U.S. FOOD & DRUG ADMINISTRATION

October 15, 2021

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 Assay
EUA Number:	EUA202301
Laboratory:	Gravity Diagnostics, LLC
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, nasopharyngeal (NP), and oropharyngeal (OP) swab specimens collected by a healthcare provider (HCP) from any individual, including individuals without symptoms or other reasons to suspect COVID-19. Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are collected using the Everlywell COVID-19 Test Home Collection Kit and Kwokman Diagnostics COVID-19 Home Collection Kit when used consistent with their respective authorizations. Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected in a healthcare setting using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device from individuals suspected of COVID-19 by an HCP due to symptoms. Emergency use of this test 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 November 23, 2020, 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 Assay, 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] On December 28, 2020, your request was granted via email to update the EUA Summary of your product to add the results of testing the FDA SARS-CoV-2 Reference Panel Testing. In addition, based on your request, the November 23, 2020, letter was revised and reissued by FDA on April 1, 2021,[3] June 3, 2021[4] and August 13, 2021.[5]

On August 25, 2021, you requested to further revise your EUA. Based on this request, and having concluded that revising the August 13, 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 August 13, 2021, letter in its entirety with the revisions incorporated.[6] Pursuant to

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Gravity Diagnostics, LLC.
[2] The November 23, 2020, letter authorized the Gravity Diagnostics SARS-CoV-2 RT-PCR Assay for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal (NP), and oropharyngeal (OP) swab specimens collected by a healthcare provider (HCP) from any individual, including individuals without symptoms or other reasons to suspect COVID-19. Qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens that are self-collected at home or in a healthcare setting using the Everlywell COVID-19 Test Home Collection Kit or the Kroger Health COVID-19 Test Home Collection Kit, when determined by an HCP to be appropriate based on results of a COVID-19 questionnaire. Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected in a healthcare setting using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device from individuals suspected of COVID-19 by an HCP due to symptoms. 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 April 1, 2021, the revisions to the November 23, 2020, letter and authorized labeling included: (1) removal of the Kroger Health COVID-19 Test Home Collection Kit from the intended use and the authorized labeling, (2) updating the intended use and authorized labeling with respect to anterior nasal swab specimens self-collected using the Everlywell COVID-19 Test Home Collection Kit being tested when the Everlywell COVID-19 Test Home Collection Kit is used consistent with its authorization, (3) clarify nasal as anterior nasal and mid-turbinate nasal swabs in the intended use and authorized labeling, and (4) updates to the conditions of authorization to reflect the revised intended use and language used in more recent letters of authorization.
[4] On June 3, 2021, the revision to the April 1, 2021, letter and authorized labeling included removal of "self" from "self-collected" with respect to anterior nasal swab specimens "collected using the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization" from the intended use and the authorized labeling.
[5] On August 13, 2021, the revision to the June 3, 2021, letter and authorized labeling included: (1) updates to the Intended Use to include testing of samples collected with the Kwokman Diagnostics COVID-19 Home Collection Kit, (2) removal of Conditions L. and M. (from the April 1, 2021 letter) which were fulfilled, (3) addition of Condition L. to collect and provide performance data from testing specimens collected with the Kwokman Diagnostics COVID-19 Home Collection Kit, (4) addition of Conditions M. and N. to evaluate device performance with viral mutations, (5) addition of the "NT-AD-124B: SARS-CoV-2 RT-PCR Sample Receipt and Processing (Home Collection testing)" laboratory procedures to the authorized labeling.
[6] The revisions to the August 13, 2021, letter and authorized labeling include: (1) updated use of the MS2 internal control, which is now only added to the NTC and not all samples, (2) removal of Condition L. (from the August 13, 2021 letter) which has been fulfilled, (3) minor updates to the limitations section of relevant laboratory procedures, (4) 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," and "LT-ID-113: Dispensing PCR Master Mix using Cybio Well Vario" to the authorized labeling and remove "LT-ID-102 Infectious Disease Collection Procedure," and "NT-AD-109 Sample Collection," from the authorized labeling, and (5) update the date on the Fact Sheet for Healthcare Providers and Fact Sheet for Individuals to match the match re-issue date.

section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[7] is now authorized for use consistent with 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.[8]

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 included 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.[9]

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.

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[7] For ease of reference, this letter will use the term "your product" to refer to the Gravity Diagnostics SARS-CoV-2 RT-PCR Assay used for the indications identified above.

[8] 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).

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

Authorized Product Details

Your product is for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, mid-turbinate nasal, nasopharyngeal (NP), and oropharyngeal (OP) swab specimens collected by a healthcare provider (HCP) from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection. Your test is also authorized for use with anterior nasal swab specimens that are collected using the Everlywell COVID-19 Test Home Collection Kit and Kwokman Diagnostics COVID-19 Home Collection Kit when used consistent with their respective authorizations. In addition, your test is also authorized for use with saliva specimens collected in a healthcare setting using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device from individuals suspected of COVID-19 by an HCP due to symptoms.

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 CLIA, 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory and saliva 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

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).

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.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition G. below), that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling:

- **Positive Control (PC)**: The positive control is a diluted mix of Thermo Fisher TaqPath COVID-19 Control that contains the sequence for the three SARS-CoV-2 assay targets as well as the sequence for the RNase P assay. This control is run on every plate to monitor amplification and signal production as well as ensure the integrity of the PCR reagents.

- **Negative (No Template) Control (NTC)**: The negative control is blank extraction reagents without target nucleic acid that is extracted and processed in the real time RT-PCR along with the patient samples. This control is run on every plate to monitor for contamination during the extraction process and in the real time RT-PCR reagents.

- **Internal Control 1 (MS2)**: The MS2 internal control is a bacteriophage RNA target that is added to the NTC only, prior to nucleic acid isolation. This control monitors for reagent integrity throughout the testing procedure in the NTC.

- **Internal Control 2 (RNAse P):** The primer and probe set to detect the RNAse P internal control is included in each test run. This control monitors for nucleic extraction and ensures sample integrity of the human specimen collected for testing.

The above described product is authorized to be accompanied with laboratory procedures (described below) and 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 information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Gravity Diagnostics, LLC – Gravity Diagnostics SARS-CoV-2 RT-PCR Assay

- Fact Sheet for Patients: Gravity Diagnostics, LLC – Gravity Diagnostics SARS-CoV-2 RT-PCR Assay

The above described product, when accompanied by the "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," "NT-AD-124A: SARS-CoV-2 RT-PCR Sample Receipt and Processing (from healthcare providers)," "LT-ID-113: Dispensing PCR Master Mix using Cybio Well Vario" laboratory procedures, "NT-AD-124B: SARS-CoV-2 RT-PCR Sample Receipt and Processing (Home Collection testing)" laboratory procedures, the EUA Summary (identified above) and the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be distributed to and used by the 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, 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:

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 healthcare providers and relevant public health authorities, as appropriate.

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. Such requests 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, Fact Sheet for Patients and all instructions related to the collection of specimens using the Everlywell COVID-19 Test Home Collection Kit, the Kwokman Diagnostics COVID-19 Home Collection Kit, and the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device.

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.[10] 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 with the Everlywell COVID-19 Test Home Collection Kit, the Kwokman Diagnostics COVID-19 Home Collection Kit, and the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device, any occurrence of false results with your product and report any such events 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-EUAReporting@fda.hhs.gov).

K. You must collect information on the performance of your product. You will report to the 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 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

[10] 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.

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.

M. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to 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 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.

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 or the Kwokman Diagnostics COVID-19 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 when testing saliva specimens collected using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device authorized for use with your product must have in place a suitable specimen receipt and accessioning protocol SOP and/or follow your specimen accessioning protocol.

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

S. 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.

T. 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.

U. 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

V. 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

W. 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.

X. 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.

Y. 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 been authorized 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