August 13, 2021

Jina Yeon
Kwokman Diagnostics, LLC
2082 Business Center Dr., Suite 240
Irvine, CA 92612

Device:	Kwokman Diagnostics COVID-19 Home Collection Kit
EUA Number:	EUA210238
Company:	Kwokman Diagnostics, LLC
Indication:	For use to collect anterior nasal (nasal) swab specimens at home from individuals age 18 years or older (self-collected, unsupervised), when determined to be appropriate by a healthcare provider and only for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with the Kwokman Diagnostics COVID-19 Home Collection Kit.
Authorized Laboratories:	Testing is limited to laboratories designated by Kwokman Diagnostics, LLC that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests and that run the specimens collected from the Kwokman Diagnostics COVID-19 Home Collection Kit on an IVD molecular test that is indicated for use with the Kwokman Diagnostics COVID-19 Home Collection Kit when used consistent with its authorization.

Dear Jina Yeon:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Kwokman Diagnostics, LLC.
[2] For ease of reference, this letter will use the term "your product" to refer to the Kwokman Diagnostics COVID-19 Home Collection Kit used for the indication identified above.

involves the virus that causes COVID-19.[3] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[4]

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 Section 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 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen, and that the known and potential benefits of your product when used for such use, 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]

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 home collection kit intended for use to collect anterior nasal (nasal) swab specimens at home from individuals age 18 years or older (self-collected, unsupervised), when

[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).
[4] U.S. Department of Health and Human Services, *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 17335 (March 27, 2020)
[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

determined to be appropriate by a healthcare provider. Nasal swab specimens collected using the Kwokman Diagnostics COVID-19 Home Collection Kit are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the nasal swabs is maintained in the specimen packaging and is only for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with the Kwokman Diagnostics COVID-19 Home Collection Kit.

When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The Kwokman Diagnostics COVID-19 Home Collection Kit includes the following materials or other authorized materials (as may be requested under Condition K. below): pre-labeled shipping pack, outer box, inner box, instructions for use, biohazard specimen transport bag with absorbent sheet, flocked polyester nasal swab, and sample tube containing 0.9% saline.

Testing is limited to laboratories designated by Kwokman Diagnostics, LLC that are certified under the CLIA, 42 U.S.C. §263a, and meet requirements to perform high complexity tests and that run the specimens collected with your product on an IVD molecular test that is indicated for use with your product when used consistent with its authorization.

The above described product, is authorized to be accompanied with authorized labeling (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas). "Authorized labeling" includes the following documents: EUA Summary, "The Kwokman Diagnostics COVID-19 Home Collection Kit" instructions, and the "SOP-11 Kwokman Diagnostics Home Collection Kit Specimen Accessioning" standard operating procedure.

The above described product, when accompanied by the authorized labeling (identified above) is authorized to be distributed to and used by individuals (accompanied only by the "The Kwokman Diagnostics COVID-19 Home Collection Kit" instructions) and authorized laboratories (accompanied by all authorized labeling) as set forth in this letter and pursuant to the conditions in this EUA, 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 authorized product, when used to diagnose COVID-19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen, and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product for such use.

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 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen 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, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

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

Kwokman Diagnostics, LLC (You) and Authorized Distributor(s)[6]

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)); 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 with the shipped product the "The Kwokman Diagnostics COVID-19 Home Collection Kit" instructions.

C. You and authorized distributor(s) must make available on your website(s) the "The Kwokman Diagnostics COVID-19 Home Collection Kit" instructions.

D. You and authorized distributor(s) must inform authorized laboratories and relevant

[6] "Authorized Distributor(s)" are identified by you, Kwokman Diagnostics, LLC., in your EUA submission as an entity allowed to distribute your product.

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

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which your product is distributed.

F. 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.

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.

Kwokman Diagnostics, LLC (You)

H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. You must notify FDA of any authorized laboratories designated by Kwokman Diagnostics, LLC to use your product, including the name, address, and phone number of any authorized laboratories.

J. You must provide authorized distributor(s) and authorized laboratories 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.

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, 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.

L. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the kits released for distribution have the clinical and analytical performance claimed in the authorized labeling.

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You must have a process in place to track adverse events, including any occurrence of false results with your product, 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).

P. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using anterior nasal swab specimens collected with the Kwokman Diagnostics COVID-19 Home Collection Kit during that timeframe and stratified by age group, including how many kits were requested and sent for home collection to individuals, how many kits were distributed and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for the Kwokman Diagnostics COVID-19 Home Collection Kit. Thereafter, monthly reporting must continue until FDA informs you that the cumulative data submitted within the monthly reports has sufficiently assessed updates made to your collection kit.

Authorized Laboratories

Q. Authorized laboratories testing nasal swab specimens self-collected using your product must have in place a suitable specimen receipt and accessioning SOP when accepting specimens for testing, such as the "SOP-11 Kwokman Diagnostics Home Collection Kit Specimen Accessioning" standard operating procedure.

R. Authorized laboratories using your product must use it only in conjunction with COVID-19 in vitro diagnostic (IVD) molecular tests that are authorized for use with your product.

S. Authorized laboratories 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) and you (via email: info@kwokmandiagnostics.com or phone: 949-891-0895) any suspected occurrence of false positive or false negative results linked to use of your product and significant deviations from the established performance characteristics of your product of which they become aware.

Kwokman Diagnostics, LLC. (You), Authorized Distributors and Authorized Laboratories

T. You, authorized distributors, and authorized laboratories using your product 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.

Conditions Related to Printed Materials, Advertising and Promotion

U. 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 the applicable requirements set forth in in section 501(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

V. 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.

W. 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;
- This product has been authorized only for the home collection and maintenance of anterior nasal swab specimens as an aid in 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 medical devices under Section 564(b)(1) of the 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 medical devices during the COVID-19 outbreak 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