July 8, 2021

Peggy Newell
Deputy Provost
Office of the Provost
Harvard University
Massachusetts Hall
Cambridge, MA 02138

Device:	Quaeris SARS-CoV-2 Assay
EUA Number:	EUA210157
Laboratory:	Harvard University Clinical Laboratory (HUCL)
Indication:	Qualitative detection of nucleic acid from the SARS-CoV-2 virus in self-collected (unsupervised) or healthcare provider-collected anterior nasal swab specimens at home or in a healthcare setting (which includes in a community-based setting) using the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) by individuals 18 years of age or older suspected of COVID-19 when determined to be appropriate by a healthcare provider. Emergency use of this test is limited to the authorized laboratory.
Authorized Laboratory:	Testing is limited to Harvard University Clinical Laboratory (HUCL), located at B139 Northwest Laboratories, 52 Oxford Street, Cambridge MA 02138, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Peggy Newell:

On May 21, 2021, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Quaeris SARS-CoV-2 Assay for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in self-collected (unsupervised) or healthcare provider-collected anterior nasal swab specimens at home or in a healthcare setting (which includes in a community-based setting) using the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) by individuals 18 years of age or older suspected of COVID-19 when determined to be appropriate by a healthcare provider pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Harvard University Clinical Laboratory (HUCL).

Testing was limited to Harvard University Clinical Laboratory (HUCL), located at B139 Northwest Laboratories, 52 Oxford Street, Cambridge MA 02138, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

On June 29, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on your request and having concluded that revising the May 21, 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 May 21, 2021, letter in its entirety with the revisions incorporated.[2] 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 product[3] is hereby 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.[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:

[2] The revisions to the May 21, 2021 letter and authorized labeling include: (1) addition of additional site-specific self-collection instructions (mail-in and on-site) for the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) to be used at Massachusetts Institute of Technology, (2) revise the HCP fact sheet with updated web links, and (3) update the Letter of Authorization to include the additional self-collection instructions for use and update the Conditions of Authorization to add additional conditions related to testing of circulating variants (new Conditions U and V).

[3] For ease of reference, this letter will use the term "your product" to refer to the Quaeris SARS-CoV-2 Assay used for the indication identified above

[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).

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.[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 real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in self-collected (unsupervised) or healthcare provider-collected anterior nasal swab specimens at home or in a healthcare setting (which includes in a community-based setting) using the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) by individuals 18 years of age or older suspected of COVID-19 when determined to be appropriate by a healthcare provider. Specimens collected using the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) can be transported dry for testing.

The SARS-CoV-2 nucleic acid is generally detectable in anterior nasal swab 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.

The COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) includes the following materials or other authorized materials (as may be requested under Condition O. below):

- For return of collected specimens at a designated on-site collection location:

This kit is not for shipping of specimens to the laboratory and must be returned to a designated on-site collection location (e.g., on a university campus). This kit consists of a sterile packaged medical grade hydrophobic polymer nasal swab with a threaded lid attached, a collection tube with a threaded end, a barcode card, a sealable biohazard bag, and instructions for use.

- For return of samples to the laboratory by shipping:

This kit consists of a sterile packaged medical grade hydrophobic polymer nasal swab with a threaded lid attached, a collection tube with a threaded end, a barcode card, instructions for use, a

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

biohazard bag, a rigid outer safety box with UN3373 marking, an absorbent pad, and a shipping envelope with a prepaid return label.

Individuals must follow all specimen collection and mailing/return instructions provided with the collection kit.

The Quaeris SARS-CoV-2 Assay includes the following materials or other authorized materials: Luna Universal Probe one-Step RT-qPCR kit, primers, RNaseIn Plus RNase inhibitor, and Positive Control. To use your product, SARS-CoV-2 nucleic acid from anterior nasal swab specimens is reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition O. below), that are processed in the same way as the patient specimens 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 labeling:

- Negative Template Control (NTC1) – phosphate buffered saline used to monitor for cross contamination during sample inactivation.
- Negative Template Control (NTC2) – nuclease-free water used to monitor for cross contamination during rRT-PCR set-up.
- Positive Control – molecular grade nuclease-free water spiked with a mixture of control plasmids; used to monitor the integrity of the rRT-PCR reagents and process.
- Endogenous Internal Control – RNAse P used to verify proper assay set-up, sample integrity, and collection of biological material.

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 authorized labeling.

The above described product is authorized to be accompanied with the laboratory procedures (described below), the EUA Summary (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 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: Harvard University Clinical Laboratory (HUCL) - Quaeris SARS-CoV-2 Assay
- Fact Sheet for Patients: Harvard University Clinical Laboratory (HUCL) - Quaeris SARS-CoV-2 Assay

The above described product, when accompanied by the "Harvard University Clinical Laboratory Quaeris SARS-Cov-2 PCR Assay SOP" laboratory procedures, EUA Summary, and two fact sheets, is authorized to be used by the authorized laboratory under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL), when accompanied by the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory On-Site Instructions," the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory Mail-In Instructions," the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory On-site Instructions for Massachusetts Institute of Technology," or "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory Mail-in Instructions for Massachusetts Institute of Technology," is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" refers to the "Harvard University Clinical Laboratory Quaeris SARS-Cov-2 PCR Assay SOP" laboratory procedures, EUA Summary, two fact sheets, "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory On-Site Instructions," the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory Mail-In Instructions," the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory On-site Instructions for Massachusetts Institute of Technology," and the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory Mail-in Instructions for Massachusetts Institute of Technology."

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, distribution 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:

Harvard University Clinical Laboratory (HUCL), (You) and Authorized Distributor(s)[6]

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 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 and authorized distributor(s) must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

C. You and authorized distributor(s) must make available the relevant instructions in the shipped kit, i.e., "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory On-Site Instructions," the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory Mail-In Instructions," the "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory On-site Instructions for Massachusetts Institute of Technology," or "COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory Mail-in Instructions for Massachusetts Institute of Technology," and make all instructions available on your website.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) is distributed.

E. You and authorized distributor(s) must maintain customer complaint files concerning the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) on record. You must report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

F. 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.

G. You and authorized distributor(s), must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such

[6] "Authorized Distributor(s)" are identified by you, Harvard University Clinical Laboratory (HUCL), in your EUA submission as an entity allowed to distribute the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL).

records will be made available to FDA for inspection upon request.

Harvard University Clinical Laboratory (HUCL), (You)

H. You must notify FDA of any authorized distributor(s) of the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL), including the name, address, and phone number of any authorized distributor(s).

I. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. You must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

K. You must notify relevant public health authorities of your intent to run your product.

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

M. You must 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.

N. You must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted. When testing self-collected specimens using your product, you must have in place a suitable specimen receipt and accessioning SOP.

O. 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 not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted 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) and require appropriate authorization from FDA prior to implementation.

P. You must evaluate the analytical limit of detection and assess traceability[7] of your

[7] 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 product.

product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must 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 submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL), for use with your product during that timeframe, including how many kits were activated via the online portal, purchased from an authorized distributor for home collection, or collected at a community-based site or distribution center, 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.

R. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL), and report any such events 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).

S. You must collect information on the performance of your product. You will report to DMD/OHT7-OIR/OPEQ/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.

T. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

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.

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.

Conditions Related to Printed Materials, Advertising and Promotion

W. 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 meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

X. 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.

Y. 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 for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure