April 28, 2023

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

Device:	iHealth COVID-19 Antigen Rapid Test Pro
EUA Number:	EUA210536
Company:	iHealth Labs, Inc.
Indication:	Qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 in direct anterior nasal (nares) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from 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. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Mr. Feng:

On January 14, 2022, 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 Pro, 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] In addition, FDA revised the

[1] For ease of reference, this letter will use the term "you" and related terms to refer to iHealth Labs, Inc.
[2] The January 14, 2022, letter authorized the iHealth COVID-19 Antigen Rapid Test Pro for the qualitative detection of of SARS-CoV-2 nucleocapsid antigens from direct anterior nasal swab samples from individuals who are suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset or from individuals 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. Emergency use of the test was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a,

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.[3] Further, based on a subsequent request, FDA granted an update on December 27, 2022.[4]

On November 14, 2022, you requested that CDRH amend your EUA. Based on this request, and having concluded that revising the January 14, 2022, 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 January 14, 2022, letter in its entirety with the revisions incorporated.[5] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section III) of this reissued letter, your product[6] is now authorized for use consistent with the indication described above.

On February 4, 2020, as amended on March 15, 2023, 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, or a significant potential for a public health emergency, that affects, or 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.[7]

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that meet the requirements to perform moderate, high, or waived complexity tests. The iHealth COVID-19 Antigen Rapid Test Pro was also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

[4] On December 27, 2022, your request was granted to update the iHealth COVID-19 Antigen Rapid Test Pro to extend the shelf-life expiration date to 15 months when stored at 2˚C – 30˚C, based on the results of your ongoing stability studies.

[5] The revisions to the January 14, 2022, 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) include with results of additional reactivity studies, (3) updating the iHealth COVID-19 Antigen Rapid Test Pro outerbox labels to include either "made in China" or by "iHealth Manufacturing Inc." options, (4) deleting Condition of Authorization U. in the January 14, 2022, letter as fulfilled, (5) deleting Condition of Authorization T. in the January 14, 2022 letter in accordance with the Repeat Testing Revision Letter dated November 1, 2022, (6) addition of Conditions of Authorization L. and M. (below) 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, (7) remove the Waiver of Certain Requirements section (due to addition of Condition L.), (8) updating the Fact Sheet for Healthcare Providers and Fact Sheet for Patients with the revised intended use and for consistency with more recent authorizations, and (9) updating the Letter of Authorization for consistency with language used in more recent authorizations.

[6] For ease of reference, this letter will use the term "your product" to refer to the iHealth COVID-19 Antigen Rapid Test Pro for the indication identified above.

[7] 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*. February 4, 2020. 85 FR 7316 (February 7, 2020). U.S. Department of Health and Human Services, *Amended Determination of a Public Health Emergency or Significant Potential for a Public*

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 Pro 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.[8]

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 immunoassay intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 in direct anterior nasal (nares) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from 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. Your product does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection.

Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b). March 15, 2023. 88 FR 16644 (March 20, 2023) ("Amended Determination").

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

Positive results indicate the presence of the viral antigens, but clinical correlation with patient 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 and the agent detected may not be the definitive cause of disease.

All negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results 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 measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Testing of anterior nasal (nares) swab specimens using your product, as outlined in the "iHealth COVID-19 Antigen Rapid Test Pro Instructions for Use," is limited to laboratories certified under CLIA that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The direct anterior nasal swab specimen is tested with your product according to the "iHealth COVID-19 Antigen Rapid Test Pro Instructions for Use." The iHealth COVID-19 Antigen Rapid Test Pro includes the materials or other authorized materials (as may be requested under Condition P. below) necessary to collect, process and test anterior nasal swab specimens as described in the "iHealth COVID-19 Antigen Rapid Test Pro Instructions for Use." Your product also includes the use of an optional mobile application (App), the iHealth COVID-19 Test Pro App, that includes step-by-step based instructions and can be downloaded onto a compatible smartphone.[9]

Your product requires various types of quality control, including the procedural internal control that is built in the "control line" of the test device and the positive and negative controls, or other authorized control materials (as may be requested under Condition P. below), that are processed in the same way as the patient samples. All controls must generate expected results in order for a test to be considered valid, as outlined in the "iHealth COVID-19 Antigen Rapid Test Pro Instructions for Use" and the "iHealth COVID-19 Antigen Rapid Test Pro External Control Swabs" instructions for use.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the "iHealth COVID-19 Antigen Rapid Test Pro Instructions for Use."

The labeling entitled "iHealth COVID-19 Antigen Rapid Test Pro Instructions for Use," "iHealth COVID-19 Antigen Rapid Test Pro Quick Reference Instructions," "iHealth COVID-19 Antigen

[9] 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 O. below.

Rapid Test Pro External Control Swabs" instructions for use (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), and the following fact sheets 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 Providers: iHealth Labs, Inc. - iHealth COVID-19 Antigen Rapid Test Pro
- Fact Sheet for Patients: iHealth Labs, Inc. - iHealth COVID-19 Antigen Rapid Test Pro

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section III), is authorized to be distributed to and used by authorized laboratories 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.

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)[10]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (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 your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) will include a physical copy of the authorized "iHealth COVID-19 Antigen Rapid Test Pro Quick Reference Instructions" with each shipped kit of your product, to authorized laboratories, and must make the authorized "iHealth COVID-19 Antigen Rapid Test Pro Instructions for Use," electronically available with the opportunity to request a copy in paper form, and after such request, promptly provide the requested information without additional cost.

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

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number distributed.

G. You and authorized distributor(s) must collect information on the performance of your product. You will report 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-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

[10] "Authorized Distributor(s)" are identified by you, iHealth Labs, Inc., in your EUA submission as an entity allowed to distribute your product.

H. 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.

I. You and authorized distributor(s) must make available the control material, "iHealth COVID-19 Antigen Rapid Test Pro External Control Swabs" with the "iHealth COVID-19 Antigen Rapid Test Pro External Control Swabs" instructions for use, or other authorized control materials (as may be requested under Condition P. below), at the same time as your product.

iHealth Labs, Inc. (You)

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

K. 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 (e.g., Fact Sheets).

L. 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/OPEQ/CDRH a notification of compliance within this three-month timeframe.

M. 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.

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

O. If requested by FDA, you must submit 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 it within 48 hours of the request.

P. 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.

Q. You must evaluate the analytical limit of detection and assess traceability[11] of your product with any FDA-recommended reference material(s), if requested by FDA. After submission to and review and concurrence with the data by FDA, you must update 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/OPEQ/CDRH.

R. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

S. 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-EUAReporting@fda.hhs.gov).

T. 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.

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

Authorized Laboratories

W. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

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

X. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

Y. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

Z. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

AA. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov), and you (via frr.covid19@ihealthlabs.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

BB. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

iHealth Labs, Inc. (You), Authorized Distributor(s) and Authorized Laboratories

CC. You, authorized distributor(s), and authorized laboratories 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.

Conditions Related to Printed Materials, Advertising and Promotion

DD. 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.

EE. 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.

FF. 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 for use by authorized laboratories;

- 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure