



September 15, 2021

Alicia Y. Zhou
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Device: Color COVID-19 Self-Swab Collection Kit with Saline
EUA Number: EUA203116
Company: Color Health, Inc.
Indication: For use by any individual 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19 for collection of anterior nasal swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider, and only for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with the Color COVID Self-Swab Collection Kit with Saline.
Authorized Laboratories: Testing is limited to laboratories designated by Color Health Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Dear Alicia Y. Zhou:

On April 14, 2021 based on your¹ request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Color COVID-19 Self-Swab Collection Kit with Saline for use by individuals 18 years or older, including individuals without symptoms or other reasons to suspect COVID-19 for unsupervised self-collection of anterior nasal swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider, and only for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with the Color COVID Self-Swab Collection Kit with Saline pursuant to Section 564 of the Federal Food, Drug, and

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

Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to laboratories designated by Color Health Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

On August 13, 2021, you requested to revise your Emergency Use Authorization (EUA). Based on this request and having concluded that revising the April 14, 2021 EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act, FDA is reissuing the April 14, 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 product³ is now intended for 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-19.⁴ 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.⁵

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 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:

² The revisions to the April 14, 2021, letter and authorized labeling include: (1) updates to the intended use to enable collection “by any individual age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance)...” (2) updates to the collection kit components including a change to the biohazard bag as well as the shipping box, and (3) modification to Condition O. to solicit post-collection usability feedback from parents/guardians performing collection in very young children (2 to 4-year-olds).

³ For ease of reference, this letter will use the term “your product” to refer to Color COVID-19 Self-Swab Collection Kit with Saline 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).

⁵ 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).

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 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.⁶

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 collection kit intended for use by any individual 18 years or older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19 for collection of anterior nasal swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider. Once collected, the human anterior nasal swab specimen, which may include SARS-CoV-2 RNA, is maintained in 0.9% saline and transported at ambient temperature to an authorized laboratory. The authorized laboratory then runs the specimen using an IVD molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with the Color COVID-19 Self-Swab Collection Kit with Saline. When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The Color COVID-19 Self-Swab Collection Kit with Saline includes the following materials or other authorized materials (as may be requested under Condition M. below): shipping box (at home collection), mailer shipping envelope with prepaid return shipping label and UN3373 label (at home collection), specimen biohazard bag with absorbent pouch, sterile packaged spun polyester swab, plastic sterile collection tube filled with saline, barcode card, instructions for collection (at home or healthcare setting (on-site) collection).

The labeling entitled “Color COVID-19 Self-Swab Collection Kit with Saline At-home Instructions,” “Color COVID-19 Self-Swab Collection Kit with Saline On-site Instructions,” 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 standard operating procedure (SOP): “Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit with Saline,” is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as “authorized labeling.”

⁶ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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 and used 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 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 specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the collected human 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:

Color Health, Inc. (You) and Authorized Distributor(s)⁷

- 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 and authorized distributor(s) must make available all instructions related to the collection of anterior nasal swab specimens (i.e., the Color COVID-19 Self-Swab Collection Kit with Saline At-home Instructions and/or the Color COVID-19 Self-Swab Collection Kit with Saline On-site Instructions) in the shipped kit and make available all instructions on your website(s).
- C. 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, or the authorized labeling.
- D. 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.
- E. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.
- 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.

Color Health, Inc. (You)

- G. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- H. You must notify FDA of any authorized laboratories designated by Color Health, Inc. to use your product, including the name, address, and phone number of any authorized laboratories.
- I. You must provide authorized distributor(s), authorized laboratories with a copy of this EUA and communicate any subsequent revisions that might be made to this EUA and its authorized accompanying materials.

⁷ “Authorized Distributor(s)” are identified by you, Color Health, Inc., in your EUA submission as an entity allowed to distribute the Color COVID-19 Self-Swab Collection Kit with Saline.

- J. You must comply with the following requirements under 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).
- K. 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.
- L. 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 the Color COVID-19 Self-Swab Collection Kit with Saline 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.
- M. 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 requests 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.
- N. You must have a process in place to track adverse events associated with the Color COVID-19 Self-Swab Collection Kit with Saline, including any occurrences of false results with your product, and report any such events to FDA pursuant to 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).
- O. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using anterior nasal swab specimens collected with the Color COVID-19 Self-Swab Collection Kit with Saline during that timeframe, 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. In addition, for kits provided for specimen collection from very young children (2 to 4-year-olds), you must solicit post-collection usability feedback from parents/guardians performing collection to further assess the ease of use of the kit in this age group. Thereafter, monthly reporting must continue until FDA informs you that the cumulative data submitted within the monthly reports has sufficiently assessed your collection kit.

- P. You must verify the stability of SARS-CoV-2 RNA in specimens collected using the Color COVID-19 Self-Swab Collection Kit with Saline in an FDA agreed upon post authorization study within 2 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Authorized Laboratories

- Q. Authorized laboratories testing anterior nasal swab specimens collected using your product must follow the “Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit with Saline” standard operating procedure when accepting specimens for testing.
- R. 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 your product.
- S. 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 (844-352-6567) 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.

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

- T. 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

- U. 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 requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.
- V. 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.
- W. 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 home collection and maintenance of anterior nasal swab specimens as an aid in 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure