November 24, 2020

Christina Kong, MD
Medical Director
Pathology & Clinical Lab Services for Stanford Health Care
300 Pasteur Drive, Room L235
Stanford, CA 94305-5324

Device:	SARS-CoV-2 RT-PCR Assay
Company:	Stanford Health Care Clinical Virology Laboratory
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, nasal, and mid-turbinate nasal swabs in Viral Transport Medium and bronchoalveolar lavage fluid from individuals suspected of COVID-19 by their healthcare provider (HCP). This test is also for use with nasal swab specimens that are self-collected at home or in a healthcare setting using the Vera COVID-19 Test Unsupervised Collection Kit, from individuals (18 years of age and older) suspected of COVID-19 by their healthcare provider. Testing is limited to the Stanford Health Care Clinical Virology Laboratory, located at 3375 Hillview Avenue, Palo Alto, CA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high-complexity tests.

Dear Dr. Kong:

On April 8, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter determining that your SARS-CoV-2 PCR Assay met the criteria for issuance under section 564(c) of the Act to be eligible for authorization under the March 31, 2020, Emergency Use Authorization (EUA) for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (High Complexity LDT Umbrella EUA) for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens collected

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Stanford Health Care Clinical Virology Laboratory.

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). As authorized under the High Complexity LDT Umbrella EUA, testing of your test was limited to Stanford Health Care Clinical Virology Laboratory, located at 3375 Hillview Avenue, Palo Alto, CA, the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests pursuant to the Scope of Authorization and Conditions of Authorization of that EUA.

On September 18, 2020, you requested to revise your product's intended use as originally specified by the High Complexity LDT Umbrella EUA, to add testing of nasal swab specimens collected at home or in a healthcare setting using the Vera COVID-19 Test Unsupervised Collection Kit when determined to be appropriate by a healthcare provider. In response to your request, and because the requested revision is beyond the Scope of Authorization of the High Complexity LDT Umbrella EUA, FDA is hereby authorizing the use of your product[2] used for the indication identified above pursuant to Section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this letter of authorization.

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.[3]

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 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, as 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] For ease of reference, this letter will use the term "your product" to refer to the entire test system, i.e., SARS-CoV-2 RT-PCR Assay, Vera COVID-19 Test Unsupervised Collection Kit, controls, ancillary reagents, and other materials, authorized under this EUA as outlined in the Scope of Authorization (Section II) and Conditions of Authorization (Section IV).

[3] 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.[4]

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 test system that includes the SARS-CoV-2 RT-PCR Assay, controls, ancillary reagents, other materials, and the Vera COVID-19 Test Unsupervised Collection Kit. Your product is authorized to be used by Stanford Health Care Clinical Virology Laboratory, despite the fact that your product does not meet certain requirements otherwise required by applicable federal law.

The test is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, nasal, and mid turbinate nasal swabs in Viral Transport Medium and bronchoalveolar lavage fluid from individuals suspected of COVID-19 by their healthcare provider (HCP).

Your product is also authorized for use with nasal swab specimens that are self-collected at home or in a healthcare setting using the Vera COVID-19 Test Unsupervised Collection Kit, from individuals (18 years of age and older) suspected of COVID-19 by their healthcare provider.

Testing is limited to the Stanford Health Care Clinical Virology Laboratory, located at 3375 Hillview Avenue, Palo Alto, CA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high-complexity tests.

The SARS-CoV-2 RNA 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.

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

To use your test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from upper respiratory 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.

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 J. below), that are to be run as outlined in the authorized labeling. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling:

- RNase P in patient samples (Extraction Control) – internal control used verify that nucleic acid is present in every specimen processed.

- Negative/Extraction Control - pooled negative nasopharyngeal samples monitors for any cross-contamination that occurs during the RT-PCR process and also serves as an extraction control. One negative control is included on each run.

- NTC (No Template Control) - RNase-, DNase-free water is used to monitor the possibility of sample contamination in the assay run and is included on every run.

- SARS-CoV-2 Positive Control - synthesized single stranded DNA (ssDNA) of the SARS-CoV-2 E gene is used to verify that the assay run is performing as intended. One positive control is included on each run.

The above described test is authorized to be accompanied with laboratory procedures (described below) and 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 information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Stanford Health Care Clinical Virology Laboratory - SARS-CoV-2 RT-PCR Assay
- Fact Sheet for Patients: Stanford Health Care Clinical Virology Laboratory - SARS-CoV-2 RT-PCR Assay

The above described test, when accompanied by the "2019 novel Coronavirus (SARS-CoV-2) Real-Time, RT-PCR" protocol, the "Vera Specimen Receipt," the EUA Summary (identified above) 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 Vera COVID-19 Test Unsupervised Collection Kit is authorized to be distributed and used as part of the above described product for use with the test as set forth in this EUA.

"Authorized labeling" is defined as "2019 novel Coronavirus (SARS-CoV-2) Real-Time, RT-PCR" protocol, the "Vera Specimen Receipt," the EUA Summary (identified above), the two Fact Sheets, and the "Welcome to your Vera COVID-19 Test Unsupervised Collection Kit" self-collection instructions.

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 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:

Stanford Health Care Clinical Virology Laboratory (You) and Authorized Distributor(s) [5]

A. You and authorized distributors will make available all instructions related to the self-collection of nasal swab specimens using the Vera COVID-19 Test Unsupervised

[5] "Authorized Distributor(s)" are identified by you, Stanford Health Care Clinical Virology Laboratory, in your EUA submission as an entity allowed to distribute the Vera COVID-19 Test Unsupervised Collection Kit.

Collection Kit, both in the shipped kit and on your website.

B. Through a process of inventory control, you and authorized distributor(s) will maintain records of the numbers and locations to which the Vera COVID-19 Test Unsupervised Collection Kit are distributed.

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

D. 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.

E. You and authorized distributors using your product 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.

Stanford Health Care Clinical Virology Laboratory (You)

F. 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).

G. You will make available on your website(s) the authorized Fact Sheet for Healthcare Providers and Fact Sheet for Patients.

H. You will notify FDA of any authorized distributor(s) of the Vera COVID-19 Test Unsupervised Collection Kit, including the name, address, and phone number of any authorized distributor(s).

I. You will provide authorized distributor(s) and relevant public health authorities with a copy of this EUA and communicate to authorized distributor(s) and relevant public health authorities any subsequent revisions that might be made to this EUA and the authorized accompanying materials.

J. 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.

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

L. You will have a process in place to track adverse events, including any occurrence of false results with your product, including with the Vera COVID-19 Test Unsupervised Collection Kit, 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).

M. You will collect information on the performance of your product and 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 the test of which you become aware.

N. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with any new self-collection kit authorized for use with your product during that timeframe, including 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.

O. 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.

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

Q. When testing specimens self-collected using any authorized self-collection kits for use with your product you must follow any Specimens Accessioning protocols provided with the authorized self-collection kit and/or outlined in your Self Collection Specimen Receipt and Accessioning SOP when accepting specimens for testing.

[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 product.

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

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

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

Conditions Related to Printed Materials, Advertising and Promotion

U. 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.

V. No descriptive printed matter, including advertising and 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.

W. All descriptive printed matter, including 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;
- This product has been authorized 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,
- 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 authorization is terminated or revoked sooner.

The emergency use of you 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