April 2, 2021

Joseph T. Walsh, Jr., PhD
Interim Vice President for Economic Development and Innovation
University of Illinois
346 Henry Administration Building, MC-365
506 South Wright St.
Urbana, IL 61801

Device:	covidSHIELD
EUA Number:	EUA202555
Company:	University of Illinois Office of the Vice President for Economic Development and Innovation
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected without preservatives in a sterile collection tube or into a sterile collection tube with straw, in the presence of a trained observer (adult trained on how to collect saliva samples), from individuals who are either suspected of COVID-19 by their healthcare provider or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested at least weekly and with no more than 168 hours between tests. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories designated by the University of Illinois Office of the Vice President for Economic Development and Innovation, that includes the University of Illinois Veterinary Diagnostic Laboratory, University of Illinois Urbana Champaign School of Veterinary Medicine, located at 2001 S. Lincoln Ave, Urbana, IL 61802, that are also 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. Walsh:

On Febuary 24, 2021, based on your[1] request that the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the covidSHIELD for the qualitative

[1] For ease of reference, this letter will use the term "you" and related terms to refer to University of Illinois Office of the Vice President for Economic Development and Innovation.

detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected without preservatives in a sterile collection tube or into a sterile collection tube with straw, in the presence of a trained observer (adult trained on how to collect saliva samples), from individuals who are suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Emergency use of this test was limited to authorized laboratories.[2]

On March 26, 2021, you requested to amend your EUA. Based on your request, and having concluded that revising the Febuary 24, 2021, 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 Febuary 24, 2021, letter in its entirety with the revisions incorporated.[3] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[4] is now authorized for use consistent with the indication described 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.[5]

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 included 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.

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[2] The Febuary 24, 2021, letter defined "Authorized Laboratories" as laboratories "designated by the University of Illinois Office of the Vice President for Economic Development and Innovation, that includes the University of Illinois Veterinary Diagnostic Laboratory, University of Illinois Urbana Champaign School of Veterinary Medicine, located at 2001 S. Lincoln Ave, Urbana, IL 61802, that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests."

[3] The revisions to the Febuary 24, 2021, letter and authorized labeling include: (1) revisions to the intended use and authorized labeling documents, including the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect current information known about serial testing as outlined in the March 16, 2021, FDA "*Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing*" (https://www.fda.gov/media/146695/download), which includes testing of individuals without symptoms or other epidemiological reasons to suspect COVID-19, and (2) updates to the Conditions of Authorization to require a post-authorization clinical study to support the serial testing claim.

[4] For ease of reference, this letter will use the term "your product" to refer to the covidSHIELD used for the indication identified above.

[5] 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).

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.[6]

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 saliva specimens that are collected without preservatives in a sterile collection tube or into a sterile collection tube with straw, in the presence of a trained observer (adult trained on how to collect saliva samples), from individuals who are either suspected of COVID-19 by their healthcare provider or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested at least weekly and with no more than 168 hours between tests. The SARS-CoV-2 nucleic acid is generally detectable in saliva 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

Testing is limited to laboratories designated by the University of Illinois Office of the Vice President for Economic Development and Innovation, that includes the University of Illinois Veterinary Diagnostic Laboratory, University of Illinois Urbana Champaign School of

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

Veterinary Medicine, located at 2001 S. Lincoln Ave, Urbana, IL 61802, that are also certified under the CLIA and meet requirements to perform high complexity tests.

To use your product, authorized laboratories are required to acquire and use, according to the authorized instructions for use, commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling (described below). Saliva is first heat-treated followed by treatment with Tris buffer and Tween20 detegent to release viral RNA. The sample is then directly used as input where the SARS-CoV-2 nucleic acid is 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 J below), that 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:

- Internal Control - MS2 phage control which is required as a reverse transcription and PCR amplification positive control.
- Negative Control - UltraPure DNase- and RNase-free water which monitors for contamination of the PCR reagents.
- Positive Control - external control that contains the SARS-CoV-2 RNA genomic regions targeted by the kit and monitors for failures of RT-qPCR reagents and reaction conditions.

The above described product, is authorized to be used pursuant to the 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/in-vitro-diagnostics-euas), and accompanied by the following product-specific information pertaining to the emergency use, which you and authorized laboratories are required to make available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: University of Illinois Office of the Vice President for Economic Development and Innovation – covidSHIELD

- Fact Sheet for Patients: University of Illinois Office of the Vice President for Economic Development and Innovation - covidSHIELD

The above described product, when used pursuant to the "covidSHIELD University of Illinois Saliva Test for SARS-CoV-2: covidSHIELD Instructions for Use" laboratory procedures, the EUA Summary (identified above) and accompanied by the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be used by 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 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, 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:

University of Illinois Office of the Vice President for Economic Development and Innovation (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 must make your product available with the authorized labeling to authorized laboratories.

C. You must make available on your website(s) the Fact Sheet for Healthcare Providers

and the Fact Sheet for Patients.

D. You 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 and authorized labeling.

E. 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.

F. You must have a process in place to train saliva collection observers to ensure the safe use of the device.

G. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.

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 must 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 must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.[7] After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

L. You must evaluate the clinical performance of your product to support the screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 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 must update the authorized labeling to reflect the additional testing. Such labeling

[7] 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.

updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. You must track adverse events, including any occurrence of false results, from testing at your institution and report to FDA pursuant to 21 CFR Part 803 via Medwatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.

Authorized Laboratories

N. 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.

O. 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 ancillary reagents and authorized materials required to use your product are not permitted.

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

Q. 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.

R. Authorized laboratories must collect information on the performance of your product and report 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 to you (covidSHIELD@uillinois.edu) and Medwatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.

S. All laboratory personnel using your product must be appropriately trained in 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.

University of Illinois Office of the Vice President for Economic Development and Innovation (You) and Authorized Laboratories

T. You and authorized laboratories using your product must 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

U. 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 applicable requirements set forth in in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

V. 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.

W. 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 the 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