December 17, 2021

Louise Laurent, M.D., Ph.D.
UCSD BCG EXCITE Lab
UCSD Biomedical Sciences Building
9500 Gilman Drive
Room 1202
La Jolla, CA 92093

Device:	UCSD EXCITE COVID-19 Test
EUA Number:	EUA210524
Laboratory:	UCSD BCG EXCITE Lab
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are either Healthcare Provider collected from individuals of any age, or collected at home (which includes in a community-based setting) with adult assistance from individuals 2 years of age or older, or self-collected by any individuals 15 years of age or older, including from individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider, using the UCSD EXCITE COVID-19 Sampling Kit.
Authorized Laboratories:	Testing is limited to UCSD BCG EXCITE Lab located at 9500 Gilman Drive, San Diego, CA 92161 that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Dr. Laurent:

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).

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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to UCSD BCG EXCITE Lab.
[2] For ease of reference, this letter will use the term "your product" to refer to the UCSD EXCITE COVID-19 Test used for the indication identified above.

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.[3]

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 anterior nasal swabs specimens that are either Healthcare Provider collected from individuals of any age, or collected at home (which includes in a community-based setting) with adult assistance from individuals 2 years of age or older, or self-collected by any individuals 15 years of age or older, including from individuals without symptoms or other reasons to suspect COVID-19, when

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

determined to be appropriate by a healthcare provider, using the UCSD EXCITE COVID-19 Sampling Kit.

Testing is limited to UCSD BCG EXCITE Lab located at 9500 Gilman Drive, San Diego, CA 92161 that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

The UCSD EXCITE COVID-19 Sampling Kit consists of either:

Kit A (for distribution to individuals for home collection without supervision by a healthcare provider or trained staff member)**:** A flocked anterior nares swab, a collection tube containing MAWI iSwab-Microbiome collection media, and specimen collection instructions placed into a recyclable "clamshell" type of container.

Kit B (For use by individuals at a designated testing site under supervision by a healthcare provider or trained staff member)**:** A flocked anterior nares swab and collection tube containing MAWI iSwab-Microbiome collection media. Specimen collection instructions will be displayed at the sample collection sites.

Individuals must follow all specimen collection and return instructions provided with the collection kit.

The SARS-CoV-2 nucleic acid is generally detectable in anterior nasal swab 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 anterior nasal swab 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.

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 EUA Summary.

- Internal Positive Control (IPC) – endogenously expressed RNase P gene naturally present in all human samples – used to ensure adequate sample collection and

adequate performance of the RNA extraction process, PCR assay reagents and RnaseP Probe.
- External Positive Control - contains the SARS-CoV-2 RNA genomic regions targeted by the kit. The positive control is used to monitor for expected performance of the PCR assay reagents and viral N/S/Orflab gene probes.
- No Viral Template Control – Molecular grade, Nuclease-free, non DEPC-treated water to which RPP30 plasmid is added – used to monitor non-specific amplification, performance of the RNAseP probe, cross contamination during experimental setup and nucleic acid contamination of reagents.

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/in-vitro-diagnostics-euas), as well as the "Sample Accessioning and Plating Using the Hamilton Microlab Star" standard operating procedures (SOP), "USC EXCITE COVID-19 Test, Viral RNA Extraction Process" SOP, the UCSC EXCITE COVID-19 Test SOP, the UCSD EXCITE COVID-19 Sampling Kit Instructions for Use, 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: UCSD BCG EXCITE Lab - UCSD EXCITE COVID-19 Test
- Fact Sheet for Patients: UCSD BCG EXCITE Lab - UCSD EXCITE COVID-19 Test

The above described product, when accompanied by the EUA Summary, the "Sample Accessioning and Plating Using the Hamilton Microlab Star" SOP, the "USC EXCITE COVID-19 Test, Viral RNA Extraction Process" SOP, the "UCSC EXCITE COVID-19 Test" SOP, and the two fact sheets, is authorized to be used by the authorized laboratory under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The UCSD EXCITE COVID-19 Sampling Kit with the "UCSD EXCITE COVID-19 Sampling Kit Instructions for Use" 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 "Sample Accessioning and Plating Using the Hamilton Microlab Star" SOP, the "USC EXCITE COVID-19 Test, Viral RNA Extraction Process" SOP, the "UCSC EXCITE COVID-19 Test" SOP, "UCSD EXCITE COVID-19 Sampling Kit Instructions for Use," and the two fact sheets.

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, 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:

UCSD BCG EXCITE Lab (You)

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 must 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 must notify the relevant public health authorities of your intent to run your product.

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

E. You 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.

F. You must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and all instructions related to collection with the UCSD EXCITE COVID-19 Sampling Kit.

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

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) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the 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[5] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must 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.

L. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the UCSD EXCITE COVID-19 Sampling Kit and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) pursuant to 21 CFR Part 803.

M. 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 product and use your product in accordance with the authorized laboratory procedure.

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

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.

O. You must make available all instructions related to the self-collection of anterior nasal swab specimens in each shipped kit of the UCSD EXCITE COVID-19 Sampling Kit (Kit A) and ensure sites using Kit B receive and display such instructions.

P. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with the UCSD EXCITE COVID-19 Sampling Kit 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 self-collection kit.

Q. When testing specimens self-collected using the UCSD EXCITE COVID-19 Sampling Kit you must follow the "Sample Accessioning and Plating Using the Hamilton Microlab Star" standard operating procedure when accepting specimens for testing.

R. 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 (via email: CDRH-EUA-Reporting@fda.hhs.gov).

S. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding 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.

Conditions Related to Printed Materials, Advertising and Promotion

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

U. 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.

V. 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 laboratory;

- 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