October 31, 2024

Jonathan Chan
Senior Regulatory Affairs Specialist
DNA Genotek Inc.
3000 - 500 Palladium Drive
Ottawa, ON, K2V 1C2 Canada

Devices:	ORAcollect·RNA ORE-100
Company:	DNA Genotek Inc.
Indication:	The ORAcollect·RNA ORE-100 saliva collection device is intended for use by individuals to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA).

Dear Jonathan Chan:

On October 28, 2020, based on your[1] request the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the ORAcollect·RNA OR-100 and ORAcollect·RNA ORE-100 saliva collection devices, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.[2]

On April 25, 2024, you requested that FDA further amend the Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the October 28, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb3(g)(2)(C)), FDA is reissuing the October 28, 2020, letter in its entirety with the revisions incorporated.[3] Accordingly, your product[4] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

[1] For ease of reference, this letter will use the term "you" and related terms to refer to DNA Genotek Inc.
[2] The October 28, 2020, letter authorized the the ORAcollect·RNA OR-100 and ORAcollect·RNA ORE-100 saliva collection devices for use by individuals to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA).
[3] The revisions to the October 28, 2020 letter and authorized labeling include: (1) removal of the ORAcollect·RNA OR-100 as an authorized saliva collection device, (2) minor edits to the authorized labeling that were either to fix typographical errors or were clarifying in nature, and (3) updates made for consistency with language used in more recent authorizations.
[4] For ease of reference, this letter will use the term "your product" to refer to the ORAcollect·RNA ORE-100 used for the indication identified above.

On February 4, 2020, as amended on March 15, 2023, 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, or a significant potential for a public health emergency, that affects, or 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.[5] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under Section 564(a) of the Act.[6]

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 upon which FDA relied is contained in the EUA Summary (identified below). FDA has cleared 510(k)'s for the collection, transport, and storage of human clinical specimens, including saliva, to facilitate downstream molecular diagnostic testing at a laboratory, but these are not adequate and available alternatives to your product.[7]

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, by serving as an appropriate means to collect, stabilize, and maintain during transport, saliva specimens suspected of

[5] 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*. February 4, 2020. 85 FR 7316 (February 7, 2020). U.S. Department of Health and Human Services, Amended Determination of a Public Health Emergency or Significant Potential for a Public Health Emergency Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b). March 15, 2023. 88 FR 16644 (March 20, 2023) ("Amended Determination").

[6] U.S. Department of Health and Human Services, *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 17335 (March 27, 2020)

[7] To date, FDA has cleared two 510(k)'s for the collection, transport, and storage of human clinical specimens, respiratory and/or saliva, to facilitate downstream molecular diagnostic testing at a laboratory (under Product Code QBD); the DNA/RNA Shield Collection Tube (upper and lower respiratory and saliva; K202641) and the Spectrum Saliva Collection Device (saliva only; K223497). The devices are intended to be used by a health care provider for samples suspected of containing SARS-CoV-2. Available information indicates that these are not adequate and available alternatives to your product.

containing SARS-CoV-2 RNA, and that the known and potential benefits of your product when used for such use, 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.[8]

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 intended for use by individuals to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA). The devices may be used for specimen self-collection by a layperson (unsupervised).[9]

The ORAcollect·RNA ORE-100 saliva collection device includes the following materials or other authorized materials (as may be requested under Condition I. below): Tyvek-Polyester primary packaging, patient Instructions for Use (IFU), collection tube and sponge collector, double-ended tube cap, stabilizing liquid and collection tube wrap around label.

Authorized labeling includes the following documents: EUA Summary, and the "ORAcollect·RNA ORE-100 Instructions for sample collection" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas).

The above described product, with the authorized labeling provided as set forth in the Conditions of Authorization (Section IV) below, is authorized to be distributed and used as set forth in this letter and pursuant to the conditions in 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 by serving as an appropriate means to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 RNA, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section

[8] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[9] While this EUA does not authorize your product as a standalone self-collection device, the ORAcollect•RNA ORE-100 may be included as a component of an authorized or cleared self-collection kit (e.g., as part of a kit that is authorized under its own EUA for use by an individual to collect saliva specimens at home).

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:

DNA Genotek Inc. (You) and Authorized Distributor(s)[10]

A. Your product must comply with the following labeling requirements pursuant to 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), the authorized labeling and must make available with the shipped product the

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

"ORAcollect·RNA ORE-100 Instructions for sample collection."

C. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers of your product and locations to which your product is distributed.

D. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

E. 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.

F. You and authorized distributors 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.

DNA Genotek Inc. (You)

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

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

I. 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 your 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 Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

J. 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).

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

L. 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 those within 48 hours of the request.

M. You will track adverse events associated with your product and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should also immediately be reported to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

Conditions Related to Printed Materials, Advertising and Promotion

N. 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 meet the requirements set forth in section 501(a), (q)(1), and (r) of the Act, as applicable,and FDA implementing regulations.

O. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this device is safe or effective for the detection of SARS-CoV-2.

P. 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;
- This product has been authorized only to collect, stabilize, and maintain during transport, saliva specimens suspected of containing SARS-CoV-2 ribonucleic acid (RNA), 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 medical devices 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 medical devices during the COVID-19 outbreak 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure