November 8, 2021

Aarthi Srinivasan
Regulatory Affairs
Verily Life Sciences
269 E Grand Ave.
South San Francisco, CA 94080

Device:	Verily COVID-19 RT-PCR Test
EUA Number:	EUA202054
Laboratory:	Verily Life Sciences
Indications:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 anterior nasal, mid-turbinate nasal, nasopharyngeal, and oropharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider (HCP). This test is also for individually tested anterior nasal swab specimens that are self-collected at home (which includes in a community-based setting), without the supervision of a HCP, by individuals 18 years or older using the Verily COVID-19 Nasal Swab Kit when determined to be appropriate by a HCP. This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 12 individual anterior nasal, mid-turbinate nasal, nasopharyngeal or oropharyngeal swab specimens (collected by a HCP) or anterior nasal swab specimens (self-collected at home using the Verily COVID-19 Nasal Swab Kit) using either a Standard Dorfman pooling strategy or a 2D pooling strategy, and where each specimen is collected using individual vials containing transport media. Testing is limited to the Verily Life Sciences laboratory, located at 249 E Grand Avenue, South San Francisco, CA 94080, 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 Aarthi Srinivasan:

On September 8, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Verily COVID-19 RT-PCR Test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal, and oropharyngeal swab specimens) from individuals suspected of COVID-19 by their HCP and for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 12 individual upper respiratory specimens (such as nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swab specimens) collected by a HCP using individual vials containing transport media, from individuals suspected of COVID-19 by their HCP 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 Verily Life Sciences laboratory, located at 249 E Grand Avenue, South San Francisco, CA 94080, which is certified under CLIA, 42 U.S.C. §263a, and meets requirements to perform high complexity tests. Based on your requests, FDA reissued the letter on December 18, 2020[2] and March 30, 2021.[3] In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[4]

On August 24, 2021, you requested to further amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the March 30, 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 March 30, 2021, letter in its entirety with the

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Verily Life Sciences.
[2] On December 18, 2020, the revisions to the September 8, 2020, letter and authorized labeling included: (1) the addition of qualitative detection of nucleic acid from SARS-CoV-2 in individual nasal swab specimens that are self-collected at home (which includes in a community-based setting) without the supervision of a HCP by individuals 18 years or older using the Verily COVID-19 Nasal Swab Kit when determined to be appropriate by a HCP based on a COVID-19 questionnaire, (2) updates to the healthcare provider and patient fact sheets, including some additional warnings/precautions around the use of a self-collection kit and testing without a specimen collection control, and (3) updates to the conditions of authorization for authorized distributors of the Verily COVID-19 Nasal Swab Kit and other clarifying revisions.
[3] On March 30, 2021, the revisions to the December 18, 2020 letter and authorized labeling included: (1) revision of the intended use to include pooling of up to 12 individual anterior nasal swab specimens self-collected at home using the Verily COVID-19 Nasal Swab Kit using individual vials containing transport media, addition of a statement indicating that specimens collected without an endogenous human specimen control may yield negative results if the specimen was not properly collected and additional updates to reflect language used in more recent authorizations, (2) update the home collection instructions for use to add on-line activation, and additional updates to reflect language used in more recent authorizations, (3) update the standard operating procedure to include pooling of self-collected anterior nasal specimens, change required testing of RNAse P for self-collected specimens to optional testing, extension of the sample stability from 48 hours to 98 hours, addition of a limitation regarding performance with circulating variants and additional updates to reflect language use in more recent authorizations, (4) update the Specimen Accessioning SOP to extend sample stability from 48 hours to 98 hours and additional updates to reflect language used in more recent authorizations, (5) addition of label sheets and self-collected specimen activation screens, and (6) revise the December 18, 2021 Letter of Authorization to reflect language used in more recent authorizations, the removal of Condition T (related to the questionnaire), Condition U (to submit a summary report for self-collected specimens, which was fulfilled) and Condition V (performance of a study to assess adequacy of self-collected specimens which was fulfilled).
[4] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download.

revisions incorporated.[5] 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[6] test is now authorized 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.[7]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indications above. A summary of the performance information FDA relied upon is included 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;

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]

[5] The revisions to the March 30, 2021 letter and authorized labeling include: (1) revision to the intended use to use either a Standard Dorfman pooling strategy or a 2D pooling strategy when testing pooled samples, and other clarifying revisions (2) addition of risk-mitigation language regarding pooling to the EUA Summary and SOP, (3) addition of Condition U. to further evaluate pooling performance, and (4) addition of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions V. and W. below)
[6] For ease of reference, this letter will use the term "your product" to refer to the Verily COVID-19 RT-PCR Test.
[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*. 85 FR 7316 (February 7, 2020).
[8] 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 indications above.

Authorized Product Details

Your product is a real time reverse transcription polymerase chain reaction (rRT-PCR) test intended for qualitative detection of nucleic acid from SARS-CoV-2 anterior nasal, mid-turbinate nasal, nasopharyngeal, and oropharyngeal swab specimens from individuals suspected of COVID-19 by their HCP.

This test is also for individually tested anterior nasal swab specimens that are self-collected at home (which includes in a community-based setting) without the supervision of a HCP, by individuals 18 years or older using the Verily COVID-19 Nasal Swab Kit when determined to be appropriate by a HCP.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 12 individual anterior nasal, mid-turbinate nasal, nasopharyngeal or oropharyngeal swab specimens (collected by a HCP) or anterior nasal swab specimens (self-collected at home using the Verily COVID-19 Nasal Swab Kit) using either a Standard Dorfman pooling strategy or a 2D pooling strategy, and where each specimen is collected using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive, inconclusive, or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. Anterior nasal swab specimens that are self-collected may or may not be tested with an endogenous human specimen 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.

Testing is limited to Verily Life Sciences laboratory, located at 249 E Grand Avenue, South San Francisco, CA 94080, 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.

To use your product, 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).

The product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition L 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 Control: The negative control monitors for any potential cross-contamination that could occur during the nucleic acid extraction process or RT-PCR assay. Molecular grade, nuclease free water is used in place of sample nucleic acid for this control. This control is added to each extraction run and carried through RT-PCR.
- Positive Control: The TaqPath COVID-19 Control is used as positive control that serves as an amplification control for the ORF1ab, N gene, and S gene amplicon sequences. The positive control is used to verify proper assay set-up and reagent integrity. This control is added to one RT-PCR reaction in each run.
- Internal (MS2 Phage) Control: The internal MS2 phage control serves as an internal process control for nucleic acid extraction to ensure that clinical samples and controls do not inhibit the RT-PCR.
- No Template Control (NTC): The no template control is molecular-grade, nuclease-free water and is used to monitor non-specific amplification, cross-contamination during PCR setup, and nucleic acid contamination of PCR reagents. This control is added to one RT-PCR reaction in each run.

The above described product is authorized to be accompanied by 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), as well as the "Verily PI, Verily COVID-19 RT-PCR Test" standard operating procedures (SOP), "Verily PI, COVID-19 Specimen Accessioning" SOP, and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Verily Life Sciences – Verily COVID-19 RT-PCR Test
- Fact Sheet for Patients: Verily Life Sciences – Verily COVID-19 RT-PCR Test

The above described product, when accompanied by the EUA Summary, "Verily PI, Verily COVID-19 RT-PCR Test" SOP, "Verily PI, COVID-19 Specimen Accessioning" SOP, and the two fact sheets is authorized to be used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Verily COVID-19 Nasal Swab Kit with the "COVID-19 Nasal Swab Kit Instructions – Digital Activation" and/or the "COVID-19 Nasal Swab Kit Instructions – Non-Digital

Activation" with the Verily Nasal Swab Label Sheet, is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" refers to "Verily PI, Verily COVID-19 RT-PCR Test" SOP, the "Verily PI, COVID-19 Specimen Accessioning" SOP, the "COVID-19 Nasal Swab Kit Instructions – (Digital Activation)," the "COVID-19 Nasal Swab Kit Instructions – (Non-Digital Activation)," the Verily Nasal Swab Label Sheet, the EUA Summary, and the two Fact Sheets."

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 indications 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:

Verily Life Sciences (You) and Authorized Distributor(s)[9]

[9] "Authorized distributors" are identified by you (Verily Life Sciences) in your EUA submission as an entity allowed to distribute the Verily COVID-19 Nasal Swab Kit.

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

D. You and authorized distributor(s) must collect information on the performance of your product. You will report to FDA 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.

E. You and authorized distributors must make available the applicable instructions (the Verily Nasal Swab Label Sheet with the "COVID-19 Nasal Swab Kit Instructions – Digital Activation" and/or the "COVID-19 Nasal Swab Kit Instructions – Non-Digital Activation") related to the self-collection of nasal swab specimens using the Verily COVID-19 Nasal Swab Kit, in the shipped kit and make available all instructions ("COVID-19 Nasal Swab Kit Instructions – Digital Activation" and the "COVID-19 Nasal Swab Kit Instructions – Non-Digital Activation") on your website(s).

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Verily COVID-19 Nasal Swab Kit is distributed.

G. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

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 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.

Verily Life Sciences (You)

J. You must notify FDA of any authorized of any authorized distributor(s) of the Verily COVID-19 Nasal Swab Kit, 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 distributors any subsequent revisions that might be made to this EUA and its authorized accompanying materials.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and 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.

M. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA[10]. After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

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

O. You must have a process in place to track adverse events, including any occurrence of false results with your product, including the Verily COVID-19 Nasal Swab Kit, and report to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should also be immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email:CDRH-EUAReporting@fda.hhs.gov).

P. 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.

Q. You must 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.

[10] 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.

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

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 must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing."

U. You will further evaluate the pooling performance of your product in an FDA agreed upon post authorization study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/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 regarding 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.

X. You must use the "Monitoring Plan" procedure in the "PI, Verily COVID-19 RT-PCR Test" laboratory procedures to evaluate the appropriateness of continuing to use pooling strategies for testing patient specimens based on the recommendations in the protocol.

Y. You must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the "Monitoring Plan" procedure. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request, and will be made available within a reasonable time after 12 months from the date of their creation.

Conditions Related to Printed Materials, Advertising and Promotion

Z. 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 applicable requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and implementing regulations.

AA. 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.

BB. All descriptive printed matter (except the Verily Nasal Swab Label Sheet), 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 the authorized laboratory;
- 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,

_____
Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure