January 6, 2022

Jorge Sepulveda, M.D., Ph.D.
Chief Medical Analytics Officer
George Washington University Public Health Laboratory
800 22nd Street NW
Washington, DC 20052

Device:	GWU SARS-CoV-2 RT-PCR Test
EUA Number:	EUA202180
Laboratory:	George Washington University Public Health Laboratory
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate, nasopharyngeal and oropharyngeal swab specimens, nasal washes and aspirates and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. This test is also for use with anterior nasal swab specimens that are self-collected at home by individuals 16 years of age and older using the GWU COVID-19 Test Home Collection Kit when determined to be appropriate by a healthcare provider. Testing is limited to the George Washington University Public Health Laboratory, located at Science and Engineering Hall, 800 22nd St. NW, Washington, DC 20052 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 Dr. Sepulveda:

On August 7, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the GWU SARS-CoV-2 RT-PCR Test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasal, mid-turbinate, nasopharyngeal and oropharyngeal swabs) 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). Testing was limited to the George Washington University Public Health Laboratory, located at Science and Engineering Hall, 800 22nd St. NW, Washington, DC 20052 which is certified under Clinical Laboratory Improvement

[1] For ease of reference, this letter will use the term "you" and related terms to refer to George Washington University Public Health Laboratory.

Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests. FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[2]

On October 26, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the August 7, 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 August 7, 2020, letter in its entirety with the revisions incorporated.[3] Accordingly, your product[4] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

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:

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

[3] The revisions to the August 7, 2020, letter and authorized labeling include: (1) update of the intended use to include the use of the GWU COVID-19 Test Home Collection Kit, to specifically list specimen types appropriate for testing and additional edits to reflect language used in more recent authorizations, (2) update to reflect language used in more recent authorizations, (3) modification of Conditions F and L (below) and addition of new Conditions of Authorization O, P and Q (below) related to the self-collection kit, consolidation of Conditions of Authorization K to Q of the August 7, 2020, letter into new Condition J (below) and incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions R and S below), and (4) update the Fact Sheet for Healthcare Providers to include information on self-collection.

[4] For ease of reference, this letter will use the term "your product" to refer to the GWU SARS-CoV-2 RT-PCR Test 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).

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.[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 qualitative test for the detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate, nasopharyngeal and oropharyngeal swab specimens, nasal washes and aspirates and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with anterior nasal swab specimens that are self-collected at home by individuals 16 years of age and older using the GWU COVID-19 Test Home Collection Kit when determined to be appropriate by a healthcare provider. Anterior nasal swab specimens collected using the GWU COVID-19 Test Home Collection Kit can be transported at ambient temperature for testing.

Testing is limited to the George Washington University Public Health Laboratory, located at 800 22nd St. NW, Washington, DC 20052, 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 nucleic acid 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from the 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 described in the authorized labeling (described below).

[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.

The GWU COVID-19 Test Home Collection Kit consists of materials required to collect, store and maintain the anterior nasal swab specimen, as described in the "GWU COVID-19 Test Home Collection Kit" Instructions for Use.

Your product requires control materials, or other authorized control materials (as specified under Condition J. below), specified in the EUA Summary.

The above described product, is authorized to be accompanied with the laboratory procedures bundle,[7] 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), and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: George Washington University Public Health Laboratory - GWU SARS-CoV-2 RT-PCR Test
- Fact Sheet for Patients: George Washington University Public Health Laboratory - GWU SARS-CoV-2 RT-PCR Test

The above described product, when accompanied by the laboratory procedures bundle, EUA Summary, and the two Fact Sheets is authorized to be used by the George Washington University Public Health Laboratory under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The GWU COVID-19 Test Home Collection Kit with the "GWU COVID-19 Test Home Collection Kit" Instructions for Use 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 laboratory procedures bundle, EUA Summary, two fact sheets, and "GWU COVID-19 Test Home Collection Kit" Instructions for Use.

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

[7] The laboratory procedures bundle includes "GWU COVID-19 PCR Test" laboratory procedures; the "Standard Operating Procedure: Sample Accessioning" SOP, the "Standard Operating Procedure GWU COVID-19 qRT-PCR Test", "Standard Operating Procedure: GWU COVID-19 RT-PCR TEST Sample Intake and Automated Processing", the "Standard Operating Procedure GWU COVID-19 qRT-PCR Test RNA Extraction Using MagMAX-96 Viral RNA Isolation Kit."

(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:

George Washington University Public Health Laboratory (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 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.

C. You must notify the relevant public health authorities of your intent to run your product.

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

E. 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.

F. You must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients and all instructions related to collection with the GWU COVID-19 Test Home Collection Kit.

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 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.

I. You must collect information on the performance of your product. You will 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.

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. Such requests should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

K. You must evaluate the analytical limit of detection and assess traceability[8] of your product with any FDA-recommended reference material(s). After submission to concurrence with the data by FDA, you must 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.

L. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the GWU COVID-19 Test Home Collection Kit and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) 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-EUAReporting@fda.hhs.gov).

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

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

procedure.

N. You 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.

O. You must make available all instructions related to the self-collection of anterior nasal swab specimens in each shipped kit of the GWU COVID-19 Test Home Collection Kit.

P. You must submit to FDA a summary report within 30 calendar days of product launch summarizing the results of any testing performed using specimens collected with the GWU COVID-19 Test Home Collection Kit 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.

Q. When testing specimens self-collected using the GWU COVID-19 Test Home Collection Kit you must follow the "Standard Operating Procedure: Sample Accessioning" SOP when accepting specimens for testing.

R. 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).

S. 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.

Conditions Related to Printed Materials, Advertising and Promotion

T. 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.

U. 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.

V. 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 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
- 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