	3.74×10^4TCID$_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus OC43	2.51×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus NL63	1.36×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	MERS-coronavirus	1.36×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
High priority organisms likely in the circulating area	Adenovirus Type 1	2.04×10^7TCID$_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 4	2.09×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 7A	2.04×10^7TCID$_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 8	1.13×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 31	1.13×10^5U/mL	No cross-reactivity	No interference
	Adenovirus Type 41	9.36×10^4TCID$_{50}$/mL	No cross-reactivity	No interference
	Human Metapneumovirus 3(hMPV-3) Type B1	3.11×10^4TCID$_{50}$/mL	No cross-reactivity	No interference
	Human Metapneumovirus 4(hMPV-4) Type B2	5.25×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Human Metapneumovirus 9(hMPV-9) Type A1	9.36×10^4TCID$_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 1	6.30×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 2	7.55×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 3	2.29×10^6TCID$_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4A	4.50×10^4TCID$_{50}$/mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4B	1.36×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Influenza A H3N2 Virus	1.13×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Influenza B Virus	3.74×10^4TCID$_{50}$/mL	No cross-reactivity	No interference
	Enterovirus Type 68	7.55×10^5TCID$_{50}$/mL	No cross-reactivity	No interference
	Enterovirus Type 71	2.29×10^6TCID$_{50}$/mL	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type A (RSV-A)	1.90×10^6TCID$_{50}$/mL	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type B (RSV-B)	3.74×10^4TCID$_{50}$/mL	No cross-reactivity	No interference

	Rhinovirus Type 1A	9.36×10^4TCID$_{50}$/mL	No cross-reactivity	No interference
	Haemophilus influenzae	6.75×10^8CFU/mL	No cross-reactivity	No interference
	Streptococcus pneumoniae	1.80×10^8CFU/mL	No cross-reactivity	No interference
	Streptococcus pyogenes	2.04×10^9CFU/mL	No cross-reactivity	No interference
	Candida albicans	3.15×10^8CFU/mL	No cross-reactivity	No interference
	Pooled human nasal wash – representative of normal respiratory microbial flora	-	No cross-reactivity	No interference
	Bordetella pertussis	3.22×10^9CFU/mL	No cross-reactivity	No interference
	Mycoplasma pneumoniae	1.35×10^8CFU/mL	No cross-reactivity	No interference
	Chlamydia pneumoniae	8.65×10^7IFU/mL	No cross-reactivity	No interference
	Legionella pneumophila	7.10×10^9CFU/mL	No cross-reactivity	No interference
	Staphylococcus aureus	3.23×10^9CFU/mL	No cross-reactivity	No interference
	Staphylococcus epidermidis	1.24×10^9CFU/mL	No cross-reactivity	No interference
	Mycobacterium tuberculosis	1.15×10^8CFU/mL	No cross-reactivity	No interference
	Pneumocystis jirovecii (PJP)	3.17×10^8CFU/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, Mycobacterium tuberculosis, Pneumocystis jirovecii and SARS-CoV-1

- Human Coronavirus HKU1 shows 36.74% homology across 82% of the nucleocapsid sequence(see Annex 2 and 3), which is relatively low. However, cross-reactivity cannot be ruled out.
- *Mycobacterium tuberculosis* shows no protein sequence homology with nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.
- *Pneumocystis jirovecii* shows no protein sequence homology with nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.
- SARS-CoV-1 shows 90.52% homology across 100% of the nucleocapsid sequence. Therefore, cross-reactivity is highly likely.

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.

The SARS-CoV-2 target 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 performance was not affected by any of the 26 potentially interfering substances listed in the table below at the concentrations tested.

Substance	Concentration in negative/positive sample	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 .

Usability Study

iHealth conducted a study to evaluate whether a home user can follow instructions provided and can successfully perform the test steps for the iHealth® COVID-19 Antigen Rapid Test, including nasal swab collection, adding sample to a test card, and correctly interpreting the results.

105 lay users, including self-collection (n=52) and collection for other lay user (n=53), participated in the study, and were instructed to self-collect or collect a sample from others (include children), complete the required procedural steps, and interpret the test results unassisted in a simulated home setting. After the simulated test, all the participants completed the knowledge assessment questionnaire and usability questionnaire.

The overall success of every task completed by all subjects enrolled was determined by unassisted professional observation. Subjects performed 96.8% (718/742) of steps/tasks correctly, and performed 98.1% (1414/1442) of knowledge assessment questionnaires correctly. More than 90% of all the participants stated the device is easy to use, including sample collection, performing the test, reading and understanding the result. 94.29% of the participants stated the instructions provided were easy to read and understood.

The sponsor also conducted additional usability study on how to prepare material when lay user obtain Test Set 2 of the iHealth COVID-19 Antigen Rapid Test . A total of 35 lay users participated in this study, 18 of them were guided by paper IFU and 17 of them were guided by APP. Subjects performed 100% (105/105) of steps/tasks correctly, and performed 97.7% (171/175) of questionnaires correctly.

Flex study

The robust use of iHealth® COVID-19 Antigen Rapid Test was demonstrated by ten (10) 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 or your result, please contact our toll-free Customer Helpline on 1-855-816-7705.

SYMBOLS IN USE

 Caution

 Do not Reuse

 Consult Instructions for Use

IVD In Vitro Diagnostic Medical Device

 Storage Temperature Limitation

 Keep in a dry place

 Keep away from direct sunlight

 Do not use if package is damage

 Manufacturer

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Made in China

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