U.S. FOOD & DRUG ADMINISTRATION

February 10, 2023

Jack Feng
iHealth Labs, Inc.
150C Charcot Ave
San Jose, CA 95131

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, or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first seven (7) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests. This test can be performed with or without the supervision of a telehealth proctor.

Dear Mr. Feng:

On November 5, 2021, based on your[1] 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 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] and

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

December 22, 2021.[4] In addition, based on subsequent requests, FDA granted updates on March 29, 2022,[5] April 4, 2022,[6] July 8, 2022,[7] and January 11, 2023.[8] Further, FDA revised the authorized uses and established one additional Condition of Authorization requiring updates to product labeling regarding repeat, or serial, testing, for all currently authorized SARS-CoV-2 antigen tests on November 1, 2022.[9]

On November 8, 2022 and November 15, 2022, you requested to amend your EUA. Based on those requests, and having concluded that revising the December 22, 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 22, 2021, letter in its entirety with the revisions incorporated.[10] Pursuant to section 564 of the Act and the Scope of Authorization

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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] On December 22, 2021, the revisions to the December 3, 2021, letter and authorized labeling included: (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) an update to Condition of Authorization S. (from the December 3, 2021 letter) 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] On March 29, 2022, your request was granted to update the iHealth COVID-19 Antigen Rapid Test to extend the shelf-life expiration date of the iHealth COVID-19 Antigen Rapid Test to 9 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies.

[6] On April 4, 2022, your request was granted to (1) distribute the iHealth COVID-19 Antigen Rapid Test under the brand name "GoToKnow COVID-19 Antigen Rapid Test," (2) update the iHealth COVID-19 Test Application (App) to fulfill Condition of Authorization S. in the December 22, 2021 letter, and (3) fulfill Condition of Authorization T. in the December 22, 2021 letter with the results summarized in your 90-day report.

[7] On July 8, 2022, your request was granted to update the iHealth COVID-19 Antigen Rapid Test to extend the shelf-life expiration date of the iHealth COVID-19 Antigen Rapid Test to 12 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies.

[8] On January 11, 2023, your request was granted to update the iHealth COVID-19 Antigen Rapid Test to extend the shelf-life expiration date of the iHealth COVID-19 Antigen Rapid Test to 15 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies.

[9] The Repeat Testing Revision Letter - November 1, 2022, can be accessed at: https://www.fda.gov/media/162799/download.

[10] The revisions to the December 22, 2021, letter and authorized labeling include: (1) incorporating your response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) updating the intended use for the iHealth COVID-19 Antigen Rapid Test to include "*This test can be performed with or without the supervision of a telehealth proctor*" to facilitate a telehealth proctor supervised workflow, (3) adding Conditions of Authorization I. and J. associated with the telehealth proctor supervised workflow, (4) adding Condition of Authorization O. to facilitate requesting additional box labels, (5) deleting Conditions of Authorization S. and T. in the December 22, 2021 letter as fulfilled through data submitted to the agency, (6) deleting Condition of Authorization Q. in the December 22, 2021 letter in accordance with the Repeat Testing Revision Letter dated November 1, 2022, (7) addition of Condition of Authorization P. related to meeting the requirements of either ISO 13485 or 21 CFR 820 and removal of Conditions of Authorization related to meeting subparts of 21 CFR 820, (8) remove Waiver of Certain Requirements section (due to addition of Condition P.), (9) updating the Fact Sheet for Healthcare Providers with the revised intended use, (10) adding additional box labels for 4- and 6-packs, (11) updating the iHealth COVID-19 Antigen Rapid Test outer

(Section II) and Conditions of Authorization (Section III) of this reissued letter, your product[11] 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.[12]

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.[13]

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box labels to include information specific for the telehealth proctor supervised workflow and include either "made in China" or by "iHealth Manufacturing Inc." options, (12) update the authorized labeling for the brand name "GoToKnow COVID-19 Antigen Rapid Test," to be consistent with the updates made to the iHealth COVID-19 Antigen Rapid Test, with the exception of adding a telehealth proctor supervised workflow, and (13) updating the Letter of Authorization for consistency with language used in more recent authorizations.

[11] 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.

[12] 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).

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

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 virus. 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. This test is authorized for individuals with symptoms of COVID-19 within the first seven (7) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. This test can be performed with or without the supervision of a telehealth proctor. 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 (nares) 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.

All negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control measures, such as isolating from others and wearing a mask. 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. 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 and to receive appropriate medical care 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.[14]

The iHealth COVID-19 Antigen Rapid Test includes the materials or other authorized materials (as may be requested under Condition N. and O. below), required to collect the anterior nasal (nares) swab sample and perform the test procedure, as described in the "iHealth COVID-19 Antigen Rapid Test Instruction for use" and the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider 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[15] (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 III), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers[16]: 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 III) 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

[14] 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 N. below.
[15] The "iHealth COVID-19 Antigen Rapid Test" box labels include boxes for 1-, 2-, 4-, 5-, 6- or 40-pack kits, manufactured either "in China" or by "iHealth Manufacturing Inc." and "iHealth COVID-19 Antigen Rapid Test" box labels for additional test kits numbers/options as may be requested, and for which you receive appropriate authorization, in accordance with Condition O. below. The iHealth COVID-19 Antigen Rapid Test kits numbers/options are described in the "iHealth COVID-19 Antigen Rapid Test Healthcare Provider Instructions for Use".
[16] 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).

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 III). 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. 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)[17]

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 (see Footnote 15) 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.

[17] "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.

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/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.

I. You and authorized distributor(s) must ensure that any telehealth proctor, whether hired by you or a third-party, is appropriately trained with training materials as agreed to with DMD/OHT7/OPEQ/CDRH, on the processes for providing instructions and documenting results, with respect to use of your product.

J. You and authorized distributor(s) must ensure that any telehealth proctor provider that provides services related to use of your product has processes in place to track and promptly report any adverse events or other performance concerns about the use of your product to you. You must ensure that such telehealth provider adequately trains appropriate personnel about such processes.

iHealth Labs, Inc. (You)

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

L. 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.

M. 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.

N. 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/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

O. You may request new box labels to allow additional test kits numbers/options for your product. Such additional labeling requests to this EUA should be submitted to and require concurrence of DMD/OHT7/OPEQ/CDRH prior to implementation.

P. Within three months of the date of this letter, you must establish and maintain a quality system that is appropriate for your product's design and manufacture, and that meets the requirements of either the 2016 edition of ISO 13485 or 21 CFR Part 820. You must submit to DMD/OHT7-OIR/OPEQ/CDRH a notification of compliance within this three-month timeframe.

Q. If requested by FDA, you must submit associated documents or records related to your quality system for FDA review within 48 hours of the request.

R. 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.

S. 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.

T. You must evaluate the analytical limit of detection and assess traceability[18] 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/OPEQ/CDRH.

U. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7/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

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

testing if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

V. 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).

W. 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/OPEQ/CDRH.

X. 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/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

Y. 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.

Z. 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.

AA. 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.

IV. 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,

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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure