July 9, 2021

Alicia Y. Zhou, PhD
Chief Science Officer
Color Health, Inc.
831 Mitten Road, Suite 100
Burlingame, CA 94010

Device:	Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC
EUA Number:	EUA210223
Laboratory:	Color Health, Inc.
Indication:	A direct to consumer product for testing of anterior nasal swab specimens collected at home (which includes in a community-based setting), using the Color COVID-19 Self-Swab Collection Kit DTC when used consistent with its authorization. Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC is limited to the authorized laboratory.
Authorized Laboratory:	Testing is limited to Color Health, Inc., located at 863 Mitten Road, Burlingame, CA 94010, which 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. Zhou:

On March 19, 2021, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC, a direct to consumer product for testing of anterior nasal swab specimens self-collected at home (which includes in a community-based setting), using the Color COVID-19 Self-Swab Collection Kit DTC by any individuals, 18 years or older, including individuals without symptoms or other reasons to suspect COVID-19, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to Color Health, Inc., located at 863 Mitten Road, Burlingame, CA 94010, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a., and meets requirements to perform high complexity tests.

On July 9, 2021, based on your request to amend your Emergency Use Authorization (EUA) and having concluded that revising the March 19, 2021, EUA is appropriate to protect the

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

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 March 19, 2021, letter in its entirety with the revisions incorporated.[2] 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[3] is now intended for the indications 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.[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, 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

[2] The revisions to the March 19, 2021, letter and authorized labeling include: (1) revision to the intended use to indicate testing of anterior nasal swab specimens collected at home (which includes in a community-based setting), using the Color COVID-19 Self-Swab Collection Kit DTC when used consistent with its authorization, (2) change in the assay format to include an initial screening assay followed by reflex testing for "candidate" positive specimens, and (3) addition of Conditions Q. and R. below to evaluate the impact of SARS-CoV-2 viral mutations on product performance.

[3] For ease of reference, this letter will use the term "your product" to refer to the Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC used for the indication identified above.

[4] 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).

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.

Authorized Product Details

The Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC is a direct to consumer product for testing of anterior nasal swab specimens collected at home (which includes in a community-based setting), using the Color COVID-19 Self-Swab Collection Kit DTC when used consistent with its authorization.

Testing of collected anterior nasal swab specimens is limited to Color Health, Inc., located at 863 Mitten Road, Burlingame, CA 94010, which is certified under CLIA, 42 U.S.C. §263a., and meets requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA 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 RNA. 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 infection.

Use of your product is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

To use your product, SARS-CoV-2 nucleic acid is first extracted from anterior nasal swab specimens, collected using the Color COVID-19 Self-Swab Collection Kit DTC, using a bead-based RNA extraction method. The extracted RNA is reverse-transcribed and amplified by loop-mediated isothermal amplification (LAMP). Targeted regions of viral or human RNA are amplified during isothermal incubation using a strand-displacing polymerase. The incorporation of dNTP's during amplification causes a pH change in the reaction which is visually detectable with pH-sensitive dyes and measured spectrophotometrically.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K. below), that are to be run as outlined in the authorized labeling. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling:

- Extraction Positive - control (synthetic SARS-CoV-2 RNA and Human Total RNA)

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

included in each extraction batch and carried through the full LAMP procedure; should exhibit positive signal for all three SARS-CoV-2 targets and the internal RNase P control. A lack of amplification would indicate that there was reagent or process failure during extraction or LAMP.

- Extraction No Template Control (NTC) - included in each extraction batch and carried through the full LAMP procedure; should not produce positive signal for any SARS-CoV-2 targets or the internal RNase P target. Amplification would indicate that there was contamination during extraction and/or with the LAMP reagents.

- RNase P (internal control)- should yield positive signal in every clinical specimen in order for the sample to be valid. Failure to detect RNase P in one specimen would invalidate that specific specimen and indicate extraction failure for that sample.

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 authorized labeling.

Your is authorized to be accompanied with the labeling submitted as part of the EUA request (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 individuals:

- Fact Sheet for Healthcare Providers: Color Health, Inc. - Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC
- Fact Sheet for Individuals: Color Health, Inc. - Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Individuals, the "Color SARS-CoV-2 RT-LAMP Diagnostic Assay (Rx) and Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC Standard Operating Procedure" (collectively referenced as "authorized labeling"), is authorized to be used by the authorized laboratory 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, 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:

Color Health, Inc. (You)

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 must inform the 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 from your product to relevant public health authorities, as appropriate. You must also have a process in place for reporting test results via the agreed upon process as authorized by the EUA for the Color COVID-19 Self-Swab Collection Kit DTC.

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 and Fact Sheet for Individuals.

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 laboratory procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and/or authorized materials required to use your product are not permitted.

I. When testing anterior nasal swab specimens collected using the Color COVID-19 Self-Swab Collection Kit DTC authorized for use with your product you must follow any specimen accessioning protocol provided with the collection kit when accepting specimens for testing.

J. 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.

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. 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.

L. 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.[6] After submission to and review of and concurrence with the data, FDA will update the EUA Summary to reflect the additional testing.

M. You must have a process in place to track adverse events, including any occurrence of false results with your product, including with the Color COVID-19 Self-Swab Collection Kit DTC, in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, must immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

N. You must submit to FDA a summary report within 30 calendar days of authorization

[6] 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.

summarizing the results of any testing performed using anterior nasal swab specimens collected with the Color COVID-19 Self-Swab Collection Kit DTC during that timeframe, including including how many kits were activated via the online portal, purchased from an authorized distributor for home collection, or collected at a community-based site or distribution center, how many kits were processed, how many specimens were rejected during accessioning and the reasons for rejection, and the positivity rate of the first Color COVID-19 Self-Swab Collection Kit DTC lot.

O. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product, and use your product in accordance with the authorized laboratory procedure.

P. You 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.

Q. 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.

R. 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.

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, as applicable, and FDA implementing regulations.

T. No descriptive printed matter, advertising, and 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 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,

_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure