September 9, 2020

Ginine Beyer
Kaiser Permanente Mid-Atlantic States
6111 Executive Blvd.
Rockville, MD 20850

Device:	KPMAS COVID-19 Test
Company:	Kaiser Permanente Mid-Atlantic States
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected by KPMAS Health Plan members observed at home via telemedicine, using the KPMAS COVID-19 Home Collection Kit. Specimens are collected from individuals who are suspected of COVID-19 by their healthcare provider and from any individual, including from individuals without symptoms or other reasons to suspect COVID-19. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratory:	Testing is limited to the KPMAS Regional Laboratory, Rockville MD, 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 Ms. Beyer:

On June 13, 2020 based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of your product[2] for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasal swab specimens self-collected by KPMAS Health Plan members observed at home via telemedicine, using the KPMAS COVID-19 Home Collection Kit, 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). The June 13, 2020 letter authorizing emergency use of this test limited testing to the KPMAS Regional Laboratory, Rockville MD, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets requirements to perform high complexity tests.

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Kaiser Permanente Mid-Atlantic States (KPMAS).
[2] For ease of reference, this letter will use the term "your product" to refer to the KPMAS COVID-19 Test which is authorized for use as described in this letter with the KPMAS COVID-19 Home Collection Kit, for the indication identified above.

On July 31, 2020, you requested to amend your Emergency Use Authorization (EUA) to include testing of specimens collected from individuals without symptoms or other reasons to suspect COVID-19. Based on that request, and having concluded that revising the June 13, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the June 13, 2020, letter in its entirety with the revisions incorporated.[3] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, this test is now intended for the indications described above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[4]

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.[5]

[3] The revisions to the June 13, 2020, letter include: (1) revised intended use to include testing of specimens collected from individuals without symptoms or other reasons to suspect COVID-19, (2) revised Conditions of Authorization to reflect more recent authorizations, (3) updated EUA Summary to include the data to support aysmptomatic testing, and (4) updated healthcare provider and patient fact sheets to reflect asymptomatic testing claims and also include language used in more recent authorizations.

[4] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

[5] 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 indication above.

Authorized Product Details

Your product is for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasal swab specimens self-collected by KPMAS Health Plan members observed at home via telemedicine, using the KPMAS COVID-19 Home Collection Kit. Specimens are collected from individuals who are suspected of COVID-19 by their healthcare provider and from any individual, including from individuals without symptoms or other reasons to suspect COVID-19.

Use of this test is limited to KPMAS Regional Laboratory, Rockville MD, 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. The KPMAS COVID-19 Home Collection Kit, or other authorized self-collection kits, will provide specimen collection materials and materials for mailing specimens to the authorized laboratory for testing using the KPMAS COVID-19 Test. Patients should follow all specimen collection and mailing instructions provided in the kit. Medical Oversight of the process is provided by KPMAS healthcare teams. An electronic order for home collection kit will be placed in the patient's electronic medical chart, if the patient is eligible for COVID-19 testing based on the guidelines set by the KPMAS and the Centers for Disease Control and Prevention.

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

Your product is used for detection of SARS-CoV-2 nucleic acid and is an integrated nucleic acid testing system that fully automates all steps necessary to perform sample processing through amplification, detection, and data reduction. The assay incorporates an internal control, or other authorized control materials, to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error. SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasal swab specimens. All controls must generate expected results in order for a test to be considered valid, as outlined in the authorized procedures submitted as part of the EUA request.

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 Instructions for Use.

The above described product, is authorized to be accompanied with the labeling submitted as part of the EUA request, and as described in the "EUA summary" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), 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: KPMAS COVID-19 Test
- Fact Sheet for Patients: KPMAS COVID-19 Test

The above described product, when accompanied by the "EUA Summary," Fact Sheet for Healthcare Providers, Fact Sheet for Patients, the "Kaiser Permanente Mid Atlantic States (KPMAS) COVID-19 Home Collection Kit" instructions and the Standard Operating Procedures (SOP) bundle for the KPMAS COVID-19 Test (collectively referenced as "authorized labeling") is authorized to be used by the KPMAS Regional Laboratory, Rockville MD, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used as described within and used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, and storage of your product.

IV. Conditions of Authorization

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

Kaiser Permanente Mid-Atlantic States (You)

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

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

C. You will notify the relevant public health authorities of your intent to run your authorized test.

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

E. 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.

F. You will make available on your website the Fact Sheet for Healthcare Providers, Fact Sheet for Patients, "KPMAS COVID-19 Home Collection Kit" instructions, and patient instructions for other authorized home specimen collection kits.

G. You are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

H. You will use your authorized test as outlined in the authorized labeling. Deviations from the authorized test 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.

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

J. You will collect information on the performance of your authorized test. 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 authorized test of which you become aware.

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

L. You will evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will 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.

M. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using nasal or other applicable 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.

N. You will track adverse events associated with the KPMAS COVID-19 Home Collection Kit, or any other home specimen collection kit authorized for use with your product, including occurrences of false results and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

O. You will make available all instructions related to the self-collection of nasal swab specimens using the KPMAS COVID-19 Home Collection Kit, or any other home specimen collection kit authorized for use with your product, both in the shipped kit and on your website.

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

Q. You will ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

R. 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.

[6] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

S. No descriptive printed matter, including advertising or promotional materials, relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

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

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure