October 15, 2020

Steve B. Kleiboeker, Ph.D.
Vice-president, Research and Development
Viracor Eurofins Clinical Diagnostics
1001 NW Technology Drive
Lee's Summit, MO 64086

Device:	Viracor SARS-CoV-2 assay
Company:	Viracor Eurofins Clinical Diagnostics
Indication:	This test is authorized for the following indications for use: Qualitative detection of SARS-CoV-2 viral ribonucleic acid (RNA) in nasopharyngeal swab, nasal swab, nasopharyngeal wash, nasal wash, oropharyngeal swab and bronchoalveolar lavage from individuals suspected of COVID-19 by their healthcare provider (HCP). This test is also authorized for use with the EmpowerDX At-Home COVID-19 PCR Test Kit for individuals to self-collect nasal swabs at home, when determined by a HCP to be appropriate based on the results of an online COVID-19 questionnaire. Qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples containing up to five individual nasopharyngeal swab specimens that are collected by a HCP using individual vials containing transport media, from individuals suspected of COVID-19 by their HCP. Testing is limited to Viracor Eurofins Clinical Diagnostics, located at 1001 NW Technology Dr., Lee's Summit, MO which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meets the requirements to perform high complexity tests.

Dear Dr. Kleiboeker:

On April 6, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Viracor Eurofins Clinical Diagnostics.

letter determining that your product[2] met the criteria for issuance under section 564(c) of the Act to be eligible for authorization under the March 31, 2020, Emergency Use Authorization (EUA) for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (High Complexity LDT Umbrella EUA) for the qualitative detection of SARS-CoV-2 viral ribonucleic acid (RNA) in respiratory specimens from individuals suspected of COVID-19, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). As authorized under the High Complexity LDT umbrella EUA, testing of your test was limited to Viracor Eurofins Clinical Diagnostics, the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests pursuant to the Scope of Authorization and Conditions of Authorization of that EUA.

On July 27, 2020, and August 12, 2020, you requested to revise the Scope of Authorization, and thus the test's intended use as originally specified by the High Complexity LDT Umbrella EUA to add pooling of specific clinical specimens and include testing of nasal swab specimens collected with the EmpowerDX At-Home COVID-19 PCR Test Kit, respectively. In response to these requests, because the requested revisions[3] are beyond the Scope of Authorization of the High Complexity LDT Umbrella EUA, FDA is hereby authorizing the use of your product used for the indication identified above pursuant to Section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this letter of authorization.

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.[4]

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).

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[2] For ease of reference, this letter will use the term "your product" to refer to the Viracor SARS-CoV-2 assay used for the indication identified above.

[3] The July 27, 2020, and August 12, 2020, revisions requested include: (1) revisions to the intended use and authorized labeling documents to include testing of pooled samples containing up to five individual nasopharyngeal swab specimens that are collected by a HCP using individual vials containing transport media, from individuals suspected of COVID-19 by their HCP, (2) revisions to the intended use and authorized labeling documents to include use of your product with the EmpowerDX At-Home COVID-19 PCR Test Kit for individuals to self-collect nasal swabs at home, when determined by a healthcare provider (HCP) to be appropriate based on the results of an online COVID-19 questionnaire, (3) inclusion of an additional primer/probe set detecting human RNaseP to ensure an adequate biological specimen is collected from self-collected specimens, (4) updates to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language more consistent with recent authorizations.

[4] 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).

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, as 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.[5]

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 of SARS-CoV-2 viral RNA in nasopharyngeal swab, nasal swab, nasopharyngeal wash, nasal wash, oropharyngeal swab and bronchoalveolar lavage from individuals suspected of COVID-19 by their healthcare provider.

Your product is also authorized for use with the EmpowerDX At-Home COVID- 19 PCR Test Kit for individuals to self-collect nasal swabs at home, when determined by a healthcare provider (HCP) to be appropriate based on the results of an online COVID-19 questionnaire with a HCP.

This test is also for the qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples containing up to five individual nasopharyngeal swab specimens that are collected by a HCP using individual vials containing transport media, from individuals suspected of COVID-19 by their HCP. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

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

Testing is limited to Viracor Eurofins Clinical Diagnostics, located at 1001 NW Technology Dr., Lee's Summit, MO, which is certified under CLIA and meets the requirements to perform high complexity tests.

The SARS-CoV-2 RNA 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from upper respiratory 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.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition E below), that are to be run as outlined in the authorized labeling. 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 home-collected specimens: The RP primer and probe set is included to test for human RP, to ensure an adequate biological specimen is collected from home-collected specimens.
- Internal Control – MS2 added to every clinical specimen prior to extraction. Monitors internal lysis, extraction and amplification.
- Negative control - known negative phosphate buffered saline monitors for any cross-contamination that occurs during the RT-PCR process.
- Negative No Template Control - RNase-, DNase-free water is used to monitor the possibility of sample contamination in the assay run and is used once on every PCR assay plate.
- Positive Controls - two *in vitro* transcribed RNA SARS-CoV-2 positive amplification curve controls (low and high) is used to verify that the assay run is performing as intended.
- A positive template control cloned plasmid DNA representing the N gene of SARS-CoV-2 verifies that the assay run is performing as intended and is included in each testing run.

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 Instructions for Use.

The above described product is authorized to be accompanied with labeling submitted as part of the EUA request (listed below), and as described in 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: Viracor Eurofins Clinical Diagnostics - Viracor SARS-CoV-2 assay
- Fact Sheet for Patients: Viracor Eurofins Clinical Diagnostics - Viracor SARS-CoV-2 assay

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the following Viracor Eurofins Clinical Diagnostics - standard operating procedures (SOPs) bundle[6] (collectively referenced as "authorized labeling") is authorized to be used by the authorized laboratory, 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

[6] The SOP bundle consists of: 21120.8916 Coronavirus SARS-CoV-2 RT-PCR Performance, 21120.705 NucliSens easyMAG & eMAG Total Nucleic Acid Extraction, 21120.461 Real-Time PCR and RT-PCR Using ABI 7500 SDS Instruments, 21120.435 Specimen Collection and Transport, 21120.595 Specimen Processing Guide, 21120.596 Clinical Laboratory Processing Guide, 21120.586 Specimen Receipt and Accessioning, 21120.764 Oligonucleotide Mix Preparation and Quality Control Procedure, 21120.556 Acceptable Assay Standard Values, 21120.517 Analytical Quality Control - Quality Control Procedures, 21120.578 PCR and RT-PCR Acceptance and Retest Criteria, 21120.7065 Comparison Report Evaluating the BioMerieux E-MAG Performance to the BioMerieux easyMag for DNA-RNA Extraction, 21120.551 Quality Control Testing of the Negative Extraction Controls (NECs) for Clinical Testing, 21120.9655 Self Collection Specimen Receipt and Accessioning, 21120.9591 Pooled SARS-CoV-2 RT-PCR Performance, 21120.9152 KingFisher MagMax Viral Pathogen Nucleic Acid Isolation.

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:

Viracor Eurofins Clinical Diagnostics (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 make available on your website(s) the authorized Fact Sheet for Healthcare Providers and Fact Sheet for Patients.

C. You will 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 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.

E. 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.

F. You will evaluate the analytical limit of detection and assess traceability[7] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

[7] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

G. You will have a process in place in accordance with 21 CFR Part 803 to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

H. You 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) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which you become aware.

I. You will additionally track adverse events associated with any home specimen collection kit authorized for use with your product, including occurrences of false results and report 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).

J. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with any new home-collection kit authorized 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 home-collection kit.

K. You 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.

L. When using specimen pooling strategies when testing patient specimens with your product you will include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing."

M. You will use your product as outlined in the authorized labeling. Deviations from the authorized labeling, 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.

N. When implementing pooling strategies for testing patient specimens you must use the "Monitoring of pooling strategy" available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

O. When testing specimens self-collected using any authorized home specimen collection kits for use with your product you must follow any Specimens Accessioning protocols provided with the authorized self-collection kit and/or outlined in your Self Collection

Specimen Receipt and Accessioning SOP when accepting specimens for testing.

P. You must notify the relevant public health authorities of your intent to run the test.

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

R. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

S. You 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.

T. You will keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the monitoring of pooling strategy. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request, and will be made available within a reasonable time after 12 months from the date of their creation.

Conditions Related to Printed Materials, Advertising and Promotion

U. 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 the applicable requirements set forth in the Act and FDA regulations.

V. No descriptive printed matter, including advertising and 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.

W. All descriptive printed matter, including 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;
- This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- 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 authorization is terminated or revoked sooner.

The emergency use of you 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