August 12, 2022

E. Karl Enters, Ph.D.
VP, Regulatory Affairs
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 anterior nasal swab specimens that are collected at home using the GENETWORx Covid-19 Nasal Swab Test Collection Kit by individuals age18 years and older (self-collected), 14 years and older (self-collected under adult supervision) or 4 years and older (collected with adult assistance) 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. Enters:

On December 15, 2020, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the GENETWORx Covid-19 Nasal Swab Test, 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] Based on your

[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] The December 15, 2020, letter authorized emergency use of the GENETWORxCovid-19 Nasal Swab Test 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. Emergency use of this test was limited to RCA Laboratory Services LLC located at 4060 Innslake Drive, Glen Allen, VA 23060 and Testing Centers of

requests, FDA granted updates to the authorized labeling on February 12, 2021,[3] May 10, 2021,[4] May 14, 2021,[5] and November 17, 2021.[6] In addition, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.[7]

On April 25, 2022, FDA received a request from you to amend the EUA. Based on that request, having concluded that revising the December 15, 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 December 15, 2020, letter in its entirety with revisions incorporated[8] to authorize the emergency use of your product.[9] Pursuant to section 564 of the Act, Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product is now intended for the indication above.

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 met the requirements to perform high complexity tests.

[3] On February 12, 2021, your request was granted to update the EUA Summary of the GENETWORx Covid-19 Nasal Swab Test to add an online ordering system through your web portal. FDA updated the Fact Sheet for Healthcare Providers and EUA Summary to reflect more recent policy and authorizations.

[4] On May 10, 2021, your request was acknowledged by email to update the EUA Summary of the GENETWORx Covid-19 Nasal Swab Test with the results of the FDA SARS-CoV-2 Reference Panel testing.

[5] On May 14, 2021, your request was granted to update the EUA Summary of the GENETWORx Covid-19 Nasal Swab Test to include data from a sample adequacy clinical study to fulfill a Condition of Authorization. In addition, FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect more recent authorizations.

[6] On November 17, 2021, your request was granted to add the Aptima Direct Load Tube Collection Kit as an authorized specimen collection device.

[7] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download.

[8] The revisions to the December 15, 2020, letter and authorized labeling include: (1) update the name of the collection kit used with the GENETWORx Covid-19 Nasal Swab Test from "*GENETWORx Covid-19 Nasal Swab Test Kit*" to "*GENETWORx Covid-19 Nasal Swab Test Collection Kit*," (2) revise the intended use to clarify "*nasal swab*" as "*anterior nasal swab*" and add specimen collection from minors - "*collected at home using the GENETWORx Covid-19 Nasal Swab Test Collection Kit, by individuals age 18 years and older(self-collected), 14 years and older (self-collected under adult supervision) or 4 years and older (collected with adult assistance) suspected of COVID-19, when determined to be appropriate by a healthcare provider,*" (3) updates to the letter and authorized labeling, including the Fact Sheets, to reflect the revised intended use and also for consistency with language used in more recent authorizations, (4) simplify the GENETWORx Covid-19 Nasal Swab Test Collection Kit workflow by eliminating the steps that require patients to complete information on the Specimen Collection Tube and the Specimen Confirmation Form, (5) add an activation card into the GENETWORx Covid-19 Nasal Swab Test Collection Kit to remind patients to register their kits upon receipt, (6) add an "Instrument Qualification Protocol" for end users using the LGC Intelliqube instrument, Model number DS-IQ1804, (7) updates to the laboratory standard operating procedures (SOPs) (described below) to reflect the revised GENETWORx Covid-19 Nasal Swab Test Collection Kit workflow and updates to some of the SOP titles, (8) updates to the EUA Summary to include details of the revised GENETWORx Covid-19 Nasal Swab Test Collection Kit workflow, update the usability studies with data on specimen collection in minors, (9) update the authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, (10) incorporate Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (P. and Q., below) and add Condition of Authorization R. (below) based on the revised intended use, and (11) removal of Condition of Authorization K. O. and P. from the December 15, 2020 letter (fulfilled).

[9] 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.

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.[10]

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.[11]

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 anterior nasal swab specimens collected at home using the GENETWORx Covid-19 Nasal Swab Test

[10] 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).

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

Collection Kit by individuals age18 years and older (self-collected), 14 years and older (self-collected under adult supervision) or 4 years and older (collected with adult assistance) suspected of COVID-19, when determined to be appropriate by a healthcare provider. Specimens collected using the GENETWORx Covid-19 Nasal Swab Test Collection Kit can be transported at ambient temperature for testing.

The SARS-CoV-2 RNA is generally detectable in anterior 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.

Testing of anterior nasal swab specimens using your product, as outline in the authorized labeling (described below), is limited to 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.

Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents (as may be requested under Condition M. below) commonly used in clinical laboratories as described in the authorized labeling. Your product also requires the use of authorized control materials, or other authorized control materials (as may be requested under Condition M. below), as described in the authorized labeling.

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

The above described product is authorized to be accompanied with laboratory procedures (described below), the "Your GENETWORx Covid-19 Nasal Swab Test Kit Instructions," the "GENETWORx Covid-19 Nasal Swab Test Collection Kit" Activation Card and 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 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 "Sample Accessioning - Genetworx COVID-19 Nasal Swab Test" SOP, "Genetworx Covid-19 Nasal Swab Test" SOP, "RNase P Assay for detection of RNASEP 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, "Instrument Qualification Protocol," "Your GENETWORx Covid-19 Nasal Swab Test Collection Kit Instructions", "GENETWORx Covid-19 Nasal Swab Test Collection Kit" Activation Card, EUA Summary (identified above) and the two Fact Sheets (collectively referenced to as "authorized labeling") is authorized to be distributed and used by 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 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) and Authorized Distributor(s) [12]

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 Fact Sheet for Patients.

C. You and authorized distributor(s) must make available the "Your GENETWORx Covid-19 Nasal Swab Test Kit Instructions" and the "GENETWORx Covid-19 Nasal Swab Test Collection Kit" Activation Card in the shipped kit and available on your website(s)

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, or the authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers (of kits and lot numbers) and locations to which the GENETWORx Covid-19 Nasal Swab Test Collection Kit is distributed.

F. You and authorized distributor(s) must maintain customer complaint files concerning the GENETWORx Covid-19 Nasal Swab Test 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.

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

RCA Laboratory Services LLC dba GENETWORx (You)

H. You must notify FDA of any authorized distributor(s) of the GENETWORx Covid-19 Nasal Swab Test Collection Kit, including the name, address, and phone number of any authorized distributor(s).

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

[12] "Authorized Distributor(s)" are identified by you, RCA Laboratory Services LLC dba GENETWORx, in your EUA submission as an entity allowed to distribute the GENETWORx Covid-19 Nasal Swab Test Collection Kit.

J. You must 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.

K. You must collect information on the performance of the test. You must 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.

L. You must maintain records of test usage at the authorized laboratories.

M. 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 requests 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.

N. 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.[13] 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.

O. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the GENETWORx Covid-19 Nasal Swab Test Collection Kit, 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).

P. 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 (via email: CDRH-EUA-Reporting@fda.hhs.gov).

[13] 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.

Q. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding 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.

R. You must submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using anterior nasal swab specimens collected using the updated workflow for the GENETWORx Covid-19 Nasal Swab Test Collection Kit during that timeframe stratified by age group, and including how many kits were requested and sent for home collection to individuals, how many kits were distributed and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for the GENETWORx Covid-19 Nasal Swab Test Collection Kit.

Authorized Laboratories

S. 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.

T. 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.

U. Authorized laboratories testing authorized specimens self-collected using the GENETWORx Covid-19 Nasal Swab Test Collection 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.

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

W. 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.

X. 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 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.

Y. 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), Authorized Distributor(s), and Authorized Laboratories

Z. You, authorized distributor(s), and 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

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, as applicable, 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 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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Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure