March 5, 2021

Roderick Castillo
Director, Regulatory and Clinical Affairs
Cue Health Inc.
4890 Carroll Canyon Road, Suite 100
San Diego, CA 92121

Device:	Cue COVID-19 Test for Home and Over The Counter (OTC) Use
EUA Number:	EUA210180
Company:	Cue Health Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nasal) swab specimens collected with the Cue Sample Wand. This test is intended for use in adults (self-swabbing) or children ≥2 years of age (swabbed by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19. The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is authorized for non-prescription home use.

Dear Roderick Castillo:

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 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]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Cue Health Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the Cue COVID-19 Test for Home and Over The Counter (OTC) Use used for the indication identified above.
[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "The Cue COVID-19 Test for Home and Over The Counter (OTC) Use Instructions For Use" (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 (as described in the Scope of Authorization of this letter (Section II)) in certain individuals for the detection of SARS-CoV-2 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 such product; and,

3. There is no adequate, approved, and available alternative to the emergency use of your product for diagnosing COVID-19.[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.

The Authorized Product

Your product is a molecular diagnostic test for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nasal) swab specimens collected with the Cue Sample Wand. Your product is intended for use in adults (self-swabbing) or children ≥2 years of age (swabbed by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19 and is authorized for non-prescription home use.

The SARS-CoV-2 viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral RNA, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results in an asymptomatic individual are presumptive and confirmation with a molecular assay performed in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, if necessary, for patient management may be performed. Negative

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

results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. It is important that an individual consult their healthcare provider to discuss their results and whether additional testing is necessary.

Test results will be reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC). Automatic test result reporting will be performed by Cue Health using the Cue Health App and the Cue Health secure cloud server.

Your product includes the Cue COVID-19 Test Cartridge Pack that contains one or more foil pouches. Each foil pouch contains: one (1) single-use Cue COVID-19 Test Cartridge and one (1) single-use, wrapped sterile Cue Sample Wand. Your product also includes the Cue Health Monitoring System (Cue Cartridge Reader), provided separately, and the Cue Health Mobile Application (App) that must be downloaded onto a compatible mobile smart device. The user then follows the step-by-step instructions included in the Cue Health Mobile App to complete the test. The test cannot be run without the instructions on the App displaying.

Your product is an automated assay that utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids. When the user inserts the Cue Sample Wand with anterior nasal specimen into the Cue COVID-19 Test Cartridge coupled to the Cue Health Monitoring System (Cue Cartridge Reader), the test automatically begins. Heating, mixing, amplification, and detection take place within the cartridge. The current flow from the electrodes is converted to a positive or negative result (based on a pre-determined cutoff).

Your product includes and is required to have an internal control material, or other authorized control materials (as may be requested under Condition L below), that are processed along with the specimen. The internal control must generate the expected result in order for a test result to be considered valid.

The following labeling is collectively referred to as "authorized labeling":

- "Cue Health Mobile Application (Cue Health App)" software application;
- "Cue COVID-19 Test for Home and Over The Counter (OTC) Use" box label, "The Cue COVID-19 Test for Home and Over The Counter (OTC) Use Instructions For Use", "Cue Health Monitoring System User Manual", "Cue Health Monitoring System Quick Reference Instructions", CUE COVID-19 TEST FAQ, Fact Sheet for Individuals, and the Fact Sheet for Healthcare Professionals, which are available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

Your product, when accompanied by the authorized labeling, is authorized to be distributed to and used by individuals, as set forth in 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 such 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 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, when used consistent with 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 for 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:

Cue Health Inc. (You) and Authorized Distributor(s) [5]

A. You and authorized distributor(s) must make available "The Cue COVID-19 Test for Home and Over The Counter (OTC) Use Instructions For Use", "Cue Health Monitoring System User Manual", "Cue Health Monitoring System Quick Reference Instructions", CUE COVID-19 TEST FAQ, Fact Sheet for Individuals, and the Fact Sheet for Healthcare Professionals related to the use of your product on your website(s) and via the App.

B. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the

[5] "Authorized Distributor(s)" are identified by you, Cue Health Inc., in your EUA submission as an entity allowed to distribute the Cue COVID-19 Test for Home and Over The Counter (OTC) Use.

authorized labeling.

C. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number distributed to each location.

D. You and authorized distributor(s) must maintain customer complaint files 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.

E. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware in accordance with 21 CFR Part 803. You must report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

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.

G. You and authorized distributor(s) 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.

Cue Health Inc. (You)

H. 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).

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

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

K. You must make the authorized "The Cue COVID-19 Test for Home and Over The Counter (OTC) Use Instructions For Use", "Cue Health Monitoring System User Manual", "Cue Health Monitoring System Quick Reference Instructions", CUE COVID-19 TEST FAQ, Fact Sheet for Individuals, and the Fact Sheet for Healthcare Professionals electronically available on your website. Additionally, you must provide the opportunity to request a copy of the above named authorized labeling documents in paper form, and after such request, promptly provide the requested labeling at no additional cost.

L. 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 shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the 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) and require appropriate authorization from FDA prior to implementation.

M. You will comply with the following requirements pursuant to FDA regulations: 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).

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

O. 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.

P. You must evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will 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.

Q. You must further evaluate the usability and user comprehension of your product in an FDA agreed upon post authorization study within 3 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH) and submit to FDA for review.

R. You must implement the agreed upon reporting-related software updates to the Cue Health Mobile Application (App) within 3 months of this letter and notify FDA upon implementation. Upon implementation, you must ensure automatic test result reporting, using the Cue Health App and the Cue Health secure cloud server, to relevant public health authorities in accordance with local, state, and federal requirements.

Conditions Related to Printed Materials, Advertising and Promotion

S. 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 and FDA implementing regulations.

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

T. 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.

U. 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 by FDA under an EUA;
- 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure