U.S. FOOD & DRUG ADMINISTRATION

January 14, 2022

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:	This test is authorized for the following indications for use:
	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 when tested at least weekly and with no more than 168 hours between tests.
	Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected at home or in a community-based setting by individuals age 16 years and older (self-collected) or 6 years and older (collected with adult assistance) using the SHIELD Saliva Collection Kit, when determined to be appropriate by a healthcare provider.
	Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to eight individual saliva specimens (using specified workflows) that are collected without preservatives in a sterile collection tube or into a sterile collection tube with a 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 when tested at least weekly with no more than 168

	hours between tests or saliva specimens collected using the SHIELD Saliva Collection Kit. 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 February 24, 2021, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the covidSHIELD for the 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 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] Subsequently, based on your request, the letter was revised and reissued by FDA on April 2, 2021[3] and August 26, 2021.[4]

On November 5, 2021, you requested to further revise your EUA. Based on this request, and having concluded that revising the August 26, 2021 EUA is appropriate to protect the public

[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.
[2] The February 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] On April 2, 2021, the revisions to the February 24, 2021, letter and authorized labeling included: (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] On August 26, 2021, the revisions to the April 2, 2021 letter and authorized labeling included: (1) updating the intended use to include testing with saliva specimens that are collected at home or in a community-based setting by individuals age 16 years and older (self-collected) or 6 years and older (collected with adult assistance) using the SHIELD Saliva Collection Kit, when determined to be appropriate by a healthcare provider, (2) addition of Conditions S. and T. to evaluate device performance with viral mutations, and (3) addition and revision of Conditions of Authorization to authorize use of the SHIELD Saliva Collection Kit.

health or safety under section 564(g)(2)(C) of the Act, FDA is reissuing the August 26, 2021 letter in its entirety with the revisions incorporated.[5] 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[6] 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.[7]

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.

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;

[5] The revisions to the August 26, 2021 letter and authorized labeling include: (1) revisions to the intended use to include testing of pooled samples containing up to eight individual saliva specimens (using specified workflows) that are collected without preservatives in a sterile collection tube or into a sterile collection tube with a 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 with no more than 168 hours between tests or saliva specimens collected using the SHIELD Saliva Collection Kit, (2) addition of the option to use a forced-air oven to perform the heat pre-treatment step of saliva specimens, (3) addition of the Gilson PipetMax robotic liquid handling system to automate the manual pre-analytical steps for saliva pre-treatment prior to running the RT-PCR, (4) minor modifications to the RUO thermocycler qualification protocol in Appendix B of the Instructions for Use (IFU), (5) addition of "Appendix E: Protocol for Monitoring of Specimen Pooling Testing Strategies" in the IFU, (6) addition of Conditions AA., BB. and CC. for laboratories using specimen pooling strategies, (7) modification of Condition Q. to extend the timeline to provide clinical performance data to support the screening claim, and (8) updates to the patient and healthcare provider fact sheets to include specimen pooling.

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

[7] 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).

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.[8]

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 when tested at least weekly and with no more than 168 hours between tests. Your product is also for use with saliva specimens that are collected at home or in a community-based setting by individuals age 16 years and older (self-collected) or 6 years and older (collected with adult assistance) using the SHIELD Saliva Collection Kit, when determined to be appropriate by a healthcare provider.

Your product is also for use with pooled samples containing up to eight individual saliva specimens (using specified workflows) that are collected without preservatives in a sterile collection tube or into a sterile collection tube with a 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 when tested at least weekly with no more than 168 hours between tests or saliva specimens collected using the SHIELD Saliva Collection Kit. 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.

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

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

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 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.

A single SHIELD Saliva Collection Kit includes items required to collect, store and maintain the specimen as described in the EUA Summary. The Multipack option includes up to five(5) of each item and additional multipack options for which you receive appropriate authorization, in accordance with Condition O. below will be described in the EUA Summary.

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 detergent 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 O 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 accompanied by the labeling 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/in-vitro-diagnostics-euas) and the following fact sheets pertaining to the emergency use, which are required to be made 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 accompanied by the "covidSHIELD University of Illinois Saliva Test for SARS-CoV-2: covidSHIELD Instructions for Use" laboratory procedures, the EUA Summary, and the two fact sheets 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.

The SHIELD Saliva Collection Kit with the "SHIELD Saliva Collection Kit Instructions for Use" and the "covidSHIELD Read Me First" instructions is authorized to be distributed and used as part of the above described product as set forth in this EUA.

"Authorized labeling" refers to the EUA Summary, the "covidSHIELD University of Illinois Saliva Test for SARS-CoV-2: covidSHIELD Instructions for Use", the two Fact Sheets, the "SHIELD Saliva Collection Kit Instructions for Use" and the "covidSHIELD Read Me First" instructions.

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) and Authorized Distributor(s)[9]

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 the Fact Sheet for Patients.

C. You and authorized distributor(s) must make available all instructions related to the collection of saliva specimens using the SHIELD Saliva Collection Kit, both in the distributed kit and on your website.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the SHIELD Saliva Collection Kit is distributed.

E. You and authorized distributor(s) must maintain customer complaint files concerning the SHIELD Saliva 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.

F. 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.

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

[9] "Authorized Distributor(s)" are identified by you, University of Illinois Office of the Vice President for Economic Development and Innovation, in your EUA submission as an entity allowed to distribute the SHIELD Saliva Collection Kit.

G. You must make your product available with the authorized labeling to authorized laboratories.

H. You must notify FDA of any authorized distributor(s) of the SHIELD Saliva Collection Kit, including the name, address, and phone number of any authorized distributor(s).

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

J. 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.

K. 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.

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

M. 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.

N. 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.

O. 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.

P. 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.[10] After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

[10] 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. 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 2 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 updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. 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.

S. 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.

T. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to 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.

Authorized Laboratories

U. 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.

V. 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.

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

X. 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.

Y. Authorized laboratories must collect information on the performance of your product,

including the SHIELD Saliva Collection Kit, 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.

Z. 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.

AA. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must 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."

BB. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Protocol for Monitoring of Specimen Pooling Testing Strategies" available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

CC. Authorized laboratories must 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 Protocol for Monitoring of Specimen Pooling Testing Strategies. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request and must be made available within a reasonable time after 12 months from the date of their creation.

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

DD. You, authorized distributors 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

EE. 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, as applicable, and FDA implementing regulations.

FF. 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.

GG. 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 the 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure