March 26, 2021

Roderick Castillo
Director, Regulatory and Clinical Affairs
Cue Health Inc.
4980 Carroll Canyon Road, Suite 100
San Diego, CA 92121

Device:	Cue COVID-19 Test
EUA Number:	EUA200248
Company:	Cue Health Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal swabs or in previously collected anterior nasal swab specimens in viral transport media from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Mr. Castillo:

On June 10, 2020, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Cue COVID-19 Test pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.[2] On August 20, 2020, FDA granted updates to the authorized labeling at your request.[3]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Cue Health Inc.

[2] The June 10, 2020, letter authorized the Cue COVID-19 Test for the following indication: Qualitative detection of nucleic acid from SARS-CoV-2 in direct nasal swabs from individuals who are suspected of COVID-19 by their healthcare provider. Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. This test was authorized for use at the Point of Care (POC), i.e., in patient care settings operating

On January 21, 2021, you requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the June 10, 2020, 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 June 10, 2020, letter in its entirety with the revisions incorporated.[4] 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[5] 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.[6]

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 the "Cue COVID-19 Test 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, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

---

under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

[3] On August 20, 2020, FDA granted the following updates to the authorized labeling; (1) add testing of previously collected nasal specimens in viral transport media and (2) update the test protocol and Quick Reference Index to include instructions for the new specimen type.

[4] The revisions to the June 10, 2020, letter and authorized labeling include: (1) updating the indication to include testing of previously collected anterior nasal specimens in viral transport media, as granted in a previous request (see footnote 4), (2) updating the intended use to include testing of anterior nasal swab specimens collected "from individuals with or without symptoms or other epidemiological reasons to suspect a COVID-19" based on additional clinical data, (3) clarifying nasal as anterior nasal in the intended use and authorized labeling, (4) updating the list of compatible mobile smart devices that can run the Cue Health App, (5) updating the *in silico* inclusivity analysis, (6) updating the labeling to reflect the results of further clinical performance evaluations performed to satisfy Condition of Authorization U. in the June 10, 2020 letter, and (7) updates to the Conditions of Authorization to reflect the revised intended use, fulfillment of Condition U (deleted), and language used in more recent letters of authorization, e.g., consolidation of several conditions in new Condition K below.

[5] For ease of reference, this letter will use the term "your product" to refer to the Cue COVID-19 Test used for the indication identified above.

[6] 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 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.[7]

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 for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal swabs or in previously collected anterior nasal specimens in viral transport media from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. The SARS-CoV-2 nucleic acid is generally detectable in anterior nasal 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 in an asymptomatic individual are presumptive and confirmation may be performed for patient management, if necessary, with a different molecular test in a laboratory.

Your product is comprised of the Cue Health Monitoring System (Cue Cartridge Reader), the Cue COVID-19 Test Cartridge, the Cue Sample Wand, and the Cue Mobile Application (Cue Health App) on compatible mobile smart devices named on the Cue Health website at www.cuehealth.com. To use your product, a direct nasal swab specimen is collected from an individual using the Cue Sample Wand before being inserted into the Cue COVID-19 Test Cartridge and run on the Cue Cue Cartridge Reader, connected to the Cue Health App on compatible mobile smart devices named on the Cue Health website at www.cuehealth.com.

Testing is authorized for use in laboratories certified under CLIA that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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

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 Cartridge Reader, the test automatically begins. Heating, mixing, amplification, and detection take place within the cartridge. The current flow from the electrodes provides a semi-quantitative nanoampere measurement that is converted to a positive or negative result (based on a pre-determined cutoff). The Cue COVID-19 Test Cartridge Pack includes three (3) or ten (10) single-use Cue COVID-19 Test Cartridges and three (3) or ten (10) single-use wrapped sterile Cue Sample Wands.

Your product requires the following control material, or other authorized control material (as may be requested under Condition K. below), that are processed in the same way as the specimens and are required to be included with each batch of specimens tested with your product. The control listed below must generate the expected result in order for a test to be considered valid, as outlined in the Instructions For Use:

- Internal Control - RNase P serves as the internal control for presence of human cellular material in the sample and proper assay execution. This internal control has been designed to control for sample inhibition, amplification, and assay reagent function.

Your product also requires use of the Cue COVID-19 Test Positive Control Swab and Negative Control Swab. These swab controls that are required but not provided, or other authorized controls (as may be requested under Condition K. below), are to be run as outlined in the Instructions For Use, described below. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions For Use.

The labeling entitled "Cue COVID-19 Test Instructions For Use," "Cue COVID-19 Test Quick Reference Instructions (QRI)," "Cue Health Monitoring System User Manual," and the "Cue Health Monitoring System quick start guide" (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, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling"::

- Fact Sheet for Healthcare Providers: Cue Health Inc. - Cue COVID-19 Test
- Fact Sheet for Patients: Cue Health Inc. - Cue COVID-19 Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed to and 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 consistently 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 consistently 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), 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:

Cue Health Inc. (You) and Authorized Distributor(s)[8]

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).

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

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) must make available "Cue COVID-19 Test Instructions For Use," "Cue COVID-19 Test Quick Reference Instructions (QRI)," "Cue Health Monitoring System User Manual," "Cue Health Monitoring System quick start guide" related to the use of your product on your website(s) and via the Cue Mobile Application (Cue Health App). Additionally, you must provide the opportunity to request a copy of the above named authorized labeling documents in paper form, and after such request, you must promptly provide the requested labeling at no additional cost.

E. 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.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You must report to FDA 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.

H. 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.

Cue Health Inc. (You)

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 amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

K. 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 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.

L. You must comply with the following requirements under 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).

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

N. 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 US. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You will evaluate the analytical limit of detection and assess traceability[9] 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.

P. You must have a process in place to track adverse events, including any occurrence of false results with your product and report to FDA in accordance with 21 CFR Part 803.

Authorized Laboratories

Q. 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.

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

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

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

T. 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.

U. 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 (support@cuehealth.com) 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.

V. All operators using the Cue COVID-19 Test must be able to perform and interpret the test results, use appropriate personal protective equipment, and use the product in accordance with the authorized labeling.

Cue Health Inc. (You), Authorized Distributor(s) and Authorized Laboratories

W. You, authorized distributor(s), 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

X. 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.

Y. 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.

Z. 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,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure