October 22, 2020

Gloria Lee, Ph.D.
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Helix OpCo LLC
101 S. Ellsworth Ave. Suite 350
San Mateo, CA 94491

Device:	Helix COVID-19 Test
Company:	Helix OpCo LLC
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (nasopharyngeal swabs, oropharyngeal (throat) swab, mid-turbinate nasal swabs and anterior nasal swabs) from individuals suspected of COVID-19 by their healthcare provider (HCP). Qualitative detection of nucleic acid from SARS-CoV-2 in self-collected anterior nasal swab specimens (supervised collected in transport media or unsupervised collected in saline in a community-based distribution setting) from any individual, including individuals without symptoms or other reasons to suspect COVID-19 using the Helix Self-Collection Kit when directly ordered and provided by a HCP. Testing is limited to the Helix Laboratory located at 9875 Towne Centre Drive, San Diego, CA 92121 which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Dr. Lee:

On July 23, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of your product,[2] for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (nasopharyngeal swabs, oropharyngeal (throat) swab, mid-turbinate nasal swabs and anterior nasal swabs) from individuals suspected of COVID-19 by their healthcare provider pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to the Helix

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Helix OpCo LLC ("Helix").
[2] For ease of reference, this letter will use the term "your product" to refer to the Helix COVID-19 Test used for the indication identified above.

Laboratory located at 9875 Towne Centre Drive, San Diego, CA 92121 which is certified under CLIA, 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

On September 11, 2020, you requested to amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the July 23, 2020 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 July 23, 2020, letter in its entirety with the revisions incorporated.[3] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, this test is now intended for the indications 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.[4]

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 contained in the EUA Summary (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;

[3] The revisions to the July 23, 2020, letter include: (1) revisions to the indication to include qualitative detection of SARS-CoV-2 in self-collected anterior nasal swab specimens (supervised specimens collected in transport media or unsupervised specimens collected in saline in a community-based distribution setting) from any individual, including individuals without symptoms or other reasons to suspect COVID-19 using the Helix Self Collection Kit when directly ordered and provided by a HCP, (2) revisions to the EUA Summary to reflect the new indication and correct typographical errors (3) revisions to fact sheets to reflect asymptomatic specimen testing and additional warnings/precautions around the absence of an internal control when self-collected specimens are tested and (4) revisions to the intended use to reflect the new indication and language in more recent authorizations.

[4] 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).

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.[5]

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 qualitative test for the detection of nucleic acid from SARS-CoV-2 in respiratory specimens listed in the indication above collected from individuals suspected of COVID-19 by their healthcare provider.

Your test is also authorized for use with self-collected anterior nasal swab specimens (supervised specimens collected in transport media or unsupervised specimens collected in saline in a community-based distribution setting) from any individual, including individuals without symptoms or other reasons to suspect COVID-19 using the Helix Self-Collection Kit when directly ordered and provided by a HCP. Specimens collected using the Helix Self-Collection Kit will be dropped off at the designated location and transported via courier for testing.

Testing is limited to the Helix Laboratory located at 9875 Towne Centre Drive, San Diego, CA 92121 which is certified under CLIA, 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Nasal swab specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

To perform the Helix COVID-19 Test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from the specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument described in the authorized labeling (described below).

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

Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request. The Helix Self-Collection Kit provides specimen collection materials and materials to safely mail specimens to the Helix Laboratory for testing using the Helix COVID-19 Test. Individuals should follow all specimen collection and mailing instructions provided in the kit.

Your product requires the following control materials, or other authorized control materials (as specified under Condition K below), that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized procedures submitted as part of the EUA request:

- Internal Positive Control (IPC) – MS2 phage control which is required as an extraction positive control. This is spiked into every well prior to extraction.

- External positive control - TaqPath COVID-19 Control contains the SARS-CoV-2 RNA genomic regions targeted by the kit. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions. One positive control will be included with each 384 well plate.

- Negative Control - molecular-grade, nuclease-free, non-DEPC-treated water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents. One negative control will be included on each 384 well plate.

The above described product is authorized to be accompanied with the labeling submitted as part of the EUA request (listed below), and as described in the EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Helix OpCo LLC – Helix COVID-19 Test
- Fact Sheet for Patients: Helix OpCo LLC – Helix COVID-19 Test

The above described product, when accompanied by the "Helix COVID-19 Test" laboratory procedures, the EUA Summary (identified above), the "Helix Self-Collection Kit Instructions (Unsupervised)," the "Helix Specimen Receipt, Quality Control, and Processing" instructions and the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be 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.

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, and storage of your product.

IV. Conditions of Authorization

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

Helix OpCo LLC (You)

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (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 will inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

C. You will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

D. You will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

E. You will make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

F. You 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.

G. You will use your product as outlined in the authorized labeling. Deviations from the authorized laboratory procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and/or authorized materials required to use your product are not permitted.

H. You will make available all instructions related to the self-collection of anterior nasal swab specimens using the Helix Self-Collection Kit, with the kit.

I. When testing authorized specimens self-collected using self-collection kits authorized for use with your product you must follow the authorized specimen accessioning protocols when accepting specimens for testing.

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

K. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) of your product. Such requests should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

L. You will evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA[6]. After submission to FDA and FDA's review of and concurrence with the data, FDA will update the EUA summary to reflect the additional testing.

M. You will submit to FDA a summary report within 30 calendar days of this letter

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your authorized test.

summarizing the results of all testing performed using all anterior nasal specimens collected with the Helix Self-Collection Kit during that timeframe, including how many kits were prescribed and used, how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized self-collection kit.

N. You will submit to FDA a summary report within 30 calendar days of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH) that summarizes the results of any testing performed using anterior nasal specimens collected in saline (unsupervised) during that timeframe, including how many kits were prescribed and used for unsupervised collection, how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection and the positivity rate of unsupervised specimens collected with the collection device.

O. You will evaluate the invalid rate for 5000 specimens in saline from unsupervised collection using a daily separate plate of RPP30 in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to FDA and FDA's review of and concurrence with the data, you will update 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.

P. You will evaluate the clinical performance of your product with specimens collected from asymptomatic individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH. After submission to FDA and FDA's review of and concurrence with the data, you will 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.

Q. When testing authorized specimens self-collected using the Helix Self-Collection Kit, or any other authorized self- specimen collection kit with your product, you must include in the test report for specific patients whose specimen(s) were self-collected the following limitation: *Specimens that are self-collected were not tested with an internal control to confirm that the specimen was properly collected. As such, unsupervised self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly."*

R. You will have a process in place to track adverse events, including any occurrence of false results with your product and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should also be immediately reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

S. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when

handling this product, and use your product in accordance with the authorized laboratory procedure.

T. You will 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.

U. You will additionally track adverse events associated with the use of the Helix Self-Collection Kit or any other self-collection kits authorized for use with your product, including occurrences of false results, and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

Conditions Related to Printed Materials, Advertising and Promotion

V. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.

W. No descriptive printed matter, including 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.

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

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test 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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure