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# iHealth COVID-19 Antigen Rapid Test


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




- FDA AUTHORIZED 15 MINS SELF-TEST
- EASY TO USE ZERO DISCOMFORT
- FOR AGES 2 AND ABOVE
- DETECT CURRENT AND NEW COVID VARIANTS

November 5, 2021

Jack Feng
iHealth Labs, Inc.
120 San Lucar Ct.
Sunnyvale, CA 94086

| | |
|---|---|
| Device: | iHealth COVID-19 Antigen Rapid Test |
| EUA Number: | EUA210470 |
| Company: | iHealth Labs, Inc. |
| Indication: | Non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with:<br><br>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.<br><br>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<br><br>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. |

Dear Mr. Feng:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to iHealth Labs, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the iHealth COVID-19 Antigen Rapid Test, used for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use" identified below.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

**I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

**II. Scope of Authorization**

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

**Authorized Product Details**

Your product 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.

[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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. Your product does not differentiate between SARS-CoV and SARS-CoV-2.

The SARS-CoV-2 nucleocapsid protein 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 your product 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 an individual with 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 the Centers for Disease Control and Prevention (CDC).

Your product is performed using anterior nasal (nares) swab samples from individuals aged 2 years or older. The individual using your product is instructed to download, register and log into the mobile application (App) and follow the step-by-step based instructions on the iHealth

COVID-19 Test App on a compatible smartphone.[5] When using your product, the individual first opens the foil pouch containing COVID-19 Test Card. The swab is then removed from its packaging and the individual collects an anterior nasal swab sample by inserting the swab into the nostril and firmly and slowly brushing the insides of the nasal wall in a circular motion at least 5 times, taking at least 15 seconds to collect the specimen, before repeating the process in the second nostril. The swab is then immediately inserted into the tube and stir at least 15 times. The swab is then removed while pressing against the sides of the tube and the tube capped with the cap. The liquid in tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in your product. Three drops of the solution are applied into the Sample Port of the COVID-19 Test Card. The individual then starts the 15 minute timer. If the extracted specimen contains SARS-CoV-2 antigens, a pink-to-purple T (Test) Line, along with a pink-to-purple C (Control) Line will appear on the COVID-19 Test Card indicating a positive result. This control line indicates that the sample has migrated across the membrane as intended and indicates that the test was correctly performed. Test results are interpreted visually after 15 minutes based on the presence or absence of visually detectable colored lines at the control line (C) and/or test line (T).

The iHealth COVID-19 Antigen Rapid Test includes the following materials or other authorized materials (as may be requested under Condition L below): COVID-19 Test Card(s), Nasal Swab(s), Tube(s) and the lay user "iHealth COVID-19 Antigen Rapid Test Instructions for Use."

Your product includes an internal control test line ("C") that must generate the expected result for a test to be considered valid, as outlined in the "iHealth COVID-19 Antigen Rapid Test Instruction for use" and the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use."

The labeling entitled "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use," the "iHealth COVID-19 Antigen Rapid Test Instruction for use," and the "iHealth COVID-19 Antigen Rapid Test" box labels (2, 5 or 40-pack) (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "iHealth COVID-19 Test" software App and the following fact sheet pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Professionals[6]: iHealth Labs, Inc. - iHealth COVID-19 Antigen Rapid Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable

[5] Compatible smartphone includes Apple iPhone running Operation System (iOS) 12 or later versions of the iOS, and Android Phones running Android 6.0 or later versions. Additional smartphone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition L. below.

[6] Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized "iHealth COVID-19 Antigen Rapid Test Instructions for Use " that will be available to end users as set forth in the Conditions of Authorization (Section IV).

federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

## III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

## IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

### iHealth Labs, Inc. (You) and Authorized Distributor(s)[7]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device

[7] "Authorized Distributor(s)" are identified by you, iHealth Labs, Inc., in your EUA submission as an entity allowed to distribute the iHealth COVID-19 Antigen Rapid Test.

including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "iHealth COVID-19 Antigen Rapid Test Instruction for use" for your product in the shipped kit using the "iHealth COVID-19 Antigen Rapid Test" box labels and electronically on your website(s).

C. You and authorized distributor(s) must maintain records of customer complaint files and report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you and authorized distributor(s) become aware.

D. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You and authorized distributor(s) 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.

**iHealth Labs, Inc. (You)**

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

K. You must make the authorized "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use" and the Fact Sheet for Healthcare Professionals electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use" and Fact Sheet for Healthcare Professionals in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

N. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[8] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling

[8] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

S. You must complete your previously agreed upon automatic test reporting-related software updates to the iHealth COVID-19 Test App within 3 months of this letter and notify DMD/OHT7-OIR/OPEQ/CDRH upon implementation. Upon implementation, you must ensure automatic test result reporting is available, using the iHealth COVID-19 Test App, to relevant public health authorities in accordance with local, state, and federal requirements.

T. You must submit to FDA a summary report within 90 calendar days of product launch summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the "iHealth COVID-19 Antigen Rapid Test Instructions for Use," along with any proposed corrective action, as necessary.

U. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUA-Reporting@fda.hhs.gov).

V. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

W. You must submit your product for any FDA-recommended independent evaluation to confirm the performance characteristics of your test, if requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

**Conditions Related to Printed Materials, Advertising and Promotion**

X. All descriptive printed matter, advertising, and promotional materials relating to the use

of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Y. No descriptive printed matter, advertising, or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

Z. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure

# FACT SHEET FOR HEALTHCARE PROVIDERS

**iHealth Labs Inc.** **November 5, 2021**

**iHealth® COVID-19 Antigen Rapid Test**

**Coronavirus Disease 2019 (COVID-19)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the iHealth® COVID-19 Antigen Rapid Test.

The iHealth® COVID-19 Antigen Rapid 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.

**All individuals who use this assay are required to receive and should carefully review the iHealth® COVID-19 Antigen Rapid Test Instruction for Use before they use the test.**

**What are the symptoms of COVID-19?**

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days. For further information on the symptoms of COVID-19 please see the link provided in the "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

**This Test is 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 symptoms of COVID-19 within the first seven (7) days of symptom onset, or 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.**

**What do I need to know about COVID-19 testing?**

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

- The iHealth® COVID-19 Antigen Rapid 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.

- The iHealth® COVID-19 Antigen Rapid 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.
- The iHealth® COVID-19 Antigen Rapid 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 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.

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). For additional information, refer to CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (see links provided in "Where can I go for updates and more information" section).

**What does it mean if the specimen tests positive for the virus that causes COVID-19?**

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The iHealth® COVID-19 Antigen Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

Test results are automatically reported through the "iHealth COVID-19 Antigen Rapid Test" App to relevant public health authorities in accordance with local, state, and federal requirements.

All healthcare providers must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

**What does it mean if the specimen tests negative for the virus that causes COVID-19?**

A negative test result for this test means that antigens

from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. In symptomatic patients, specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in "*Where can I go for updates and more information*" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in November 2020.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.

**What do I need to know about Serial Testing in Asymptomatic Individuals?**

In asymptomatic individuals, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risk of false negative results. Additional clinical studies are underway to assess the performance of rapid antigen tests when used with serial testing. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 antigen is present, but does not rule out coinfection with other pathogens.

Additional confirmatory testing with a molecular test for negative results may be necessary if there is a high

likelihood of SARS-CoV-2 infection, such as, an individual with a close contact with COVID-19 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. For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in "*Where can I go for updates and more information?*" section).

**What is an EUA?**

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or the authorization is revoked (after which the test may no longer be used).

**What are the approved available alternatives?**

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medicaldevices/device-advice-comprehensive-regulatoryassistance/medical-device-databases.

A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatoryand-policy-framework/emergency-use-authorization.

**Where can I go for updates and more information?**

***CDC webpages:***

**General:**
https://www.cdc.gov/coronavirus/2019-ncov/index.html

**Symptoms:**
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

**Healthcare Professionals:**
https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html

**Information for Laboratories:**
https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html

**Laboratory Biosafety:**
https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html

**Isolation Precautions in Healthcare Settings:**
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

**Specimen Collection:**
https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html

**Infection Control:**

https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

**Discontinuation of Isolation:**

https://www.cdc.gov/coronavirus/2019-ncov/hcp/dispositionin-home-patients.html

**FDA webpages:**

**General:** www.fda.gov/novelcoronavirus

**EUAs:(includes links to patient/individual fact sheets and manufacturer's instructions)**

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

**Distributor Contact Information:**

iHealth Labs, Inc.
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1-855-816-7705 www.ihealthlabs.com

# iHealth® COVID-19 Antigen Rapid Test

## Healthcare Provider Instructions for Use

Model: ICO-3000

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.

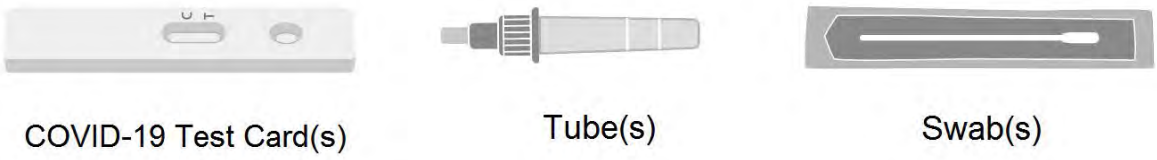
## PRODUCT DESCRIPTION

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

**Materials provided in the Test Kit:**

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

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




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 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)<br>Cause skin irritation(H315)<br>Cause serious eye damage(H318) | 0.1% |
| ProClin® 300 | Harmful if swallowed (H302)<br>Harmful if inhaled (H332)<br>Causes severe skin burns and eye damage (H314)<br>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 iHealth® COVID-19 Antigen Rapid Test is stable before 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**

Open the package, 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 the test, open the foil pouch of the COVID-19 Test Card.

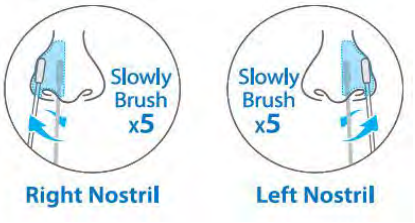

**2) Collect Sample**

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.

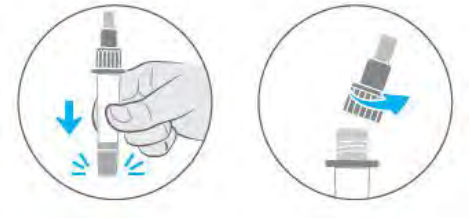
3. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 5 times. Using the same swab, repeat the same sample collection procedure for the other nostril. Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the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



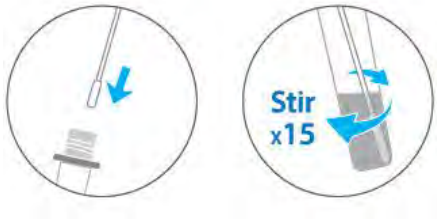

**Note:** Failure to swab properly may cause false negative results.

**3) Process Sample**

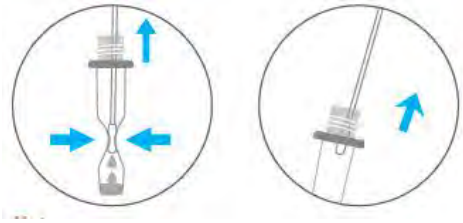
1. Tap the tube vertically on the table and twist the large orange cap to open the tube.



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

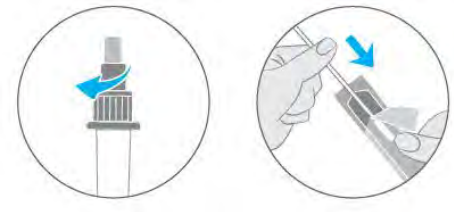



3. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.



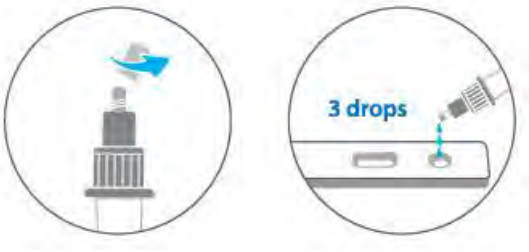
**Note**: If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

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, immediately after adding sample to the Sample Port. The result will be ready in 15 minutes.

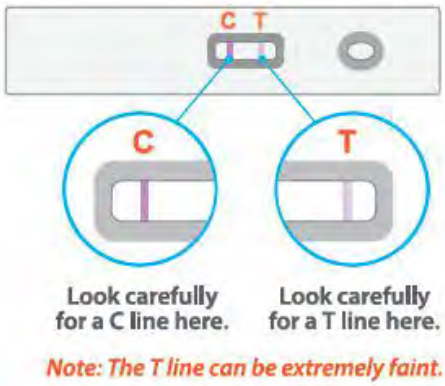

Note: DO NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

**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%<br>95% Confidence Interval: 81.4% to 98.4% | | | |
| Negative Agreement: (102/104) 98.1%<br>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.<br>[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 $20\times10^3$ $TCID_{50}$/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 | Human coronavirus 229E | $3.74\times10^4$ $TCID_{50}$/mL | No cross-reactivity | No interference |
| | Human coronavirus OC43 | $2.51\times10^5$ $TCID_{50}$/mL | No cross-reactivity | No interference |
| | Human coronavirus NL63 | $1.36\times10^5$ $TCID_{50}$/mL | No cross-reactivity | No interference |
| | MERS-coronavirus | $1.36\times10^5$ $TCID_{50}$/mL | No cross-reactivity | No interference |

| | | | | |
|---|---|---|---|---|
| same genetic family | | | | |
| High priority organisms likely in the circulating area | Adenovirus Type 1 | $2.04\times10^{7}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Adenovirus Type 4 | $2.09\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Adenovirus Type 7A | $2.04\times10^{7}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Adenovirus Type 8 | $1.13\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Adenovirus Type 31 | $1.13\times10^{5}$U/mL | No cross-reactivity | No interference |
| | Adenovirus Type 41 | $9.36\times10^{4}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Human Metapneumovirus 3(hMPV-3) Type B1 | $3.11\times10^{4}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Human Metapneumovirus 4(hMPV-4) Type B2 | $5.25\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Human Metapneumovirus 9(hMPV-9) Type A1 | $9.36\times10^{4}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Parainfluenza Virus Type 1 | $6.30\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Parainfluenza Virus Type 2 | $7.55\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Parainfluenza Virus Type 3 | $2.29\times10^{6}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Parainfluenza Virus Type 4A | $4.50\times10^{4}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Parainfluenza Virus Type 4B | $1.36\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Influenza A H3N2 Virus | $1.13\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Influenza B Virus | $3.74\times10^{4}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Enterovirus Type 68 | $7.55\times10^{5}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Enterovirus Type 71 | $2.29\times10^{6}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Respiratory Syncytial Virus Type A (RSV-A) | $1.90\times10^{6}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Respiratory Syncytial Virus Type B (RSV-B) | $3.74\times10^{4}TCID_{50}$/mL | No cross-reactivity | No interference |
| | Rhinovirus Type 1A | $9.36\times10^{4}TCID_{50}$/mL | No cross-reactivity | No interference |
| | *Haemophilus influenzae* | $6.75\times10^{8}$CFU/mL | No cross-reactivity | No interference |
| | *Streptococcus pneumoniae* | $1.80\times10^{8}$CFU/mL | No cross-reactivity | No interference |
| | *Streptococcus pyogenes* | $2.04\times10^{9}$CFU/mL | No cross-reactivity | No interference |
| | *Candida albicans* | $3.15\times10^{8}$CFU/mL | No cross-reactivity | No interference |
| | Pooled human nasal wash – representative of normal respiratory microbial flora | - | No cross-reactivity | No interference |
| | *Bordetella pertussis* | $3.22\times10^{9}$CFU/mL | No cross-reactivity | No interference |
| | *Mycoplasma pneumoniae* | $1.35\times10^{8}$CFU/mL | No cross-reactivity | No interference |
| | *Chlamydia pneumoniae* | $8.65\times10^{7}$IFU/mL | No cross-reactivity | No interference |
| | *Legionella pneumophila* | $7.10\times10^{9}$CFU/mL | No cross-reactivity | No interference |
| | *Staphylococcus aureus* | $3.23\times10^{9}$CFU/mL | No cross-reactivity | No interference |
| | *Staphylococcus epidermidis* | $1.24\times10^{9}$CFU/mL | No cross-reactivity | No interference |
| | *Mycobacterium tuberculosis* | $1.15\times10^{8}$CFU/mL | No cross-reactivity | No interference |
| | *Pneumocystis jirovecii* (PJP) | $3.17\times10^{8}$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, 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.

**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

 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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