



iHealth® COVID-19 Antigen Rapid Test

Instructions for Use

Model: ICO-3000

For use with anterior nasal swab samples
For in vitro Diagnostic Use Only

INTENDED USE

The iHealth COVID-19 Antigen Rapid Test is a visually read lateral flow immunoassay device intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigens directly in anterior nasal swab samples from individuals with signs and symptoms of COVID-19 within the first 6 days from symptom onset. This test is for non-prescription home use by individuals aged 15 years or older testing themselves, or adults testing individuals aged 2 years or older.

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

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment. Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from October 2022 to June 2023 when the COVID-19 variant Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.

PRODUCT DESCRIPTION

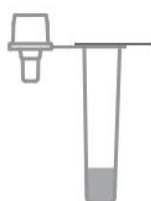
The iHealth COVID-19 Antigen Rapid Test requires the following elements for operation.

Materials provided in the Test Kit:

Kit components	Quantity					
	1 test Kit	2 tests Kit	4 tests Kit	5 tests Kit	6 tests Kit	40 tests Kit
COVID-19 Test Card(s)	1 ea/box	2 ea/box	4 ea/box	5 ea/box	6 ea/box	40 ea/box
Nasal Swab(s)	1 ea/box	2 ea/box	4 ea/box	5 ea/box	6 ea/box	40 ea/box
Tube(s)	1 ea/box	2 ea/box	4 ea/box	5 ea/box	6 ea/box	40 ea/box
Lay User Instruction for Use	1 ea/box	1 ea/box	1 ea/box	1 ea/box	1 ea/box	1 ea/box



COVID-19 Test Card(s)



Tube(s)



Swab(s)

iHealth COVID-19 Antigen Rapid Test components

Materials not provided in the kit:

- Timer
- OPTIONAL:
 - Users may follow the “iHealth COVID-19 Antigen Rapid Test” App for iOS or Android phones for step-by-step instructions to complete the test. Email address and internet connection is required to use the App.
 - Smartphone for using the optional App (supplied by the user):
 - iOS 12 or above
 - Android 9.0 or above

PRINCIPLE OF PROCEDURE

The iHealth COVID-19 Antigen Rapid Test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of SARS-CoV-2 nucleocapsid protein antigen, a component of the virus that causes COVID-19.

To begin the test, a self-collected anterior nasal swab sample in individuals aged 15 and older or individuals between the age of 2 to 14 with a swab collected by a parent or guardian. The swab is inserted into a Tube with a liquid reagent that facilitates exposure of the viral antigens to the antibodies the test uses for the detection of the SARS-CoV-2 virus. The liquid in the tube, now containing the sample, is added to the Sample Port of the COVID-19 Test Card.

If the extracted sample contains the SARS-CoV-2 virus, 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 the SARS-CoV-2 virus is 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.
- Do not use this test if you have no symptoms of COVID-19.
- Do not use on anyone under 2 years of age.
- **Serial testing should be performed in individuals with initial negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **False positive test results are more likely when prevalence of SARS-CoV-2 is low in the community.**
- **This test is not a substitute for consultation with a healthcare provider and should not be used to determine any treatments without provider supervision. Healthcare providers will consider additional information such as the patient's personal medical history and symptoms, current disease prevalence in the community, and additional test results if applicable, to help determine what steps are best for diagnosis and treatment if needed.**
- If symptoms persist or worsen, discuss the test results with a healthcare provider.
- Persons with condition that makes it difficult to use the test (e.g., problems with vision, handling the test components, or understanding test instructions or results); or persons performing this test on behalf of a person who has any of these conditions should discuss the test results with a healthcare provider.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic

lung or heart disease, compromised immune system, diabetes, and other conditions listed by the CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are necessary.

- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Wear a safety mask or other face-covering when collecting a sample from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Do not use kit past its expiration date printed on the outside of the box.
- Test components are single-use. Do not re-use.
- When collecting a nasal swab sample, use only the Nasal Swab supplied in the kit.
- 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 false results.
- Keep testing kit and kit components away from children and pets before and after use.
- Avoid contact with your eyes or mouth. Do not ingest any kit components.
- 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 the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.
- Discard and do not use any damaged or dropped Test card or material. Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.

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



test kit is stable until the expiration date marked on the packaging. Do not freeze.

QUALITY CONTROL

Each iHealth COVID-19 Antigen Rapid Test has a built-in internal procedural control. The pink or purple line appearing at the “C” position verifies proper assembly and capillary flow of the test strip. A distinct pink or purple Control Line should always appear if the test has been performed correctly. If the Control Line does not appear, the test result is invalid, and a new test should be performed using a new swab and new test kit.

TEST PROCEDURE

(OPTIONAL) Download App: Scan the QR code (below) to download the “iHealth COVID-19 Antigen Rapid Test” App through your Smartphone (iOS12.0+, Android 9.0+). For a full list of compatible smartphones, visit: <https://ihealthlabs.com/pages/support-new-ICO3000>

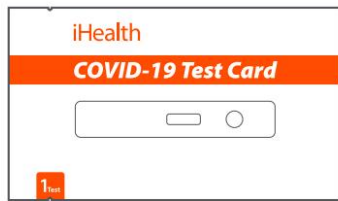


Instructions

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

1. Open the package, take out the COVID-19 Test Card in Pouch, the Tube 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

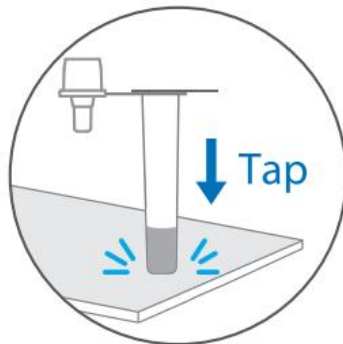


1 Tube

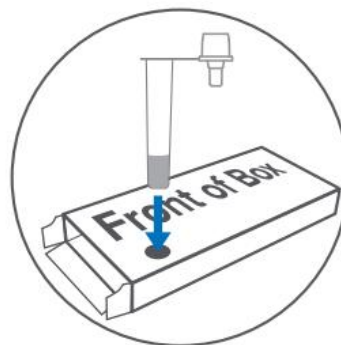


1 Swab

2. Hold the tube upright and tap the tube on the table. After that, gently peel off the seal.

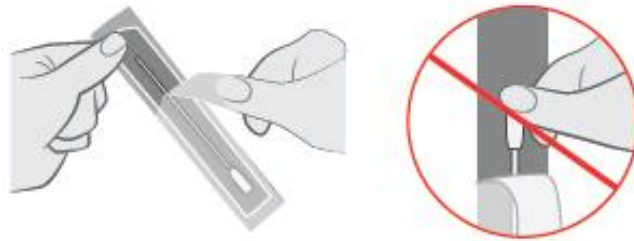


3. Place the tube in the front of box labeled "Insert tube here".

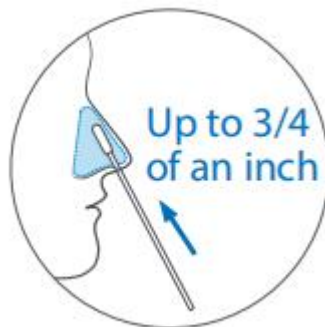


2) Collect Sample

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.

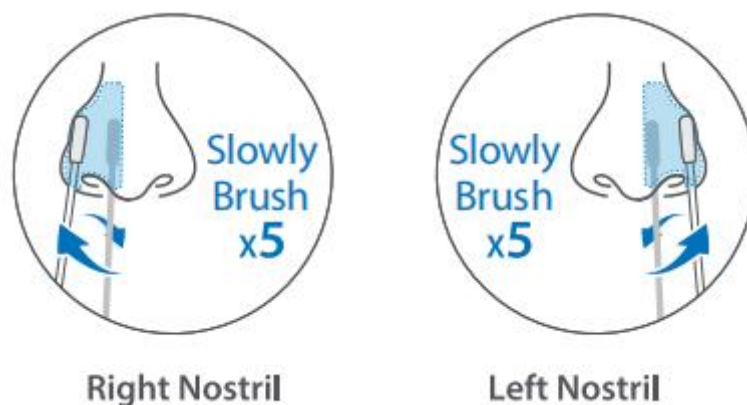


2. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.



Note: With children, the maximum depth of insertion into the nostril may be less than $\frac{3}{4}$ 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 sample and be sure to collect any nasal drainage on the swab. Be sure to brush **BOTH** nostrils with the **SAME SWAB**.



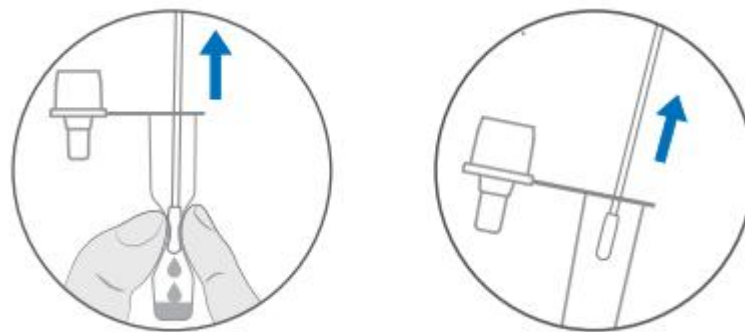
STOP: Did you swab BOTH nostrils? Inaccurate test results may occur if the nasal sample is not properly collected.

3) Process Sample

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

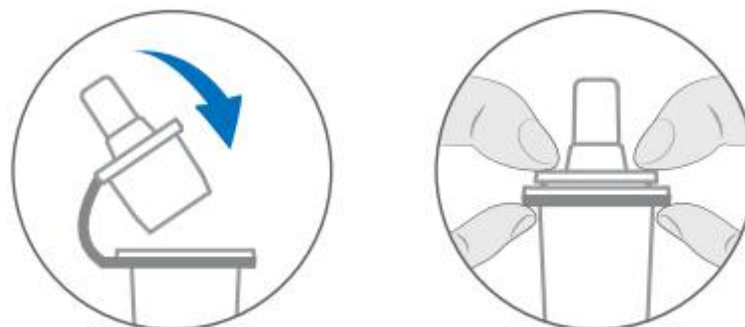


2. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.



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).

3. Close the tube by pushing the cap firmly into the tube.



4. Put the swab back into the package, safely dispose of the swab and the package.



4) Add Sample

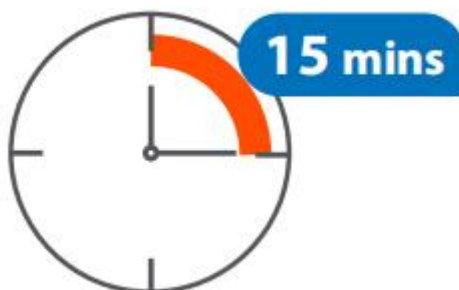
Place the Test Card on a FLAT surface and add 3 drops of sample into the Sample Port of the Test Card.



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

5) Wait 15 minutes

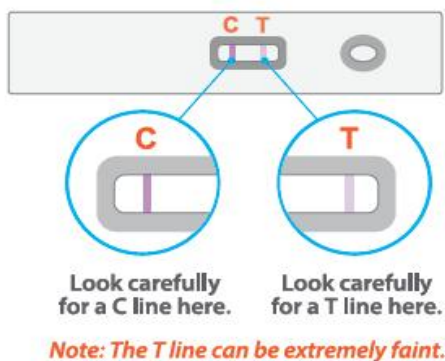
Immediately after adding sample to the Sample Port, start a 15-minute timer. For users of the App, click the "Start Timer" button on the App.



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

6) Read Result

Read test results for the C and the T lines between 15 and 30 minutes. See example below (Result shown at 2x):



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

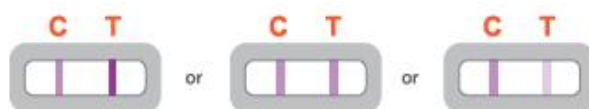
7) Test Interpretation

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

First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
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

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.

NOTE: Any pink or purple line in the correct, indicated locations, no matter how faint, should be considered an indication of a positive result. See examples of different



color grades of the test lines (T) in the images below, including faint lines in the last two images on the right.



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. 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.

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.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. All negative results should be treated as presumptive do 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.

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 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 and wash your hands.

You can report your result via MakeMyTestCount at the website:

<https://learn.makemytestcount.org/>

LIMITATIONS

- There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates). The performance of this test was established based on the evaluation of a limited number of clinical samples collected between October, 2022 and June, 2023. The clinical performance has not been established for all circulating variants, but it is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Due to the propensity of the virus to mutate, new strains emerge over time which may potentially affect the performance of this device and have serious public health implications. Additional testing with a molecular test and/or sequencing should be considered in situations where a new virus strain or variant is suspected.
- Test performance depends on the amount of virus (antigen) in the sample. A negative test result may occur if the level of virus in a sample is below the detection limit of the test, or if the sample was collected or transported improperly.
- There is a higher chance of false negative results with virus 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 virus test negative results are presumptive and confirmation with a molecular assay if necessary for patient management, may be performed.
- 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.
- This test is read visually. Because test 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). This test has not been validated for use by those with color-impaired vision.



- Failure to follow the Test Procedure may adversely affect test performance and lead to incorrect test results. Accurate results are dependent on adequate sample collection, transport, storage, and processing (as applicable).
- This test detects both viable (live) and nonviable SARS-CoV-2.
- The use of oral biotin supplements and use of biotin as a topical application may impact the performance of the test. Exposure to biotin may cause false negative results with this test.

CLINICAL PERFORMANCE

Prospective Clinical Study

Clinical performance characteristics of the iHealth COVID-19 Antigen Rapid Test were evaluated in a total of eight (8) investigational sites throughout the U.S. A total of 915 individuals with signs and symptoms of COVID-19 within the first six (6) days of symptom onset completed the study and obtained a valid result. Each Subject was provided an iHealth COVID-19 Antigen Rapid Test. Subjects fifteen (15) years and older collected an anterior nasal sample by themselves, conducted the test, interpreted and reported the 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 a highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assay to determine test performance. The iHealth COVID-19 Antigen Rapid Test when conducted by a lay user correctly identified 88.9% of positive samples. Additionally, the iHealth COVID-19 Antigen Rapid Test correctly identified 99.9% of negative samples. The performance is shown in the following table.

Clinical performance of the iHealth COVID-19 Antigen Rapid test compared with a highly sensitive RT-PCR comparator			
iHealth COVID-19 Antigen Rapid Test	RT-PCR Comparator Method		
	Positive	Negative	Total
Positive	104	1 ^b	105
Negative	13 ^a	797	810
Total	117	798	915
Positive Agreement: (104/117) 88.9%; 95% Confidence Interval: 81.9% to 93.4%			
Negative Agreement: (797/798) 99.9%; 95% Confidence Interval: 99.3% to 100.0%			
^a Of the 13 false negative samples, 1 of them was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, 12 of them were positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay. The 1 False positive sample was positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.			

Age and gender distribution and positive rate of symptomatic subjects within first 6 days of symptom onset				
Age Group (years)	Female	Male	Positive	Positivity Rate % (total positive/total tested)
2 to 13	63	66	5	3.9% (5/129)
14 to 24	139	94	33	14.2% (33/233)
25 to 64	323	206	72	13.6% (72/529)
≥65	16	8	7	29.2% (7/24)
Total	541	374	117	12.8% (117/915)

Positive results broken down by days since symptom onset				
Days Since Symptom Onset	RT-PCR Positive (+)	iHealth test Positive (+)	PPA	95 % Confidence Interval
1	4	2	50.0%	15.0% - 85.0%
2	32	32	100.0%	89.3% - 100.0%
3	37	34	91.9%	78.7% - 97.2%
4	25	22	88.0%	70.0% - 95.8%
5	12	9	75.0%	46.7% - 91.1%
6	7	5	71.4%	35.9% - 94.3%
Total	117	104	88.9%	81.9% - 93.4%

Serial Testing

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative of the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, covering a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic for at least 14 days prior to enrollment in the study and did not have a history of SARS-CoV-2 infection within three months prior to enrollment. Participants were assigned to one of three different Emergency Use Authorized SARS-CoV-2 over-the-counter rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result was 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-PCR test methods. If results of the first two molecular tests 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 status of symptoms throughout the study using the

MyDataHelps mobile application. Two-day serial antigen testing is defined as performing two antigen tests 36 to 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.

Performance of the antigen test utilizing serial testing is described in the table below.

PPA of COVID-19 Antigen Serial Testing Compared to Molecular Comparator Single Day Testing			
DAYS AFTER FIRST PCR POSITIVE TEST RESULT	Ag Positive / PCR Positive (Antigen Test Performance % PPA) SYMPTOMATIC ON FIRST DAY OF TESTING		
	1 Test	2 Tests	3 Tests
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD)

The LoD of the iHealth COVID-19 Antigen Rapid Test was established by using limiting dilutions of heat inactivated SARS-CoV-2 virus (hCoV-19/South Africa/CERI-KRISP-K040013/2022 BA.5, Omicron Variant). The virus was spiked into natural nasal swab matrix prepared by diluting raw nasal fluid in saline (1:2). This material was confirmed as SARS-CoV-2 negative by RT-PCR.

At each dilution, 50 µL samples were added to swabs and then tested through the full assay workflow, from processing in the extraction reagent to reading the test result. In this study, range finding testing was followed by final dilution testing to determine the LoD of the assay. Range finding involved testing a series of 10-fold dilutions in replicates of five (5) to determine the preliminary LoD.

Using this preliminary concentration, the LoD was confirmed with a 3-fold dilution series, using three test lots tested on consecutive days. 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) for each lot.



The LoD of the iHealth COVID-19 Antigen Rapid Test in natural nasal swab matrix is 1.33×10^4 TCID₅₀/mL. Based upon the testing procedure for this study, this LoD equates to 665 TCID₅₀/swab.

WHO SARS-CoV-2 Standard Limit of Detection

The 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368) was also tested to determine the LoD of the iHealth COVID-19 Antigen Rapid Test with a standardized material for SARS-CoV-2.

A preliminary LoD concentration with the WHO standard material was determined for the iHealth COVID-19 Antigen Rapid Test by testing a series of two-fold dilutions starting at 4000 IU/mL. Three replicates using three test kit lots were tested for this two-fold dilution series, followed by an additional series of two-fold dilutions to refine the preliminary LoD. The preliminary LoD was then confirmed by testing an additional twenty (20) replicates with each of 3 test lots.

Limit of Detection - Summary Results				
Virus Strain	LoD in NCM	LoD per Swab	#Positive/ #total Tested	Percent Detected (%)
WHO Standard (NIBSC 21/368)	4.00×10^2 IU/mL	20 IU/swab	59/60	98.3%

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 SARS-CoV-2 virus at approximately 2 x LoD.

A total of 53 commensal and pathogenic microorganisms (22 bacteria and 31 viruses) that may be present in the nasal cavity were evaluated in this study. Each of the organisms and viruses was tested in five replicates in the absence or presence of heat inactivated SARS-CoV-2 virus (BA.5, Omicron Variant).

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

Cross Reactivity (Analytical Specificity) and Microbial Interference - Summary Results				
List of Organism		Concentration tested	Cross-reactivity results	Microbial Interference results
Human coronavirus 229E		4.50×10^4 TCID ₅₀ /mL	No cross-reactivity	No interference
Human coronavirus OC43		1.36×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
Human coronavirus NL63		2.84×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
MERS-coronavirus		27.1(Ct value)	No cross-reactivity	No interference
SARS-coronavirus		1×10^5 PFU/mL	No cross-reactivity	No interference
Human coronavirus HKU1		33.8 (Ct value)*	No cross-reactivity	No interference
Adenovirus)	Adenovirus Type 1	2.82×10^6 TCID ₅₀ /mL	No cross-reactivity	No interference
	Adenovirus Type 4	2.84×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Adenovirus Type 7A	3.16×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Adenovirus Type 8	1.13×10^5 U/mL	No cross-reactivity	No interference
	Adenovirus Type 31	1.13×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Adenovirus Type 41	3.80×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
Human Metapneumovirus (hMPV)	Human Metapneumovirus 3 (hMPV-3) Type B1	0.94×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Human Metapneumovirus 4 (hMPV-4) Type B2	3.33×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Human Metapneumovirus 9 (hMPV-9) Type A1	1.13×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
Parainfluenza virus	Parainfluenza Virus Type 1	3.80×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 2	3.39×10^6 TCID ₅₀ /mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 3	1.15×10^6 TCID ₅₀ /mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4A	1.13×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Parainfluenza Virus Type 4B	9.55×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
Influenza A & B	Influenza A H3N2	1.13×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Influenza B Victoria	1.26×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
Enterovirus	Enterovirus Type 68	2.84×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference

	Enterovirus Type 71	1.13×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
Respiratory syncytial virus	Respiratory Syncytial Virus Type A (RSV-A)	1.05×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type B (RSV-B)	1.51×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
Rhinovirus Type 1A		1.13×10^5 TCID ₅₀ /mL	No cross-reactivity	No interference
<i>Haemophilus influenzae</i>		1.42×10^8 CFU/mL	No cross-reactivity	No interference
<i>Streptococcus pneumoniae</i>		7.22×10^7 CFU/mL	No cross-reactivity	No interference
<i>Streptococcus pyogenes</i>		4.60×10^8 CFU/mL	No cross-reactivity	No interference
<i>Candida albicans</i>		1.31×10^7 CFU/mL	No cross-reactivity	No interference
Pooled human nasal wash – representative of normal respiratory microbial flora		-	No cross-reactivity	No interference
<i>Bordetella pertussis</i>		1.16×10^9 CFU/mL	No cross-reactivity	No interference
<i>Mycoplasma pneumoniae</i>		2.16×10^8 CCU/mL	No cross-reactivity	No interference
<i>Chlamydia pneumoniae</i>		1.33×10^8 IFU/mL	No cross-reactivity	No interference
<i>Legionella pneumophila</i>		1.42×10^9 CFU/mL	No cross-reactivity	No interference
<i>Staphylococcus aureus</i>		1.42×10^8 CFU/mL	No cross-reactivity	No interference
<i>Staphylococcus epidermidis</i>		6.84×10^8 CFU/mL	No cross-reactivity	No interference
<i>Mycobacterium tuberculosis</i>		1.21×10^7 CFU/mL	No cross-reactivity	No interference
<i>Pseudomonas aeruginosa</i>		7.09×10^8 CFU/mL	No cross-reactivity	No interference
<i>Streptococcus salivarius</i>		1.35×10^8 CFU/mL	No cross-reactivity	No interference
<i>Corynebacterium diphtheriae</i>		3.43×10^7 CFU/mL	No cross-reactivity	No interference
<i>Escherichia coli</i>		8.16×10^8 CFU/mL	No cross-reactivity	No interference
<i>Lactobacillus Acidophilus</i>		6.58×10^7 CFU/mL	No cross-reactivity	No interference
<i>Moraxella catarrhalis</i>		5.92×10^7 CFU/mL	No cross-reactivity	No interference
<i>Neisseria elongata</i>		1.07×10^9 CFU/mL	No cross-reactivity	No interference
<i>Neisseria meningitidis</i> serogroup A		2.04×10^7 CFU/mL	No cross-reactivity	No interference
<i>Neisseria meningitidis</i> serogroup B		9.15×10^7 CFU/mL	No cross-reactivity	No interference
<i>Neisseria meningitidis</i> serogroup C		7.90×10^7 CFU/mL	No cross-reactivity	No interference
Epstein-Barr virus		0.97×10^7 cp/mL	No cross-reactivity	No interference
Mumps virus		9.55×10^5	No cross-	No

	TCID ₅₀ /mL	reactivity	interference
Cytomegalovirus (CMV)	1.13×10 ⁵ TCID ₅₀ /mL	No cross-reactivity	No interference
Measles virus	1.23×10 ⁷ TCID ₅₀ /mL	No cross-reactivity	No interference
* Note: one HKU1 NP clinical sample has been tested in 5 replicates			

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 for their impact on the performance of the iHealth COVID-19 Antigen Rapid Test.

The SARS-CoV-2 target concentration in the positive samples was approximately 2x 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 31 potentially interfering substances listed in the table below at the concentrations tested.

Endogenous Interfering Substances - Summary Results			
Substance	Concentration in negative/positive sample	Cross-reactivity	Interference
Throat lozenges, oral anesthetic and analgesic (Benzocaine)	3mg/mL	No cross-reactivity	No interference
Throat lozenges, oral anesthetic and analgesic (Menthol)	3mg/mL	No cross-reactivity	No interference
Sore throat spray (Phenol)	5% w/v	No cross-reactivity	No interference
Mucin: bovine submaxillary gland, type I-S or pooled mucous (Purified mucin protein)	2.5 mg/mL	No cross-reactivity	No interference
Whole Blood (human)	2.5%	No cross-reactivity	No interference
Leukocytes	4.8×10 ⁶ cells/mL	No cross-reactivity	No interference
Zinc (common ingredient in many nasal sprays)	5% v/v	No cross-reactivity	No interference
Nasal drops (Phenylephrine)	15% v/v	No cross-reactivity	No interference
Nasal sprays (Cromolyn)	15% v/v	No cross-reactivity	No interference
Afrin (Oxymetazoline)	15% v/v	No cross-reactivity	No interference
Saline nasal spray (Sodium chloride with preservatives)	15% v/v	No cross-reactivity	No interference

Endogenous Interfering Substances - Summary Results			
Substance	Concentration in negative/positive sample	Cross-reactivity	Interference
Nasal corticosteroids (Beclomethasone dipropionate)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Dexamethasone)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Flunisolide)	15% v/v	No cross-reactivity	No interference
Nasocort Allery 24 hour (Triamcinolone)	15% v/v	No cross-reactivity	No interference
Rhinocort (Budesonide /Glucocorticoid)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Mometasone furoate)	15% v/v	No cross-reactivity	No interference
Nasal corticosteroids (Fluticasone Propionate)	15% v/v	No cross-reactivity	No interference
(Homeopathic Luffa operculata Galphimia glauca)	1.25%	No cross-reactivity	No interference
Nasal gel (Luffa operculata sulfur)	1.25%	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash (Galphimia glauca)	15% v/v	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash (Histaminum hydrochloricum)	15% v/v	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash (Alkalol)	15% v/v	No cross-reactivity	No interference
Homeopathic allergy relief, or nasal wash (Zicam)	15% v/v	No cross-reactivity	No interference
Anti-viral drugs (Tamiflu)	5mg/mL	No cross-reactivity	No interference
Anti-viral drugs (Remdesivir)	5mg/mL	No cross-reactivity	No interference
Anti-viral drugs (Molnupiravir)	5mg/mL	No cross-reactivity	No interference
Antibiotic, nasal ointment (Mupirocin)	10mg/mL	No cross-reactivity	No interference
Hand sanitizer	15% v/v	No cross-reactivity	No interference
Hand soap	15% v/v	No cross-reactivity	No interference
Biotin*	200 ng/mL	No cross-reactivity	No interference

* Interference (false negative results) was observed for concentrations of Biotin greater than 200 ng/mL. Users who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin oral supplements should not use this test. Similarly, individuals who use topical products with biotin should not use this test.

High Dose Hook Effect

There was no High Dose Hook effect observed with the test at 3.98×10^6 TCID₅₀/mL, corresponding to 300×LOD, which is the highest concentration that was tested.

Inclusivity (Analytical Reactivity)

The analytical reactivity of the monoclonal antibodies targeting SARS-CoV-2 in the iHealth COVID-19 COVID-19 Antigen Rapid Test was evaluated with the currently available SARS-CoV-2 strains using a dilution series. Concentrations listed in the table below indicate the lowest detectable concentrations for which all five (5) replicates were positive.

Inclusivity (Analytical Reactivity) - Summary Results	
SARS-CoV-2 Variant	Lowest Variant Concentration with 5/5 positive replicates [TCID₅₀/mL]
SARS-CoV-2 virus (USA-WA1/2020)	4.57×10^3
B.1.1.7 (Alpha)	9.55×10^3
B.1.351 (Beta)	3.80×10^3
P.1 (Gamma)	1.7×10^3
B.1.617.2 (Delta)	1.26×10^4
B.1.1.529 (Omicron)	5.01×10^2
BA.2. (Omicron)	1.0×10^3
BA.2.3 (Omicron)	1.17×10^3
BA.4 (Omicron)	6.31×10^3
BA.4.6 (Omicron)	1.00×10^4
BA.5(Omicron)	3.98×10^3
BQ.1(Omicron)	2.0×10^3
BQ.1.1(Omicron)	7.94×10^4
XBB (Omicron)	1.0×10^3

Precision/Reproducibility

The purpose of the study was to assess between-site and between-lot variability of three different lots of the iHealth COVID-19 Antigen Rapid Test. Three (3) levels of heat-inactivated SARS-CoV-2 were spiked in negative clinical matrix (NCM, Nasal fluid diluted in 1:3 Saline) as follows:

- A. Negative, NCM
- B. Low positive (1x LoD)
- C. Positive (3x LoD)

Sample panels for use on each day of the study were prepared at a central site, randomized and frozen at -70 °C for transport to the lab sites where they were thawed at room temperature before testing. The fresh frozen stability of the sample panel was confirmed by an appropriately designed fresh frozen study. The sample panel was tested in a blinded manner by three operators at three CLIA waived sites for 5 non-consecutive days.

Each operator applied 50 µL of each coded sample to each dry nasal swab. Then, the operator processed the sample per the IFU of the device. All three lots were tested by each operator on each testing day. Each sample level was tested in triplicate in each run per operator per day (i.e., 3 lots x 3 operators x 3 replicates/run x 5 days). A total of 405 tests were run for each concentration level in the panel.

The agreement of obtained results with expected results was 100% for all samples across all lots, operators, and days. Variability in results was not observed between the three independently manufactured lots. The results are summarized in the Table below:

Precision/Reproducibility Study - Summary Results			
Site	True Negative	Low Positive (1x LoD)	Positive (3x LoD)
Site 1 (External, 3 operators)	135/135	135/135	135/135
Site 2 (External, 3 operators)	135/135	135/135	135/135
Site 3 (External, 3 operators)	135/135	135/135	135/135
Total	405/405	405/405	405/405
% Agreement	100%	100%	100%
95% CI	99.1-100%	99.1-100%	99.1-100%

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.

GLOSSARY OF 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 damage



Manufacturer

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