December 15, 2020

Sarah Jacobs-Helber, PhD, HCLD(ABB)
Chief Laboratory Officer
RCA Laboratory Services LLC dba GENETWORx
4060 Innslake Drive
Glen Allen, VA 23060

Device:	GENETWORx Covid-19 Nasal Swab Test
Company:	RCA Laboratory Services LLC dba GENETWORx
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected unsupervised at home using the GENETWORx Covid-19 Nasal Swab Test Kit by individuals (18 years of age and older) suspected of COVID-19, when determined to be appropriate by a healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	RCA Laboratory Services LLC located at 4060 Innslake Drive, Glen Allen, VA 23060 and Testing Centers of America LLC located at 411 Swedeland Road, King of Prussia, PA 19406, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Dear Dr. Jacobs-Helber:

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. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of

[1] For ease of reference, this letter will use the term "you" and related terms to refer to RCA Laboratory Services LLC dba GENETWORx.
[2] For ease of reference, this letter will use the term "your product" to refer to the GENETWORx Covid-19 Nasal Swab Test used for the indication identified above.

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 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

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 for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected unsupervised at home using the GENETWORx Covid-19 Nasal Swab Test Kit by individuals (18 years of age and older) suspected of COVID-19, when determined to be appropriate by a healthcare provider.

Testing is limited to RCA Laboratory Services LLC located at 4060 Innslake Drive, Glen Allen, VA 23060 and and Testing Centers of America LLC located at 411 Swedeland Road, King of

[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.

Prussia, PA 19406, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

The SARS-CoV-2 RNA is generally detectable in nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; 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. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

The GENETWORx Covid-19 Nasal Swab Test is an integrated nucleic acid testing system with fully automated steps necessary to perform assays from sample processing through amplification, detection, and data reduction. The assay incorporates an internal control, positive control and negative control, or other authorized control materials (as may be requested under Condition I below), to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error, according to the authorized labeling. Your product also contains a separate RNase P assay to monitor the integrity of self-collected specimens. The RNase P assay must be performed with a no template control to monitor for cross-contamination during nucleic acid extraction and RT-PCR set up, as well as a human specimen control to verifythe integrity of nucleic acid extraction and RT-PCR amplification.

Your 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.

When using the GENETWORx Covid-19 Nasal Swab Test Kit, individuals must follow all specimen collection and mailing instructions provided with the self-collection kit, as described in the "Your GENETWORx Covid-19 Nasal Swab Test Kit Instructions."

The above described product is authorized to be accompanied with laboratory procedures (described below), the "Your GENETWORx Covid-19 Nasal Swab Test Kit Instructions," and 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 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: RCA Laboratory Services LLC dba GENETWORx - GENETWORx Covid-19 Nasal Swab Test
- Fact Sheet for Patients: RCA Laboratory Services LLC dba GENETWORx - GENETWORx Covid-19 Nasal Swab Test

The above described product, when accompanied by the "Registration – Genetworx COVID-19 Nasal Swab Test" sample acessioning SOP, "Genetworx Covid-19 Nasal Swab Test" SOP, "Detection of RNASE P in samples collected for the Genetworx Covid-19 Nasal Swab Test" SOP, "Human DNA_RNA 96 Extraction for Genetworx Covid-19 Nasal Swab Test" SOP,

"Your GENETWORx Covid-19 Nasal Swab Test Kit Instructions", EUA Summary (identified above) and the two Fact Sheets (collectively referenced to as "authorized labeling") is authorized to be distributed and 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, 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:

RCA Laboratory Services LLC dba GENETWORx (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 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.

C. You will make your product available with the authorized labeling to authorized laboratories.

D. You will ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. You will collect information on the performance of the test. You will report to FDA any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

F. You will make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

G. You will maintain records of the authorized laboratories and test usage.

H. 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.

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. 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.

J. You will evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.[5] After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, FDA will update the EUA Summary to reflect the additional testing.

K. You will further evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study with unsupervised, self-collected

[5] 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.

samples from individuals consistent with the indication above of your product within 2 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.

L. You will have a process in place to 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.

M. You will additionally track adverse events associated with the GENETWORx Covid-19 Nasal Swab Test Kit, including occurrences of false results and report to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

N. You must include the "Your GENETWORx Covid-19 Nasal Swab Test Kit Instructions" in the shipped kit and make it available on your website.

O. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using nasal swab specimens self-collected with the GENETWORx Covid-19 Nasal Swab Test Kit, 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 GENETWORx Covid-19 Nasal Swab Test Kit.

P. You will develop a laboratory procedure whereby authorized laboratories can verify that the RUO instrument authorized with your product is capable of performing the GENETWORx Covid-19 Nasal Swab Test with sufficient accuracy, as stated in the authorized labeling. You should submit the procedure to FDA within 21 calendar days of authorization. After DMD/OHT7-OIR/OPEQ/CDRH's review and concurrence, you will update the authorized labeling to reflect the laboratory procedure within 45 calendar days of authorization.

Authorized Laboratories

Q. Authorized laboratories using your product 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.

R. Authorized laboratories using your product will 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 testing authorized specimens self-collected using the GENETWORx Covid-19 Nasal Swab Test Kit must follow any specimens accessioning protocol provided with the self-collection kit and/or outlined in the authorized labeling when accepting specimens for testing.

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

U. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

V. Authorized laboratories will 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 phone: 610-726-1205) 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.

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.

RCA Laboratory Services LLC dba GENETWORx (You) and Authorized Laboratories

X. You and other authorized laboratories using your product will 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

Y. 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.

Z. 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.

AA. All descriptive printed matter, 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, but has been authorized for emergency use 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

- The emergency use of 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 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