U.S. FOOD & DRUG ADMINISTRATION

September 29, 2020

Ilka Warshawsky, M.D., Ph.D.
Director, Molecular Diagnostics Laboratory
Akron Children's Hospital
One Perkins Square
Akron, OH 44308

Device:	Akron Children's Hospital SARS-Co[illegible]-2 Assay
Laboratory:	Akron Children's Hospital
Indication:	Qualitative detection of nucl[illegible] acid from SARS-CoV-2 in nasopharyngeal swabs, or pharyngeal (th[illegible]oat) swabs, anterior nasal swabs, mid-turbinat[illegible] nasal s[illegible]abs, nasal aspirates, nasal washes and broncho[illegible]veo[illegible]lavage (BAL) fluid specimens from individuals suspected o[illegible]OVID-19 by their healthcare provider. Testing is lim[illegible]ted to th[illegible] Ak[illegible]n Children's Hospital located at One Perkins Squ[illegible]e, Akron, [illegible]OH 44308 which is certified under Clinical Laborato[illegible]y Im[illegible]rovem[illegible]t Amendments of 1988 (CLIA), 42 U.S.C. §263a, an[illegible] meets [illegible]quirements to perform high complexity tests.

Dear Dr. Warshawsky:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authori[illegible]ation (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Fe[illegible]al F[illegible]d, D[illegible]ug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursu[illegible]t to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Hea[illegible]h and Human Services (HHS) determined that there is a public health emergency that has a [illegible]gnificant 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.[3]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Akron Children's Hospital.
[2] For ease of reference, this letter will use the term "your product" to refer to the Akron Children's Hospital SARS-CoV-2 Assay used for the indication identified above.
[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).

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 a qualitative test for the detection of nucleic acid from SARS-CoV-2 in respiratory specimens tested in the indication above collected from individuals suspected of COVID-19 by their healthcare provider. 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from the 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 described in the authorized labeling (described below).

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

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 J 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:

- Negative (No Template) Control – PCR grade water; used to indicate contamination of the RT-PCR reagents.
- Positive Control - contains in vitro transcripts corresponding to the N gene of the SARS-CoV-2 genome and the E gene of lineage B.1 coronavirus; used to verify the integrity of the RT-PCR amplification process and reagents.
- Internal Control – heterologous control; used to monitor nucleic acid extraction and RT-PCR
- External Positive Process Control – known SARS-CoV-2 positive patient sample; used to test each new batch of extraction reagents.
- External Negative Control – phosphate buffered saline; used to test each new batch of extraction reagent.

The above described product is authorized to be accompanied with laboratory procedures (described below), 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 information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Tests
- Fact Sheet for Patients: Molecular Laboratory Developed Test (LDT) COVID-19 Authorized Tests

The above described product, when accompanied by the "Children's Hospital Medical Center of Akron SARS-CoV-2 Assay" laboratory procedures, the "Children's Hospital Medical Center of Akron SARS-CoV-2 Assay Standard Operating Procedure for Maxwell RSC 48," the "Standard Operation Procedure for Maxwell 16 MDx," and 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 COVID19, 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:

Akron Children's Hospital (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 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 will notify the relevant public health authorities of your intent to run your product.

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

E. 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.

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 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 will 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. You will collect information on the performance of your product. You will 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.

J. 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 and require appropriate authorization from FDA prior to implementation.

K. 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 and concurrence by FDA, DMD/OHT7-OIR/OPEQ/CDRH's will update the EUA Summary to reflect the additional testing.

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

[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 authorized test.

Part 803.

M. 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.

N. 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.

Conditions Related to Printed Materials, Advertising and Promotion

O. 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.

P. No descriptive printed matter, including 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.

Q. 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 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