January 22, 2021

Tammy Moncur
VP, Quality & Regulatory Affairs
Ambry Genetics Laboratory
7 Argonaut
Aliso Viejo, CA 92656

Device:	Ambry COVID-19 RT-PCR Test
EUA Number:	EUA202196
Laboratory:	Ambry Genetics Laboratory
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected in a healthcare setting using the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device from individuals suspected of COVID-19 by their healthcare provider due to symptoms. This test is also for use with saliva specimens that are self-collected unsupervised at home by individuals 18 years of age or older using the Ambry COVID-19 RT-PCR Test Saliva Collection Kit, when determined to be appropriate by a healthcare provider based on results of a COVID-19 questionnaire. Testing is limited to Ambry Genetics Laboratory located at 7 Argonaut, Aliso Viejo, CA 92656, which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Ms. Moncur:

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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Ambry Genetics Laboratory.
[2] For ease of reference, this letter will use the term "your product" to refer to the Ambry COVID-19 RT-PCR Test used for the indication identified above.

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

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 saliva specimens collected in a healthcare setting using the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device from individuals suspected of COVID-19 by their healthcare provider due to symptoms.

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[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.

This test is also for use with saliva specimens that are self-collected unsupervised at home by individuals 18 years of age or older using the Ambry COVID-19 RT-PCR Test Saliva Collection Kit, when determined to be appropriate by a healthcare provider based on results of a COVID-19 questionnaire.

Testing is limited to Ambry Genetics Laboratory located at 7 Argonaut, Aliso Viejo, CA 92656, which is certified under CLIA and meets requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in 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.

The Ambry COVID-19 RT-PCR Test Saliva Collection Kit comprises the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device, a specimen biohazard bag with an absorbent pad, the kit carboard box, a specimen tube label, a shipping package/envelope with return shipping label and instructions for specimen collection and shipment. Patients should follow all specimen collection and mailing instructions provided in the kit.

To use your product, SARS-CoV-2 nucleic acid is first extracted 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 O 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:

- Internal Positive Control (IPC) – MS2 phage control which is required as an extraction, reverse transcription and PCR amplification positive control.
- External positive control - TaqPath COVID-19 Control contains the SARS-CoV-2 RNA genomic regions targeted by the kit. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- Negative Control - molecular-grade, nuclease-free, non-DEPC-treated water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

The above described product is authorized to be accompanied with laboratory procedures (described below), 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: Ambry Genetics Laboratory - Ambry COVID-19 RT-PCR Test
- Fact Sheet for Patients: Ambry Genetics Laboratory - Ambry COVID-19 RT-PCR Test

The above described product, when accompanied by the "Ambry COVID-19 RT-PCR Test RT-PCR Work Instruction," "Ambry COVID-19 RT-PCR Test Nucleic Acid Extraction Work Instruction," "Ambry COVID-19 RT-PCR Test Saliva Collection Kit Accessioning Instructions," Ambry COVID-19 RT-PCR Test COVID-19 Online Screening Questionnaire, EUA Summary (identified above), and the two Fact Sheets, is authorized to be used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Ambry COVID-19 RT-PCR Test Saliva Collection Kit with the "Ambry COVID-19 RT-PCR Test Saliva Self-Collection & Shipping Instructions" is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" is the "Ambry COVID-19 RT-PCR Test RT-PCR Work Instruction," "Ambry COVID-19 RT-PCR Test Nucleic Acid Extraction Work Instruction," "Ambry COVID-19 RT-PCR Test Saliva Collection Kit Accessioning Instructions," Ambry COVID-19 RT-PCR Test COVID-19 Online Screening Questionnaire, EUA Summary, two Fact Sheets, and the "Ambry COVID-19 RT-PCR Test Saliva Self-Collection & Shipping Instructions."

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:

Ambry Genetics Laboratory (You) and Authorized Distributor(s) [5]

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 and authorized distributor(s) must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

C. You and authorized distributor(s) must make available all instructions related to the self-collection of specimens using the Ambry COVID-19 RT-PCR Test Saliva Collection Kit both in the shipped kit and on your website.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which Ambry COVID-19 RT-PCR Test Saliva Collection Kit is distributed.

E. You and authorized distributor(s) must maintain customer complaint files concerning the Ambry COVID-19 RT-PCR Test Saliva Collection Kit on record. You must report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

F. 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

[5] "Authorized Distributor(s)" are identified by you, Ambry Genetics Laboratory, in your EUA submission as an entity allowed to distribute the Ambry COVID-19 RT-PCR Test Saliva Collection Kit.

does not exceed, the terms of this letter of authorization.

G. You and authorized distributor(s) must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Ambry Genetics Laboratory (You)

H. You must notify FDA of any authorized distributor(s) of the Ambry COVID-19 RT-PCR Test Saliva Collection Kit, 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 authorized revisions that might be made to this EUA and the authorized accompanying materials.

J. You must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

K. You must notify the relevant public health authorities of your intent to run your product.

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

M. You 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.

N. You 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. When testing self-collected specimens using your product, you must have in place a suitable specimen receipt and accessioning SOP.

O. 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, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling 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 (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.

P. 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.[6] After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

Q. You must submit to FDA a summary report within 30 calendar days of the date of this letter summarizing the results of any testing performed using saliva specimens collected with the Ambry COVID-19 RT-PCR Test Saliva Collection Kit 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.

R. 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 the OMNIgene·ORAL OM-505/OME-505 during that timeframe, including the positivity rate for saliva specimens.

S. You must conduct a human usability survey to further evaluate the "Ambry COVID-19 RT-PCR Test Saliva Self-Collection & Shipping Instructions." You must provide a report to DMD/OHT7-OIR/OPEQ/CDRH from your observations on the first 500 self-collected samples within 60 calendar days of the date of this letter.

T. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Ambry COVID-19 RT-PCR Test Saliva Collection Kit and OMNIgene ORAL OM-505/OME-505, 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-EUA-Reporting@fda.hhs.gov).

U. You must collect information on the performance of your product. 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 product of which you become aware.

V. 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.

Conditions Related to Printed Materials, Advertising and Promotion

[6] 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.

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 in section 502(a), (q)(1), and (r) of the Act 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 has been authorized for emergency use 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure