

December 08, 2023

E. Karl Enters, Ph.D.  
VP, Regulatory Affairs  
RCA Laboratory Services LLC dba GENETWORx  
4060 Innslake Dr  
Glen Allen, VA 23060

Device: Gx HTKB SARS-CoV-2 Test

EUA Number: EUA220066

Company: RCA Laboratory Services LLC dba GENETWORx

Indication: This test is authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in mid-turbinate and anterior nasal swab specimens collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19, using the NEST collection device when determined to be appropriate by a healthcare provider.

Emergency use of this test is limited to the authorized laboratories.

Authorized Laboratories: Testing is limited to RCA Laboratory Services LLC dba GENETWORx, located at 4060 Innslake Dr, Glen Allen, VA 23060 and 670 US 1, Iselin, NJ 08830, 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:

This letter is in response to your<sup>1</sup> request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,<sup>2</sup> pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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

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<sup>1</sup> For ease of reference, this letter will use the term “you” and related terms to refer to RCA Laboratory Services LLC dba GENETWORx.

<sup>2</sup> For ease of reference, this letter will use the term “your product” to refer to the Gx HTKB SARS-CoV-2 Test used for the indication identified above.

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. 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.<sup>3</sup>

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 granted a De Novo classification request and cleared tests for the qualitative detection of nucleic acid from SARS-CoV-2, but these are not adequate and available alternatives to your product.<sup>4</sup>

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.<sup>5</sup>

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<sup>3</sup> 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”).

<sup>4</sup> To date, the FDA granted a De Novo classification request for the BioFire Respiratory Panel 2.1 (RP2.1) (Product Code: QOF; DEN200031) and cleared various tests (Search FDAs 510(k) Premarket Notification database; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>; Product codes: QOF, QWR, QQX) for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory clinical specimens. Available information indicates that these are not adequate and available alternatives to your product.

<sup>5</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

## **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 an in vitro diagnostic real-time reverse transcription polymerase chain reaction (rRT-PCR) assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in mid-turbinate and anterior nasal swab specimens collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19, using the NEST collection device when determined to be appropriate by a healthcare provider. Testing is limited to RCA Laboratory Services LLC dba GENETWORx, located at 4060 Innslake Drive, Glen Allen, VA 23060 and 670 US 1, Iselin, NJ 08830, 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.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in mid-turbinate and 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. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.

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/or epidemiological information.

To use your product, nucleic acid is first extracted, isolated and purified from mid-turbinate and anterior nasal swab 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. The Gx HTKB SARS-CoV-2 Test includes the materials (or other authorized materials as may be requested under Condition F. below) described in the EUA Summary.

Your product requires control materials (or other authorized control materials as may be requested under Condition F. below) that are described in the EUA Summary.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the EUA Summary.

The above described product is authorized to be accompanied by 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>), the laboratory Standard Operating Procedure (SOP) “Gx HTKB SARS-COV2 Test” SOP, and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and

patients (collectively referred to as “authorized labeling”):

- Fact Sheet for Healthcare Providers: RCA Laboratory Services LLC dba GENETWORx – Gx HTKB SARS-CoV-2 Test
- Fact Sheet for Patients: RCA Laboratory Services LLC dba GENETWORx - Gx HTKB SARS-CoV-2 Test

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be used by the authorized laboratories 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 consistently 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, storage, and distribution 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: 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 make available on your website(s) the authorized fact sheets.
- C. 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.
- D. You must collect information on the performance of your product. You must report to FDA 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 and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: [CDRH-EUAREporting@fda.hhs.gov](mailto:CDRH-EUAREporting@fda.hhs.gov)).
- E. 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.
- F. 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 DMD/OHT7/OPEQ/CDRH and requires appropriate authorization from FDA prior to implementation.
- G. You must evaluate the analytical limit of detection and assess traceability<sup>6</sup> of your product with any FDA-recommended reference material(s). After submission of the data to, and concurrence with the data by, FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- H. 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

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<sup>6</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

performance of your device, you must notify FDA immediately (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)).

- I. 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/OPEQ/CDRH.
- J. 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.
- K. You 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.
- L. You must notify the relevant public health authorities of your intent to run your product prior to initiating testing.
- M. You must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- N. All laboratory personnel using your product must be appropriately trained in real-time RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- O. You must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

#### **Conditions Related to Printed Materials, Advertising and Promotion**

- P. 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.
- Q. 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.
- R. 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 authorized laboratories;
- 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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Jeffrey E. Shuren, M.D., J.D.  
Director  
Center for Devices and Radiological Health  
Food and Drug Administration

Enclosure