November 23, 2020

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
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 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. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratory:	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:

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 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.[3]

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.[4]

II. Scope of Authorization

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Gravity Diagnostics, LLC.
[2] 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.
[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] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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 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 infection. Your test is also authorized for use with 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. 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 each sample prior to nucleic acid isolation and is run for every sample. This control monitors for nucleic acid extraction, reverse transcription, amplification and signal production in each sample.

- **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/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 7 and 12 with ThermoFisher TaqPath COVID-19 Combo Kit," "LT-ID-102 Infectious Disease Collection Procedure," "NT-AD-109 Sample Collection," and "NT-AD-124: SARS-CoV-2 RT-PCR Sample Receipt and Processing" 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 will make your product available with the authorized labeling to authorized laboratories.

C. You will 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 will 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 will 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 will 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, Kroger Health COVID-19 Test Home Collection Kit, and Spectrum Solutions LLC SDNA-1000 Saliva Collection Device.

I. You will evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.[5] After submission to and review of and concurrence with the data, FDA will update the EUA Summary to reflect the additional testing.

J. You will have a process in place to track adverse events, including with the Everlywell COVID-19 Test Home Collection Kit, Kroger Health COVID-19 Test Home Collection Kit, and 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 will 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 will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using nasal specimens collected with

[5] 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.

the Everlywell COVID-19 Test Home Collection Kit and the Kroger Health COVID-19 Test Home Collection Kit used 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.

M. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using saliva specimens collected with Spectrum Solutions LLC SDNA-1000 Saliva Collection Device used with your product during that timeframe, including the positivity rate for specimens collected with the authorized collection device.

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 will 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 authorized specimens self-collected using home-collection kits authorized for use with your product must have in place a suitable specimen receipt and accessioning protocol SOP and/or follow any specimen accessioning protocol provided with the self-collection kit when accepting specimens for testing.

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

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

S. Authorized laboratories using your product 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@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 will 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, including 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 the Act and FDA regulations.

W. No descriptive printed matter, including 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, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test 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 authorization is terminated or 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure