August 7, 2022

James P. Canner, PhD, NRCC, MT(AAB)
VP, Regulatory, Clinical, and Research Programs
Gravity Diagnostics, LLC
632 Russell Street
Covington, KY 41011

Device:	Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits
EUA Number:	EUA210134
Laboratory:	Gravity Diagnostics, LLC
Indication:	The Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits is a direct to consumer product for testing of anterior nasal swab specimens collected at home using either: (1) the Everlywell COVID-19 Test Home Collection Kit DTC when used consistent with its authorization; (2) the Kroger Health COVID-19 Test Home Collection Kit when used consistent with its authorization; or (3) the Gravity Diagnostics COVID-19 Test Home Collection Kit when used consistent with its authorization. Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to Gravity Diagnostics, LLC, located at 632 Russell Street, Covington, KY 41011 and 812 Russell Street, Covington, KY 41011, 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. Canner:

On February 13, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter.[2] Based on

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Gravity Diagnostics, LLC.
[2] The February 13, 2021, letter authorized the Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits for the following indications for use: For direct to consumer testing of anterior nasal swab specimens self-collected at home using either: (1) the Everlywell COVID-19 Test Home Collection Kit DTC by any individuals, 18 years or

your request, the February 13, 2021, letter was revised and reissued by FDA on March 9, 2021,[3] May 10, 2021[4] and October 15, 2021.[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 April 12, 2022, you requested to amend your EUA. Based on that request, and having concluded that revising the October 15, 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 October 15, 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 indications described above.

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older, including individuals without symptoms or other reasons to suspect COVID-19; or (2) the Kroger Health COVID-19 Test Home Collection Kit either unobserved or video-observed by any individuals, 16 years or older, including individuals without symptoms or other reasons to suspect COVID-19. Testing was limited to Gravity Diagnostics, LLC, located at 632 Russell Street, Covington, KY 41011 and 812 Russell Street, Covington, KY 41011, 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.

[3] On March 9, 2021, the revisions to the February 13, 2021, letter and authorized labeling included: (1) addition of GetMyDNA COVID-19 Test Home Collection Kit by any individuals, 18 years or older, including individuals without symptoms or other reasons to suspect COVID-19 to the intended use, (2) updating the healthcare provider fact sheet as a result of the addition of the GetMyDNA COVID-19 Test Home Collection Kit, (3) modification of the accessioning and results reporting sections of the EUA summary related to the addition of the GetMyDNA COVID-19 Test Home Collection Kit, and (4) removal of Condition of Authorization L from the February 13, 2021 letter, to develop a qualification protocol for RUO instruments, as it is fulfilled.

[4] On May 10, 2021, the revisions to the March 9, 2021, letter and authorized labeling included: (1) updates to the intended use with respect to the authorized collection kits for anterior nasal swab specimens to reflect language used in more recent authorizations and (2) minor updates to the Fact Sheet for Healthcare Providers and Fact Sheet for Individuals to reflect language used in more recent authorizations.

[5] On October 15, 2021, the revisions to the May 10, 2021, letter and authorized labeling included: (1) updating the use of the MS2 internal control, which is now only added to the NTC and not all samples, (2) updating authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, (3) add Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (M and N), (4) updating the Condition of Authorization L. to delete the 30 calendar day summary report requirement for the Kroger Health COVID-19 Test Home Collection Kit and the GetMyDNA COVID-19 Test Home Collection Kit (fulfilled), (5) updates to the laboratory procedures to update the title of the "SARS-CoV-2 (COVID-19) Detection on the Quant Studio 12 with ThermoFisher TaqPath COVID-19 Combo Kit", add "LT-ID-110 Isolation of DNA/RNA from Respiratory Samples for SARS-CoV-2 Detection," "LT-ID-113: Dispensing PCR Master Mix using Cybio Well Vario," and "NT-AD-124B: SARS-CoV-2 RT-PCR Sample Receipt and Processing (Home Collection testing)" to the authorized labeling, and (6) updating webpage links in the Fact Sheet for Healthcare Providers and update the date on the Fact Sheet for Individuals to match the re-issue 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 October 15, 2021, letter and authorized labeling include: (1) updating the name of the "GetMyDNA COVID-19 Test Home Collection Kit" to "Gravity Diagnostics COVID-19 Test Home Collection Kit" in the Intended Use and the authorized labeling, (2) delete Condition of Authorization L. from the October 15, 2021 letter (fulfilled), (3) revise the Letter of Authorization to reflect language use in more recent authorizations, and (4) updating the Fact Sheet for Healthcare Providers and the Fact Sheet for Individuals to reflect language in more recent authorizations.

[8] For ease of reference, this letter will use the term "your product" to refer to the Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits 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.[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

The Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits is a direct to consumer product for testing of anterior nasal swab specimens collected at home using either: (1) the

[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.

Everlywell COVID-19 Test Home Collection Kit DTC when used consistent with its authorization; (2) the Kroger Health COVID-19 Test Home Collection Kit when used consistent with its authorization, or (3) the Gravity Diagnostics COVID-19 Test Home Collection Kit when used consistent with its authorization.

Testing of collected anterior nasal swab specimens is limited to Gravity Diagnostics, LLC, located at 632 Russell Street, Covington, KY 41011 and 812 Russell Street, Covington, KY 41011, which are certified under CLIA , 42 U.S.C.§263, and meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA 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 RNA; 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. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection.

Use of your product is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

The collected anterior nasal swab specimens are tested with your product according to the authorized labeling (described below) . Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents (as may be requested under Condition G. below) commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

Your product requires the use of control materials, or other authorized control materials (as may be requested under Condition G. below), that are to be run 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 authorized labeling.

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), the following standard operating procedures (SOP): "ThermoFisher TaqPath SARS-CoV-2 Testing. SARS-CoV-2 (COVID-19) Detection on the Quant Studio 12 with ThermoFisher TaqPath COVID-19 Combo Kit," "LT-ID-110 Isolation of DNA/RNA from Respiratory Samples for SARS-CoV-2 Detection," "LT-ID-113: Dispensing PCR Master Mix using Cybio Well Vario," "NT-AD-124B: SARS-CoV-2 RT-PCR Sample Receipt and Processing (Home Collection testing)," and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Gravity Diagnostics, LLC - Gravity Diagnostics SARS-CoV-2 RT-PCR for use with DTC kits

- Fact Sheet for Individuals: Gravity Diagnostics, LLC - Gravity Diagnostics SARS-

CoV-2 RT-PCR for use with DTC kits

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories (i.e., limited to Gravity Diagnostics, LLC, located at 632 Russell Street, Covington, KY 41011 and 812 Russell Street, Covington, KY 41011) under 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 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:

Gravity Diagnostics, LLC (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 make your product available with the authorized labeling to authorized laboratories.

C. You 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 must ensure that authorized laboratories using your product have a process in place for reporting test results to relevant public health authorities, as appropriate. You must also ensure that authorized laboratories using your product have a process in place for providing test results via the agreed upon process as authorized by the Everlywell COVID-19 Test Home Collection Kit DTC, the Kroger Health COVID-19 Test Home Collection Kit and the Gravity Diagnostics COVID-19 Test Home Collection Kit.

E. You must maintain records of the authorized laboratories to which you distribute your product, and test usage.

F. 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.

G. 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. 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.

H. You must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and Fact Sheet for Individuals.

I. 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.[11] After submission to and review of and concurrence with the data, FDA will update the EUA Summary to reflect the additional testing.

J. You must have a process in place to track adverse events, including any occurrence of

[11] 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.

false results with your product, including with the Everlywell COVID-19 Test Home Collection Kit DTC, the Kroger Health COVID-19 Test Home Collection Kit or the Gravity Diagnostics COVID-19 Test Home Collection Kit, in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, must immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

K. You must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

L. 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).

M. 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.

Authorized Laboratories

N. Authorized laboratories using your product 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.

O. Authorized laboratories using your product 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.

P. Authorized laboratories when testing anterior nasal swab specimens collected using the Everlywell COVID-19 Test Home Collection Kit DTC, the Kroger Health COVID-19 Test Home Collection Kit or the Gravity Diagnostics COVID-19 Test Home Collection Kit authorized for use with your product must follow any specimen accessioning protocol provided with the collection kit when accepting specimens for testing.

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

R. Authorized laboratories using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate. Authorized laboratories using your product must also have a process in place for reporting test results via the agreed upon process as authorized by the Everlywell COVID-19 Test Home Collection Kit DTC, the Kroger Health COVID-19 Test Home Collection Kit and the Gravity Diagnostics COVID-19 Test Home Collection Kit.

S. 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 (via email: info@gravitydiagnostics.com) 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.

T. 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 procedure.

Gravity Diagnostics, LLC (You) and Authorized Laboratories

U. You 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

V. 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.

W. 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.

X. 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 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure