January 13, 2022

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

Device:	KPMAS COVID-19 Test
EUA Number:	EUA201446
Company:	Kaiser Permanente Mid-Atlantic States
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens collected at home (which includes on-site at KPMAS facilities) using the KPMAS COVID-19 Self-Collection Kit by any individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited laboratories designated by Kaiser Permanente Mid-Atlantic States, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Dear Dr. Beyer:

On June 13, 2020 based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the KPMAS COVID-19 Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), for the indication stated in the letter.[2] Subsequently, on September 9, 2020, March 31, 2021, and June 14, 2021 FDA reissued the letter in its entirety with revisions

[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] The June 13, 2020, letter authorized the KPMAS COVID-19 Test 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. Testing was limited 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.

incorporated.[3,4,5] 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.[6]

On August 20, 2021, you requested to amend your EUA. Based on that request, and having concluded that revising the June 14, 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 June 14, 2021, letter in its entirety with the revisions incorporated.[7] 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[8] 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.

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[3] On September 9, 2020, the revisions to the June 13, 2020, letter included: (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 asymptomatic 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] On March 31, 2021, the revisions to the September 9, 2020, letter and authorized labeling included: (1) revised intended use to remove requirement for self-collection via telemedicine, (2) Winter specimen stability data for home collection, (3) removal of aliquoting saline in-house for home collection kit, (4) updated healthcare provider and patient fact sheets to reflect the updated intended use and language used in more recent authorizations, (5) removal of Condition M. (from the September 9, 2020, letter) which was fulfilled, (6) addition of a condition of authorization to perform a usability study and revisions to provide for authorized distributors of the KPMAS COVID-19 Home Collection Kit, and (7) edits to the conditions of authorization to reflect language used in more recent authorizations.

[5] On June 14, 2021, the revisions to the March 31, 2021, letter and authorized labeling included: (1) testing of anterior nasal swab specimens collected at home using the KPMAS COVID-19 Home Collection Kit by any individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), (2) reducing the need for Human Specimen Control testing from 100% to 25% of home collected specimens, and (3) removing Condition. R (from the March 31, 2021, letter) which was fulfilled. Subsequently, a technical correction was made on June 17, 2021, to correct a date.

[6] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download.

[7] The revisions to the June 14, 2021, letter and authorized labeling include: (1) updating the intended use to authorize testing at laboratories designated by Kaiser Permanente Mid-Atlantic States which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests, (2) updating the name of the collection kit from "KPMAS COVID-19 Home Collection Kit" to "KPMAS COVID-19 Self-Collection Kit", (3) updating the intended use to specifically mention collection of anterior nasal swab specimens using the KPMAS COVID-19 Self-Collection Kit on-site at KPMAS facilities and addition of associated patient instructions for on-site specimen collection, (4) adding instructions for patients detailing the option for on-site KPMAS specimen drop-off locations and hours in addition to the current shipping instructions, (5) removing the requirement for performing an internal control (HSC) microscopic testing, (6) updating the Fact Sheet for Patients and Fact Sheet for Healthcare Providers to reflect the updates to the intended use and/or reflect more recent authorizations, (7) updating the letter of authorization that reflect the updated intended use, including the addition of authorized laboratories, and to reflect language used in more recent authorizations, and (8) incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions N. and O. below).

[8] 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 Kaiser Permanente Mid-Atlantic States (KPMAS) COVID-19 Self-Collection Kit, for the indication identified above.

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.[9]

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. 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.[10]

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 anterior nasal swab specimens collected at home (which includes on-site at KPMAS facilities using the KPMAS COVID-19 Self-Collection Kit by any individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19.

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[9] 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).

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

Use of this test is limited to laboratories designated by Kaiser Permanente Mid-Atlantic States which are certified under CLIA, 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

The KPMAS COVID-19 Self-Collection Kit provides specimen collection and storage materials and, for home collected specimens, materials for mailing or dropping off specimens to authorized laboratories for testing using the KPMAS COVID-19 Test, as described in the "KPMAS COVID-19 Self-Collection Kit In person Drop-Off Option," "Kaiser Permanente Mid-Atlantic States (KPMAS) COVID-19 Self-Collection Kit (On-site collection)" and "Kaiser Permanente Mid-Atlantic States (KPMAS) COVID-19 Self-Collection Kit (At-home collection)" collection instructions. 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 a home collection kit will be placed in the patient's electronic medical chart, when determined that testing is appropriate and a prescription is generated by the treating physician.

The SARS-CoV-2 nucleic acid is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

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, as described in the authorized labeling (described below). The assay incorporates an internal control, or other authorized control materials (as specified under Condition L. below), to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error that must generate expected results in order for a test to be considered valid, as described in the authorized labeling (described below).

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 EUA Summary.

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 Standard Operating Procedures (SOP) bundle[11] for the KPMAS COVID-19 Test and the following fact sheets pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

[11] The laboratory procedures bundle includes "KPMAS COVID-19 Test" laboratory procedures, the "Receipt and accessioning of KPMAS COVID-19 Self-Collection Kit samples for KPMAS COVID-19 Test (PCR)" and the "cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800Systems" instructions for use.

- Fact Sheet for Healthcare Providers: Kaiser Permanente Mid-Atlantic States - KPMAS COVID-19 Test
- Fact Sheet for Patients: Kaiser Permanente Mid-Atlantic States - KPMAS COVID-19 Test

The above described product, when accompanied by the EUA Summary, the Standard Operating Procedures (SOP) bundle for the KPMAS COVID-19 Test, and the two Fact Sheets is authorized to be distributed and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The KPMAS COVID-19 Self-Collection Kit with the applicable "KPMAS COVID-19 Self-Collection Kit In person Drop-Off Option," "Kaiser Permanente Mid-Atlantic States (KPMAS) COVID-19 Self-Collection Kit (On-site collection)" and "Kaiser Permanente Mid-Atlantic States (KPMAS) COVID-19 Self-Collection Kit (At-home collection)" collection instructions are 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 Standard Operating Procedures (SOP) bundle for the KPMAS COVID-19 Test, the two Fact Sheets, and the "KPMAS COVID-19 Self-Collection Kit In person Drop-Off Option," "Kaiser Permanente Mid-Atlantic States (KPMAS) COVID-19 Self-Collection Kit (On-site collection)" and "Kaiser Permanente Mid-Atlantic States (KPMAS) COVID-19 Self-Collection Kit (At-home collection)" collection instructions for use (IFUs) 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 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, 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:

Kaiser Permanente Mid-Atlantic States (You) and Authorized Distributor(s)[12]

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 authorized laboratories and 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 make available all instructions related to the collection of anterior nasal swab specimens using the KPMAS COVID-19 Self-Collection Kit, both in the shipped kit and on your website.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the KPMAS COVID-19 Self-Collection Kit is distributed.

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

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.

[12] "Authorized Distributor(s)" are identified by you, Kaiser Permanente Mid-Atlantic States, in your EUA submission as an entity allowed to distribute the KPMAS COVID-19 Self-Collection Kit.

Kaiser Permanente Mid-Atlantic States (You)

H. You must notify FDA of any authorized distributor(s) of KPMAS COVID-19 Self-Collection Kit, including the name, address, and phone number of any authorized distributor(s).

I. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any authorized revisions that might be made to this EUA and its authorized accompanying materials.

K. You must ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

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.[13] After submission to and concurrence by FDA, DMD/OHT7-OIR/OPEQ/CDRH will update the EUA Summary to reflect the additional testing.

N. 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).

[13] 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.

O. 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.

P. You must have a process in place to track adverse events, including any occurrences of false results with your product, including the KPMAS COVID-19 Self-Collection Kit, 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).

Authorized Laboratories

Q. Authorized laboratories using your product 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.

R. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized 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.

S. When testing authorized specimens self-collected using the KPMAS COVID-19 Self-Collection Kit with your product, authorized laboratories must follow any specimens accessioning protocols provided with the collection kit when accepting specimens for testing.

T. Authorized laboratories testing authorized specimens collected using the KPMAS COVID-19 Self-Collection Kit must include in the test report the following limitation: "*Specimens that are collected using the KPMAS COVID-19 Self-Collection Kit were not tested with an internal control to confirm that the specimen was properly collected. As such, unobserved collected specimens using the KPMAS COVID-19 Self-Collection Kit from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly*."

U. Authorized laboratories using your product must notify the relevant public health authorities of your intent to run your product.

V. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

W. Authorized laboratories using your product must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (Dr. Beyer; Ginine.M.Beyer@kp.org) 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.

X. 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.

Kaiser Permanente Mid-Atlantic States (You), Authorized Distributor(s) and Authorized Laboratories

Y. You, authorized distributor(s), and authorized laboratories must 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

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 requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA 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, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

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

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

V. Duration of Authorization

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

Sincerely,

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

Enclosure