August 27, 2021

Anne Wyllie, Ph.D.
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Department of Epidemiology of Microbial Diseases
350 George Street
New Haven, CT 06510

Device:	SalivaDirect DTC Saliva Collection Kit
EUA Number:	EUA210507
Company:	Yale School of Public Health, Department of Epidemiology of Microbial Diseases
Indication:	A direct to consumer (DTC) product for self-collection of saliva specimens at home (which includes in a community-based setting) from individuals aged 18 years and older, including individuals without symptoms or other reasons to suspect COVID-19, sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the SalivaDirect DTC Saliva Collection Kit.
Authorized Laboratories:	Testing is limited to laboratories designated by Yale School of Public Health Department of Epidemiology of Microbial Diseases, that includes the Clinical Molecular Diagnostics Laboratory, Department of Pathology, Yale School of Medicine, located at 310 Cedar St., New Haven, CT 06510, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Dr. Wyllie:

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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Yale School of Public Health, Department of Epidemiology of Microbial Diseases.
[2] For ease of reference, this letter will use the term "your product" to refer to the SalivaDirect DTC Saliva Collection Kit used for the indication identified 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.[3] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, 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).

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, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected human specimen, and that the known and potential benefits of your product when used for such use, 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.

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[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).

[4] U.S. Department of Health and Human Services, *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 17335 (March 27, 2020)

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

Authorized Product Details

Your product is a direct to consumer (DTC) product for self-collection of saliva specimens at home (which includes in a community-based setting) from individuals aged 18 years and older including individuals without symptoms or other reasons to suspect COVID-19, sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the SalivaDirect DTC Saliva Collection Kit.

Testing is limited to laboratories designated by Yale School of Public Health Department of Epidemiology of Microbial Diseases, that includes the Clinical Molecular Diagnostics Laboratory, Department of Pathology, Yale School of Medicine, located at 310 Cedar St., New Haven, CT 06510, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The SalivaDirect DTC Saliva Collection Kit includes the following materials or other authorized materials (as may be requested under Condition N below): a saliva collection device (either a funnel or a bulb pipette), sterile plastic collection tube, biohazard bag, absorbent sheet, alcohol pad, return shipping box, instructions for use, patient identifier sticker, activation card, UN 3373 Pak, and return label.

Negative test results are provided to the user via text, email and/or online portal. Individuals with positive, or invalid test results will be contacted by a healthcare provider. The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The SalivaDirect DTC Saliva Collection Kit is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

The above described product is authorized to be accompanied with the authorized labeling (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas). "Authorized labeling" includes the following documents: the EUA summary, the "SalivaDirect DTC Saliva Collection Kit Bulb Pipette Collection" patient instructions and Bulb Pipette Card Insert, the "SalivaDirect DTC Saliva Collection Kit Funnel Collection" patient instructions and Funnel Card insert, the "Accessioning SOP for Saliva Samples Collected by the SalivaDirect DTC Saliva Collection Kit", the Activation Card and the outer box label.

The above described product, when accompanied by the authorized labeling, is authorized to be distributed to and used by individuals (accompanied only by "SalivaDirect DTC Saliva Collection Kit Bulb Pipette Collection" patient instructions and Bulb Pipette Card Insert, or the "SalivaDirect DTC Saliva Collection Kit Funnel Collection" patient instructions and Funnel Card insert) and authorized laboratories (accompanied by all authorized labeling) as set forth in

this letter and pursuant to the conditions in the 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, by serving as an appropriate means to collect and transport human saliva specimens so that an authorized laboratory can detect SARS-Co-V-2 RNA from the self-collected specimen 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, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Yale School of Public Health, Department of Epidemiology of Microbial Diseases (You) and Authorized Distributor(s)[6]

[6] "Authorized Distributor(s)" are identified by you in your EUA submission as an entity allowed to distribute your product.

A. Your product must comply with the following labeling requirements pursuant to 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 all instructions related to the home collection of saliva specimens using the SalivaDirect DTC Saliva Collection Kit, the Activation Card and the Fact Sheet for Individuals in the shipped kit with the authorized outer box label.

C. You and authorized distributor(s) must make all patient instructions available on your website(s).

D. You and authorized distributor(s) 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. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which your product is distributed.

F. You and authorized distributor(s) must maintain customer complaint files on record. 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-EUAReporting@fda.hhs.gov) any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

G. 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.

Yale School of Public Health, Department of Epidemiology of Microbial Diseases (You)

H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. You must notify FDA of any authorized laboratories designated by Yale School of Public Health, Department of Epidemiology of Microbial Diseases to use your product, including the name, address, and phone number of any authorized laboratories.

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

K. You must ensure that the authorized laboratories using your product have a process in place for reporting test results to you, individuals, healthcare providers and relevant public health authorities, as appropriate.

L. You must maintain records of the authorized laboratories and test usage.

M. You must collect information on the performance of your product. You must report to the DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

N. 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, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the DMD/OHT7-/OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

O. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

P. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the kits released for distribution have the clinical and analytical performance claimed in the authorized labeling.

Q. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

R. You must have a process in place to track adverse events associated with the SalivaDirect DTC Saliva Collection Kit, including occurrence of false results and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should also be immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email:CDRH-EUAReporting@fda.hhs.gov).

S. You must submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using saliva specimens collected with the

SalivaDirect DTC Saliva Collection Kit during that timeframe, including how many kits were requested and sent for home collection to individuals, how many kits were shipped and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, age range of the individuals tested and the positivity rate of the SalivaDirect DTC Saliva Collection Kit.

T. You must have a process in place for reporting all test results to individuals who use the SalivaDirect DTC Saliva Collection Kit. This process must include a requirement that all positive or invalid results must be reported to individuals who collected specimens using the SalivaDirect DTC Saliva Collection Kit by a healthcare provider. This process must ensure the Fact Sheet for Individuals for the authorized IVD molecular test used on the specimen is made available to individuals with the test result, for example via weblink.

U. You must have a healthcare provider available to provide information and counseling to individuals using the SalivaDirect DTC Saliva Collection Kit. You will ensure that these healthcare providers have the Fact Sheet for Healthcare Providers that is relevant to the IVD molecular test used on the specimen, for reference.

Authorized Laboratories

V. Authorized laboratories testing specimens self-collected using the SalivaDirect DTC Saliva Collection Kit must follow your "Accessioning SOP for Saliva Samples Collected by the SalivaDirect DTC Saliva Collection Kit" when accepting specimens for testing.

W. Authorized laboratories using your product must use it only in conjunction with COVID-19 in vitro diagnostic (IVD) molecular tests that are indicated for use with the SalivaDirect DTC Saliva Collection Kit.

X. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via email: salivadirect@gmail.com) any suspected occurrence of false positive or false negative results linked to the use of your product and significant deviations from the established performance characteristics of your product of which they become aware.

Y. Authorized laboratories using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate.

Yale School of Public Health, Department of Epidemiology of Microbial Diseases (You), Authorized Distributor(s) and Authorized Laboratories

Z. You, authorized distributor(s) and authorized laboratories using your product 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

AA. 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 the applicable requirements set forth in section 501(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

BB. 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.

CC. 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;
- This product has been authorized only for the collection and maintenance of saliva specimens as an aid in 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 medical devices 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 medical devices during the COVID-19 outbreak 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