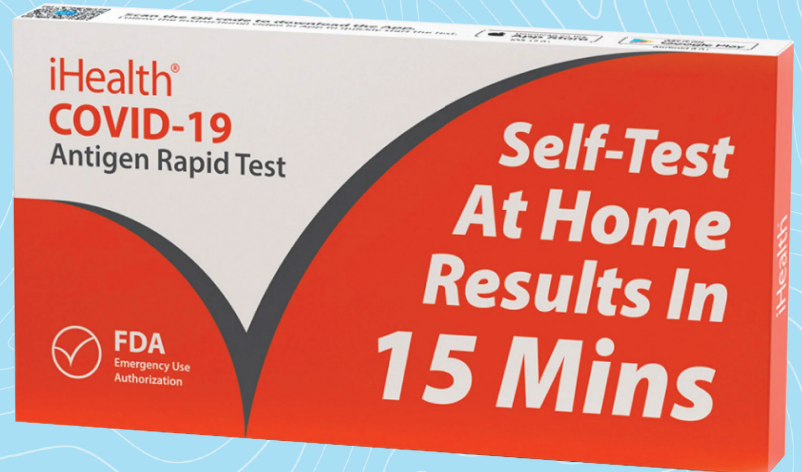




Meddek
Health Systems

COVID-19 Antigen

Rapid Diagnostic At-Home Test



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

- **Identify acute infection with 94% sensitivity and 98% specificity**
- **Rapid 15 Minute Result**
- **At-Home Use**
- **Anterior Nasal Swab Collection**
- **FDA EUA authorized**

EACH KIT CONTAINS

Test Device Nasal Swab
Extraction Vial



[MEDEKTESTKITS.COM](https://www.medektestkits.com)

📍 131 Waterman Ave
Mount Dora - FL 32757

☎ 888-996-3335



Product Information and Limitations of Sale:

- Results in 15 minutes w/ rapid testing
- Each set (box) has 1 individual test
- For use as an aid in identifying SARS-CoV-2, nucleocapsid protein antigen
- Only FDA EUA approved at-home testing kit for SARS-CoV-2

Governance

- A. The Flowflex COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID19 infection.
- B. This test is authorized for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-collected anterior nasal samples directly from individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2
- C. Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency issued on the web on March 16, 2020, by U.S. Food and Drug Administration (FDA") which may be found here:
<https://www.fda.gov/media/135659/download>
- D. The Flowflex COVID-19 Antigen Home Test is authorized for use using Anterior Nasal Swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

Compliance

- A. The Products are only for preliminary screening purposes and shall only be used to determine if additional testing is required.

Buyer Requirements

- A. Qualified parties who agree to follow the guidance in the Policy including, but not limited to, validation, FDA notification, reporting of results, Emergency Use Authorization, clinical testing and distribution.
- B. Payment must be made prior to shipment.



- C. Payments accepted: Wire transfer or Credit Card (AMEX Preferred).
- D. Order questions: Medek Health Systems, LLC - (352) 516-3072.
- E. Wire transfer questions: (352) 383-2111
- F. BANK: First National Bank of Mount Dora
ABA: 063104312
BENEFICIARY: Medek Health Systems, LLC
131 Waterman Avenue
Mount Dora, FL 32757
ACCOUNT NO: 30112085

Misc.

- A. FDA guidelines for the product are attached below.
- B. COVID-19 Antigen Rapid Diagnostic package insert is attached below.
- C. Fact sheet for healthcare providers is attached below.
- D. Fact sheet for patients is attached below.



December 22, 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:

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.

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.

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:

On November 5, 2021, based on your¹ request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the iHealth COVID-19 Antigen Rapid Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21

¹ For ease of reference, this letter will use the term “you” and related terms to refer to iHealth Labs, Inc.

U.S.C. §360bbb-3) for the indication stated in the letter.² Based on your request, FDA reissued the letter in its entirety with revisions incorporated on December 3, 2021.³

On December 11, 2021, you requested to amend your EUA. Based on that request, and having concluded that revising the December 3, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the December 3, 2021, letter in its entirety with the revisions incorporated.⁴ Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product⁵ is now authorized for use consistent with the indication described above.

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 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.⁶

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

² The November 5, 2021, letter authorized the iHealth COVID-19 Antigen Rapid Test for non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 with: (1) 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, (2) 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 and, (3) 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.

³ On December 3, 2021, the revisions to the November 5, 2021, letter and authorized labeling included: (1) offer the test kit with 1-pack option, in addition to the 2-, 5- or 40-pack options currently offered, (2) add additional model numbers to further increase production capacity, (3) update Condition of Authorization S. to maintain the original 3 month timeline afforded in the November 5, 2021, letter, and (4) updates to the Fact Sheet for Healthcare Providers to fix a minor error and update the date to match the date of reissuance.

⁴ The revisions to the December 3, 2021, letter and authorized labeling include: (1) modification of the test kit (including end user “iHealth COVID-19 Antigen Rapid Test Instruction for use,”) to offer two kit configurations: Test Set 1-includes a pre-filled Tube or Test Set 2 - empty Tube plus sealed Solution vial to further increase production capacity, (2) update Condition of Authorization S. below to maintain the original 3 month timeline afforded in the November 5, 2021, letter (and continued in December 3, 2021 letter) to 1.5 months, and (3) updates to the Fact Sheet for Healthcare Providers to fix a minor error and update the date to match the date of reissuance.

⁵ For ease of reference, this letter will use the term “your product” to refer to the iHealth COVID-19 Antigen Rapid Test for the indication identified above.

⁶ 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).

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.⁷

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. 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

⁷ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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.⁸ The individual will receive a kit with one of two possible configurations. When using your product, the individual first removes either: (1) Test Set 1 - the COVID-19 Test Card in Pouch, the Tube pre-filled with the extraction solution and the swab or (2) Test Set 2 - the COVID-19 Test Card in Pouch, empty Tube, sealed Solution and the swab. For Test Set 2, the individual proceeds to transfer the Solution into the empty Tube. For Test Set 1 and 2, the individual then 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

⁸ 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.

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), the end user “iHealth COVID-19 Antigen Rapid Test Instruction for use,” and either pre-filled Tube(s) (Test Set 1) or empty Tube(s) plus sealed Solution(s) (Test Set 2).

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 (1-, 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 Providers⁹: 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 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.

⁹ Note that the information typically found in a Fact Sheet for Individuals is contained in the authorized “iHealth COVID-19 Antigen Rapid Test Instruction for use ” that will be available to end users as set forth in the Conditions of Authorization (Section IV).

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)¹⁰

- 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 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 (1-, 2-, 5- or 40-pack) and electronically on your website(s).

¹⁰ “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.

- 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 Providers 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 Providers 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 traceability¹¹ 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 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.

¹¹ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- S. You must complete your previously agreed upon automatic test reporting-related software updates to the iHealth COVID-19 Test App within 1.5 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 Instruction 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.

iHealth® COVID-19 Antigen Rapid Test

Coronavirus
Disease 2019
(COVID-19)

December 22, 2021

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

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

FACT SHEET FOR HEALTHCARE PROVIDERS

iHealth Labs Inc.

December 22, 2021

iHealth® COVID-19 Antigen Rapid Test

Coronavirus
Disease 2019
(COVID-19)

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

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

FACT SHEET FOR HEALTHCARE PROVIDERS

iHealth Labs Inc.

iHealth® COVID-19 Antigen Rapid Test

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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 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.

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

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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-regulatory-and-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/lab/guidelines-clinical-specimens.html>

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

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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.

120 San Lucar Ct, Sunnyvale, CA 94086, USA

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

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088

FACT SHEET FOR PATIENTS

PHASE Scientific International, Ltd.

INDICAID™ COVID-19 Rapid Antigen Test

Updated: November 15, 2021

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the INDICAID™ COVID-19 Rapid Antigen Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:

<https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

What is the INDICAID™ COVID-19 Rapid Antigen Test?

The INDICAID™ COVID-19 Rapid Antigen Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19

in direct anterior nasal swab specimens. The presence of viral proteins indicate you may have been infected with the virus and are likely to be contagious.

Why was my sample tested?

You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or other risk factors and you are within the first five days of the onset of symptoms, or you are undergoing serial testing even though you do not have symptoms or other risk factors for COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your and others in your community.

What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19. Additional confirmatory testing with a molecular test for positive results may be necessary if there is a low likelihood of

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

What does it mean if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. If your test result is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than 5 days may be more likely to be negative compared to a molecular assay. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and false results may occur, repeated testing may identify more individuals with COVID-19 than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

What are the differences between antigen tests and other COVID-19 tests?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers).

AND

- Other symptoms have improved (for example, when your cough or shortness of breath has improved)
**Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation.

AND

- At least 10 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf>

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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Disease 2019
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Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying the emergency use of in vitro diagnostics, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There is not yet an approved available alternative antigen test for COVID-19. 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/medical-devices/device-advice-comprehensive-regulatory-assistance/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/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.



COVID-19 Antigen Rapid Test Instruction for use

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

This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). Please read all the information in this instruction for use before performing the test. For use with anterior nasal swab specimens. For In Vitro Diagnostic (IVD) Use Only.

Download App & Open App



Scan the QR code to download the "iHealth COVID-19 Antigen Rapid Test" App through your smartphone (iOS12.0+, Android 6.0+).

For a full list of compatible smartphones visit: <https://ihealthlabs.com/pages/support-ICO3000>

Register and Log into The App

Watch Video in App

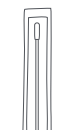
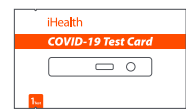
Each step has a corresponding instructional video in the App. Watch the video and perform the test according to the instructions.

Step by Step Instructions

1 Prepare Materials

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

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



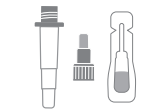
1 COVID-19 Test Card in Pouch

1 Pre Filled Tube

1 Swab

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

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

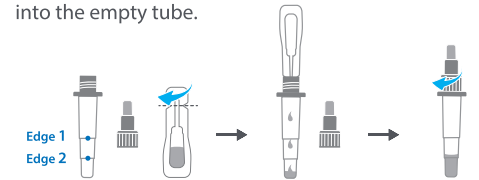


1 COVID-19 Test Card in Pouch

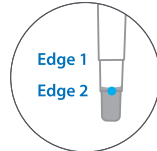
1 Empty Tube and 1 Sealed Solution

1 Swab

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



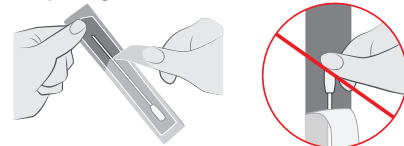
Please confirm the liquid level with or above Edge 2, then go to **Step 2 Collect Sample.**



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

2 Collect Sample

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

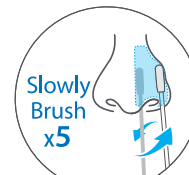


b. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.



Note: With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need to have a second person to hold the child's head while swabbing.

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



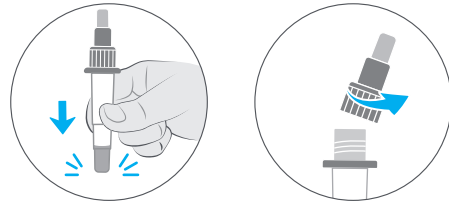
Note: Right Nostril

Left Nostril

Failure to swab properly may cause false negative results.

3 Process Sample

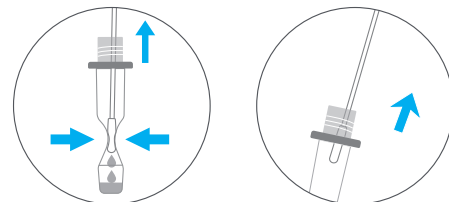
a. Tap the tube vertically on the table and twist the large orange cap to open the tube.



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

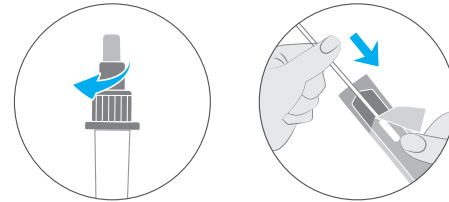


c. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.



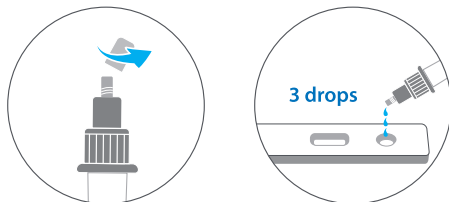
Note: If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

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



4 Add Sample

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



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

5 Wait 15 Minutes

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

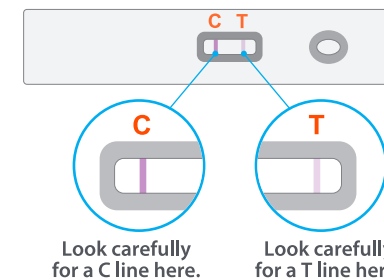


Note: Do NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

6 Read Result

Results should not be read after 30 minutes (Result shown at 2x magnification).

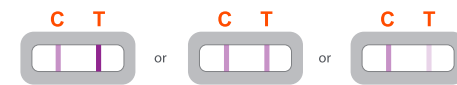
Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.



Note: The T line can be extremely faint.

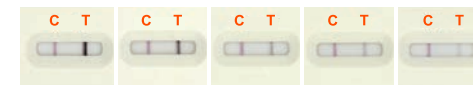
7 Test Result Explanation

Positive Result



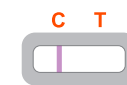
A POSITIVE result must show BOTH a C line and a T line. A positive result means that viral antigens from COVID-19 were detected and the individual is positive for COVID-19.

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 the kit components in trash.

9 Report Test Result

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

In the USA:

(1) This test is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness.
 (2) In USA - This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other virus or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.



COVID-19 Antigen Rapid Test Instructions for Use

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

This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA). Please read this instruction for use before using the test. For use with anterior nasal swab specimens. For In Vitro Diagnostic (IVD) Use Only.

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 seven (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 seven (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, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of 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 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.

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.

FREQUENTLY ASKED QUESTIONS

Will this test hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

What are the known and potential risks and benefits of this test?

Potential risks include:
– Possible discomfort during sample collection.
– Possible incorrect test results.
Potential benefits include:
– The results, along with other information, can help your healthcare provider make informed recommendations about your care.
– The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What is serial testing?

Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify individuals with COVID-19 more reliably than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional

testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. It is important that you work with your healthcare provider to help you understand the next steps you should take. 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.

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. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

What is the difference between an antigen and molecular test?

An antigen test, such as the iHealth® COVID-19 Antigen Rapid Test, detects proteins from the virus. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests are very specific for the virus, but not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider on whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen 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 a COVID-19.

How accurate is this test?

The iHealth® COVID-19 Antigen Rapid Test was compared to an FDA authorized molecular SARS-CoV-2 test using fresh self-collected or parent/guardian collected anterior nasal swab specimens and healthcare provider collected NP swab specimens. Subjects 2 years or older with or without symptoms participated in this study. The iHealth COVID-19 Antigen Rapid Test correctly identified 33 out of 35 (94.3%) of symptomatic positive samples and correctly identified 102 out of 104 (98.1%) of symptomatic negative samples in this study.

Please note that the accuracy of this test may decrease the longer you have had symptoms of infection, as the amount of virus in the sample decreases. In general, molecular RT-PCR tests are more sensitive than antigen tests and may be able to more reliably detect cases with less SARS-CoV-2, the virus that causes COVID-19.

What if you test positive?

A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine

how best to care for you based on your test result(s) along with your medical history, and your symptoms.

What if you test negative?

A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. If you receive a negative result, you should test again in 24-48 hours. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 status after testing or think you may need follow up testing, please contact your healthcare provider.

For other updated FAQ information, please see the company website: <https://www.ihealthlabs.com>

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

For up-to-date information on COVID-19, please visit the CDC COVID-19 website:

<https://www.cdc.gov/coronavirus/2019-ncov/index.html>

WARNINGS AND PRECAUTIONS

- 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.
- 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 for diagnosis of coronavirus infection by detecting COVID-19 antigen 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 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.
- 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 application (iHealth COVID-19 Antigen Rapid Test) and/or Instructions for Use.
- Once the COVID-19 Test Card is removed from the pouch, perform the test as soon as possible. Use the COVID-19 Test Card within 1 hour after opening the foil pouch.
- 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.
- Insert the swab into the tube right after taking the sample.
- 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.
- Be sure to read test result within 15-30 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 an allergic skin reaction in some people. 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.

STORAGE AND OPERATION CONDITIONS

Store iHealth® COVID-19 Antigen Rapid Test in a dry place between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. It is stable before the expiration date marked on the packaging.

HAZARDOUS INGREDIENTS FOR REAGENT SOLUTION

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

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

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Made in China

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