July 28, 2021

Ronald C. McGlennen, MD
President, Medical Director
Access Genetics, LLC, d.b.a. OralDNA Labs
7400 Flying Cloud Drive, Suite 150
Eden Prairie, MN 55344

Device:	OraRisk COVID-19 RT-PCR
EUA Number:	EUA200464
Laboratory:	Access Genetics, LLC
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab and anterior nasal (nasal) swab specimens collected in universal transport media, nasal swabs collected in saline oral rinse, and saline oral rinse specimens from individuals suspected of COVID-19 by their healthcare provider. This test is also for use with anterior nasal (nasal) swab specimens that are collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit when used consistent with its authorization. Emergency use of this test is limited to the authorized laboratory.
Authorized Laboratory:	Testing is limited to the Access Genetics, LLC laboratory, located at 7400 Flying Cloud Drive, Eden Prairie, MN 55344, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Dr. McGlennen:

On July 17, 2020 based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the OraRisk COVID-19 RT-PCR for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab and nasal swab specimens collected in universal transport media, and nasal swabs collected in oral saline rinse from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The July 17, 2020 letter authorizing emergency use of this test limited testing to the Access Genetics, LLC laboratory, located at 7400 Flying Cloud Drive, Eden Prairie, MN 55344, which is certified

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Access Genetics, LLC.

under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests. Based on your request, FDA reissued the letter on September 25, 2020. [2]

Based on your request received July 19, 2021, to amend your Emergency Use Authorization (EUA), and having concluded that revising the September 25, 2020 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 September 25, 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.

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.[5]

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 contained 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

[2] On September 25, 2020, the revisions to the July 17, 2020, letter and authorized labeling include: (1) revised intended use to include testing of saline oral rinse specimens and updates consistent with more recent authorizations, (2) revised Conditions of Authorization consistent with more recent authorizations, (3) updated EUA Summary to include data to support testing with saline oral rinse specimens alone, (4) updated SOP to include testing with saline oral rinse specimens alone, and (5) updated healthcare provider and patient fact sheets to reflect testing of saline oral rinse specimens and also include language used in more recent authorizations.

[3] The revisions to the September 25, 2020, letter and authorized labeling include: (1) revised intended use to include testing with anterior nasal (nasal) swab specimens that are collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit when used consistent with its authorization, (2) updated in silico assessment of reactivity, (3) addition of limitation statements to address the potential performance impact due to the rise of various variants of concern, (4) addition of Conditions I. and M. due to inclusion of the binx health At-home Nasal Swab COVID-19 Sample Collection Kit in the intended use, (5) addition of Conditions Q. and R. to evaluate the impact of SARS-CoV-2 viral mutations on product performance, and (6) updates to the letter to reflect language use in more recent authorizations.

[4] For ease of reference, this letter will use the term "your product" to refer to the OraRisk COVID-19 RT-PCR used for the indication identified above.

[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*. 85 FR 7316 (February 7, 2020).

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.[6]

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 nasopharyngeal swab and nasal swab specimens collected in universal transport media, nasal swabs collected in saline oral rinse, and saline oral rinse specimens from individuals suspected of COVID-19 by their healthcare provider. This test is also for use with nasal swab specimens that are collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit when used consistent with its authorization.

Testing is limited to Access Genetics, LLC laboratory, located at 7400 Flying Cloud Drive, Eden Prairie, MN 55344, which is certified under CLIA 42 U.S.C. §263a, and meets the requirements to perform high complexity tests.

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. Negative results for SARS-CoV-2 RNA from saline oral rinse 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 and purified from the specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR

[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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 K 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 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.
- No Template (Negative) Control - Nuclease-free saline is used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.
- Negative Extraction Control - RP containing pseudovirus is used as a Negative Extraction Control. The pseudovirus is combined with saline and is used as an extraction control and positive control for the RP primer and probe set
- Positive PCR Control - The positive PCR control is provided with the commercial test kit you use for the OraRisk COVID-19 RT-PCR test (i.e., the LogixSmart test kit). It is included in each PCR run and is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- LOD Extraction Control - Pseudovirus containing SARS-CoV-2 target sequence diluted to a near Limit of Detection (LoD) concentration with nuclease free saline is used to monitor assay sensitivity and reagent functionality. This control is subjected to all processing steps including RNA extraction, RT-PCR set up, and thermocycling.

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/in-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: Access Genetics – OraRisk COVID-19 RT-PCR
- Fact Sheet for Patients: Access Genetics – OraRisk COVID-19 RT-PCR

The above described product, when accompanied by the "SARS-CoV-2 (OraRisk COVID-19 RT-PCR) PCR Set-up and Detection, Result Review and Analysis", "Sample Preparation, Cell Lysis and Chemagen RNA Extraction", and "Receiving and Accessioning Clinical Laboratory Specimens" laboratory procedures, the EUA Summary (identified above) and the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be used 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, 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:

Access Genetics, LLC (You)

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 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.

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

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

E. 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.

F. You must make available on your website(s), if applicable, 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 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.

I. When testing authorized specimens collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit, you must follow receipt and accessioning protocols consistent with its authorization when accepting specimens for testing.

J. You must collect information on the performance of your product. You must report to 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) (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.

K. 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 DMD/OHT7-OIR/OPEQ/CDRH CDRH and require appropriate authorization from FDA prior to implementation.

L. 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[7]. After submission to and concurrence with the data by FDA, FDA will update the EUA

[7] 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 authorized test.

summary to reflect the additional testing. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with the binx health At-home Nasal Swab COVID-19 Sample 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.

N. You must track adverse events, including any occurrence of false results with your product and report any such events to FDA pursuant to 21 CFR Part 803.

O. 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.

P. You 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.

Q. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately.

R. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Conditions Related to Printed Materials, Advertising and Promotion

S. 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, as applicable, and FDA implementing regulations.

T. 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.

U. 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