September 21, 2021

Kenneth Van Horn, PhD, D(ABMM)
Technical Director, Microbiology
Southern California Permanente Medical Group
Regional Reference Laboratories, Chino Hills
13000 Peyton Drive
Chino Hills, CA 91709

Device:	Kaiser Permanente High Throughput SARS-CoV-2 Assay
EUA Number:	EUA203058
Company:	Southern California Permanente Medical Group
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in saliva that is self-collected unsupervised at home using the Kaiser Permanente Saliva Home Collection Kit, by individuals 18 years or older suspected of COVID-19 when determined to be appropriate by their healthcare provider. Emergency use of this test is limited to the authorized laboratory.
Authorized Laboratory:	Testing is limited to the Southern California Permanente Medical Group - Regional Reference Laboratory (SCPMG-RRL) located at 13000 Peyton Drive, Chino Hills, CA 91709 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. Van Horn:

On April 19, 2021, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Kaiser Permanente High Throughput SARS-CoV-2 Assay for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva that is self-collected unsupervised at home using the Kaiser Permanente Saliva Home Collection Kit, by individuals 18 years or older suspected of COVID-19 when determined to be appropriate 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 Southern California Permanente Medical Group - Regional Reference Laboratory (SCPMG-RRL) located at 13000 Peyton

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Southern California Permanente Medical Group.

Drive, Chino Hills, CA 91709 which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.[2]

On May 14, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on that request and having concluded that revising the April 19, 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 April 19, 2021, 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, your product[4] is now intended for 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.[5]

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;

[2] A technical correction to the address block of the letter was made on April 20, 2021.
[3] The revisions to the April 19, 2021, letter and authorized labeling include: (1) extending sample shipping stability for the Kaiser Permanente Saliva Home Collection Kit to 96 hours, (2) minor revisions to the instructional letter for specimen shipping, and (3) addition of Conditions V. and W. to evaluate device performance with viral mutations.
[4] For ease of reference, this letter will use the term "your product" to refer to the Kaiser Permanente High Throughput SARS-CoV-2 Assay used for the indication identified above.
[5] 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.[6]

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 (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens self-collected unsupervised at home using the Kaiser Permanente Saliva Home Collection Kit, by individuals 18 years or older suspected of COVID-19, when determined to be appropriate by a healthcare provider.

Testing is limited to the Southern California Permanente Medical Group - Regional Reference Laboratory (SCPMG-RRL) located at 13000 Peyton Drive, Chino Hills, CA 91709 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 saliva 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 Kaiser Permanente Saliva Home Collection Kit contains the Spectrum Solutions, LLC SDNA-1000 Saliva Collection Device with collection instructions, an outbound corrugated box, biohazard specimen bag with absorbent material, pre-labeled return shipping bag along with a digitally printed personalized letter containing the sample identification label and instructions for shipping the samples. Patients should follow all specimen collection and mailing instructions provided in the kit. Saliva specimens are transported and stored at ambient temperature and must be received in the testing laboratory within 96 hours of sample collection. Specimens are tested with the Kaiser Permanente High Throughput SARS-CoV-2 assay.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from saliva 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.

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

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 P 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 Instructions for Use:

- Positive Control – TaqPath COVID-19 Control which monitors the RT-PCR reaction set-up and reagent integrity.
- Negative Control – monitors for cross contamination during RNA extraction and the RT-PCR reaction step
- MS2 Phage Control – monitors the RNA extraction

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 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 "The Kaiser Permanente High Throughput SARS-CoV-2 Assay for use with the Kaiser Permanente Saliva Home Collection Kit", Standard Operating Procedures (SOP), and the following fact sheets pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Southern California Permanente Medical Group - Kaiser Permanente High Throughput SARS-CoV-2 Assay
- Fact Sheet for Patients: Southern California Permanente Medical Group - Kaiser Permanente High Throughput SARS-CoV-2 Assay

The above described product, when accompanied by the EUA Summary, the "The Kaiser Permanente High Throughput SARS-CoV-2 Assay for use with the Kaiser Permanente Saliva Home Collection Kit" 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 Kaiser Permanente Saliva Home Collection Kit with the "Kaiser Permanente Saliva Home Collection Kit" instructions for use bundle 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 EUA Summary, the "The Kaiser Permanente High Throughput SARS-CoV-2 Assay for use with the Kaiser Permanente Saliva Home Collection Kit" SOP, the two Fact Sheets, and the "Kaiser Permanente Saliva Home Collection Kit"

instructions for use bundle.

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, storage, and distribution of your product.

IV. Conditions of Authorization

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

Southern California Permanente Medical Group (You) and Authorized Distributor(s)[7]

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).

[7] "Authorized Distributor(s)" are identified by you, Southern California Permanente Medical Group in your EUA submission as an entity allowed to distribute the Kaiser Permanente Saliva Home Collection Kit.

B. You and authorized distributors must make available all instructions related to the self-collection of saliva specimens ("Kaiser Permanente Saliva Home Collection Kit" instructions for use bundle) using the Kaiser Permanente Saliva Home Collection Kit both in the shipped kit and on your website.

C. 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.

D. 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.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Kaiser Permanente Saliva Home Collection Kit is distributed.

F. You and authorized distributor(s) must maintain customer complaint files concerning the Kaiser Permanente Saliva Home Collection Kit 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.

G. 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.

H. You and authorized distributor(s) must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Southern California Permanente Medical Group (You)

I. You must notify FDA of any authorized distributor(s) of the Kaiser Permanente Saliva Home Collection Kit, including the name, address, and phone number of any authorized distributor(s).

J. 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).

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

L. 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.

M. 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.

N. When testing authorized specimens self-collected using Kaiser Permanente Saliva Home Collection Kit with your product you must follow any specimen accessioning protocols provided with the self-collection kit when accepting specimens for testing.

O. You must collect information on the performance of your product. You must 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.

P. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

Q. 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.[8] After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

R. You must submit to FDA a summary report within 30 calendar days of receipt of this letter summarizing the results of any testing performed using specimens collected with Kaiser Permanente Saliva Home Collection Kit for use with your product during that timeframe, including how many kits were prescribed and distributed for unsupervised collection, how many kits were returned, 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.

S. You must have a process in place to track adverse events associated with the Kaiser Permanente Saliva Home Collection Kit, including occurrences of false results and report

[8] 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.

to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, must be immediately reported to DMD/OHT-7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

T. Upon request, you must conduct post-authorization studies and/or data analysis concerning the performance of saliva specimens with your authorized test. Such studies and/or data analysis must be agreed upon between you and FDA. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of the data, FDA will consider whether additional action is appropriate, such as revision or revocation of the EUA.

U. 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.

V. You must evaluate the impact of viral mutations for your target analytes 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.

W. 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

X. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations regulations.

Y. 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.

Z. 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 the Southern California Permanente Medical Group - Regional Reference Laboratory (SCPMG-RRL) located at 13000 Peyton Drive, Chino Hills, CA 91709;

- 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure
Technical Correction on September 22, 2021, to correct the specimen stability to 96 hours on the EUA Summary and Letter of Authorization.