June 1, 2020

James P. Canner Ph.D.
VP, Regulatory, Clinical, and Research Programs
Gravity Diagnostics, LLC
632 Russell Street
Covington, KY 41011

Device:	Gravity Diagnostics COVID-19 Assay
Company:	Gravity Diagnostics, LLC
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal (NP) and oropharyngeal (OP) swab and Bronchoalveolar Lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. This test is also intended for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, specified in this EUA's authorized labeling, when determined to be appropriate by a healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratory:	Testing is limited to Gravity Diagnostics, LLC that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, 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.

[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 COVID-19 Assay used for the indication identified above.

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]

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

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 nasal, nasopharyngeal (NP) and oropharyngeal (OP) swab and Bronchoalveolar Lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider.

Nasal specimens may also be self-collected at home or in a healthcare setting by individuals using an authorized self-collection kit, as specified in this EUA's authorized labeling, when determined to be appropriate by a healthcare provider. Testing is limited to Gravity Diagnostics, LLC that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

[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.

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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasal, nasopharyngeal (NP) and oropharyngeal (OP) swab and Bronchoalveolar Lavage (BAL) 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. The Gravity Diagnostics COVID-19 Assay uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

Your product requires the following control materials, or other authorized control materials, that are to be run as outlined in the authorized procedures submitted as part of the EUA request. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized procedures submitted as part of the EUA request:

- Internal Control – targeting human RNase P (RP) mRNA - controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Positive Template Control - DNA sequence of the nCoV nucleocapsid gene monitors the integrity of the PCR reagents and process.
- No Template (Negative) Control - no-sample elution buffer used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

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 Instructions for Use.

The above described product, is authorized to be accompanied with the labeling submitted as part of the EUA request, and as described in the "EUA summary" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), and the following product-specific 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 COVID-19 Assay
- Fact Sheet for Patients: Gravity Diagnostics COVID-19 Assay

The above described product, when accompanied by the "EUA Summary," Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the "Isolation of DNA/RNA from Respiratory Swab Samples and Urine using the King Fisher Flex" Standard Operating Procedure (SOP), the SARS-CoV-2 (COVID-19) Detection on the Quant Studio 7 and 12 with Multiplex Reactions" SOP and the "NT-AD-124: SARS-CoV-2 RT-PCR Sample Receipt and Processing" SOP (collectively referenced as "authorized labeling") is authorized to be used by Gravity Diagnostics, LLC, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your authorized product, when used for diagnosing COVID-19 and used consistently 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 consistently 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), 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 will 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 will notify the relevant public health authorities of your intent to run your authorized test.

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

E. You 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.

F. You will make available on your website the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

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 will use your authorized test as outlined in the authorized test procedures submitted as part of the EUA request. Deviations from the authorized test 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. When testing authorized specimens self-collected using home-collection kits authorized for use with your product you must follow either the Specimens Accessioning protocols provided with the self-collection kit, or your equivalent SOPs when accepting specimens for testing.

J. You will collect information on the performance of your authorized test. You will report to 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 authorized test of which you become aware.

K. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

L. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. You may request the addition of other home-collection kits for use with your product, that will be named in the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition of other extraction methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You may request the addition and/or substitution of primers or probes for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

T. You will evaluate the analytical limit of detection and assess traceability[5] of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, You will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

U. 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 any new self-collection kit authorized 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.

V. You will track adverse events, including any occurrence of false results with you product and report any such events to FDA under 21 CFR Part 803.

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

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

X. You will ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Y. You will additionally track adverse events associated with use of home-collection kits authorized for use with your product, including occurrences of false results, and report to FDA under 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

Conditions Related to Printed Materials, Advertising and Promotion

Z. 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.

AA. 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.

BB. 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 authorized laboratories;
- 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 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

Enclosures