U.S. FOOD & DRUG ADMINISTRATION

April 20, 2021

Theron Gober
Director, Regulatory and Quality
OPTI Medical Systems, Inc.
235 Hembree Park Drive
Roswell, GA 30076

Device:	OPTI SARS-CoV-2 RT-PCR Test
EUA Number:	EUA200215
Company:	OPTI Medical Systems, Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (anterior nasal, mid-turbinate, nasopharyngeal, or oropharyngeal swabs, and nasopharyngeal wash/aspirate or nasal aspirate) and bronchoalveolar lavage from patients suspected of COVID-19 by their healthcare provider (HCP). Qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (anterior nasal, mid-turbinate, nasopharyngeal, or oropharyngeal swabs) collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19 infection. Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to five individual upper respiratory swab specimens (anterior nasal, mid-turbinate, nasopharyngeal or oropharyngeal swabs) that are collected by an HCP using individual vials containing transport media from individuals suspected of COVID-19 by their HCP. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Mr Gober:

On May 6, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the OPTI SARS-CoV-2 RT PCR Test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (such as nasal, nasopharyngeal, oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) from patients suspected of COVID-19 by their health care 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 laboratories certified under CLIA to perform high complexity tests. Based on your requests, FDA has granted updates to the authorized labeling on May 29, 2020,[2] July 29, 2020,[3] and January 29, 2021,[4] as well as revised and reissued the May 6, 2020, letter on January 4, 2021, with the revisions incorporated.[5]

On February 20, 2021, you requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the January 4, 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 January 4, 2021, letter in its entirety with the revisions incorporated.[6] 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[7] is now authorized for use consistent with the indication described above.

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to OPTI Medical Systems, Inc.

[2] On May 29, 2020, your request was granted to (1) add a third extraction method, the OPTI DNA/RNA Magnetic Bead Kit, for use on Thermo Scientific KingFisher Flex or Duo Prime instruments, and (2) make minor edits and clarifications.

[3] On July 29, 2020, your request was granted to (1) add a fourth extraction method, MolGen PurePrep Pathogens Extraction Kit, for use on Thermo Scientific KingFisher Flex or Duo Prime, (2) to expand use of the OPTI DNA/RNA Magnetic Bead Kit to manual extraction, and (3) make minor edits and clarifications.

[4] On January 29, 2021, your request was granted via email to update the authorized labeling to include the results of testing with the FDA SARS-CoV-2 Reference Panel.

[5] On January 4, 2021, the revisions to the May 6, 2020, letter and authorized labeling included: (1) updating the Instructions for Use (IFU) for the OPTI SARS-CoV-2 RT-PCR Test to change the test cutoff for a positive sample to align with the CDC assay; (2) updating the IFU to include analytical and clinical data from post-authorization studies; (3) updating the IFU to add the use of an Extraction Negative Control; (4) updating the IFU and Healthcare Provider Fact Sheet to remove claims for sputum and lower respiratory tract aspirates from the Intended Use; and (5) making minor edits and clarifications, including to update and consolidate conditions of authorization to reflect language used in more recent authorizations.

[6] The revisions to the January 4, 2021, letter and authorized labeling include: (1) use of the OPTI Rapid Lysis Buffer with the OPTI SARS-CoV-2 RT PCR Test; (2)) clarifying "nasal" as anterior nasal and adding testing of mid-turbinate swabs; (3) testing of pooled samples containing up to five individual upper respiratory swab specimens (anterior nasal, mid-turbinate, nasopharyngeal or oropharyngeal swabs) that are collected by an HCP using individual vials containing transport media from individuals suspected of COVID-19 by their HCP; (4) testing of upper respiratory specimens (anterior nasal, mid-turbinate, nasopharyngeal, or oropharyngeal swabs) collected from any individual, including individuals without symptoms or other reasons to suspect COVID19 infection; (5) update of the *in silico* analysis to include emerging SARS-CoV-2 variants; (6) addition of a limitation statement regarding performance with circulating variants; (7) updates to the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations; (8) inclusion of an RUO Qualification protocol in the IFU; (9) removal of Condition O. (from the January 4, 2021, letter) which was fulfilled; (10) addition of Condition O. to conduct a post-authorization clinical study and conditions related to pooling; and (11) addition of the OPTI SARS-CoV-2 RT-PCR Test product information sheet.

[7] For ease of reference, this letter will use the term "your product" to refer to the OPTI SARS-CoV-2 RT-PCR Test used for the indication identified 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 Instructions for Use (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.

Authorized Product Details

Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (anterior nasal, mid-turbinate, nasopharyngeal, or oropharyngeal swabs and nasopharyngeal wash/aspirate or nasal aspirate) and bronchoalveolar lavage from patients

[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.

suspected of COVID-19 by their healthcare provider (HCP) as well as upper respiratory specimens (anterior nasal, mid-turbinate, nasopharyngeal, or oropharyngeal swabs) collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19 infection. Testing is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to five individual upper respiratory swab specimens (anterior nasal, mid-turbinate, nasopharyngeal or oropharyngeal swabs) that are collected by an HCP using individual vials containing transport media from individuals suspected of COVID-19 by their HCP. Negative results from pooled testing should not be treated as definitive. If patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

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 upper respiratory specimens (anterior nasal, mid-turbinate, nasopharyngeal, or oropharyngeal swabs, and nasopharyngeal wash/aspirate or nasal aspirate) or bronchoalveolar lavage. 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 OPTI SARS-CoV-2 RT-PCR Test includes the following materials or other authorized materials: OPTI SARS-CoV-2 Mix (SARS-CoV-2 Mix), OPTI RNA Master Mix (RNA MMx), OPTI Positive Control (PC), and the OPTI PCR Grade Water.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition J below), that are processed in the same way as the specimens 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 Instructions for Use:

- Internal Control - RNase P (RP) control in clinical samples: The RP primer and probe set is included in each run to test for human RP, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

- Positive Control (OPTI Positive Control) - contains *in vitro* transcribed SARS-CoV-2 RNA with genomic regions targeted by the kit. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.

- Negative Control (OPTI PCR Grade Water) - PCR grade water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

- Extraction Sample Control – your product recommends use of a negative human specimen material as a human specimen control (HSC). Used as an extraction control and positive control for the RNase P primer and probe set.

- Extraction Negative Control – Molecular grade water should be included as a sample for each extraction run to monitor for cross-contamination within the extraction run.

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 labeling entitled "OPTI SARS-CoV-2 RT-PCR Test" Instructions for Use (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the OPTI SARS-CoV-2 RT-PCR Test product information sheet, and the following product-specific fact sheets pertaining to the emergency use, which is required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referred to as the "authorized labeling":

- Fact Sheet for Healthcare Providers: OPTI Medical Systems, Inc. - OPTI SARS-CoV-2 RT-PCR Test
- Fact Sheet for Patients: OPTI Medical Systems, Inc. - OPTI SARS-CoV-2 RT-PCR Test

The above described product when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed to and used by authorized laboratories 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 for the qualitative detection of SARS-CoV-2 and 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, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

OPTI Medical Systems, Inc. (You) and Authorized Distributor(s)[10]

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)); any 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 and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must include the OPTI SARS-CoV-2 RT-PCR Test product information sheet with each shipped product to authorized laboratories and will make the "OPTI SARS-CoV-2 RT-PCR Test" Instructions for Use electronically available, with the opportunity to request a copy in paper form, and promptly provide the requested information without additional cost.

D. You and authorized distributor(s) 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/or authorized labeling.

[10] "Authorized Distributor(s)" are identified by you, OPTI Medical Systems, Inc., in your EUA submission as an entity allowed to distribute your product.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

F. You and authorized distributor(s) 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 the product of which you become aware.

G. You and authorized distributor(s) 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.

OPTI Medical Systems, Inc. (You)

H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. You may request changes to this EUA, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling and fact sheets may use another name for the product, but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT 7) - 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.

K. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

L. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

M. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your

product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

N. You must evaluate the analytical limit of detection and assess traceability[11] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You will further evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study with asymptomatic individuals within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you will update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

Q. 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.

R. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

S. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

T. 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.

U. Authorized laboratories 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: COVID19@optimedical.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

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

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

W. Authorized laboratories using specimen pooling strategies when testing patient specimens with the authorized test must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "*Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing*."

X. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Specimen Pooling Implementation and Monitoring Guidelines" provided in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

Y. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Protocol for Monitoring of Specimen Pooling Strategies. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request, and must be made available within a reasonable time after 12 months from the date of their creation.

OPTI Medical Systems, Inc. (You), Authorized Distributor(s), and Authorized Laboratories

Z. You, authorized distributors, 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

AA. 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 and FDA implementing regulations.

BB. 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.

CC. 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 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 product 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 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure