

September 15, 2020

Scott Topper, Ph.D.  
VP Clinical Operations  
Color Genomics, Inc.  
831 Mitten Road, Suite 100  
Burlingame, CA 94010

Device: Color COVID-19 Self-Swab Collection Kit

Company: Color Genomics, Inc.

Indication: For use by individuals for unsupervised self-collection of nasal swab specimens at home or in a healthcare setting, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire, and for use only with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with the Color COVID-19 Self-Swab Collection Kit.

Authorized Laboratories: Testing is limited to laboratories designated by Color Genomics 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 and that run the specimens collected from the Color COVID-19 Self-Swab Collection Kit on an IVD molecular test that is indicated for use with the Color COVID-19 Self-Swab Collection Kit.

Dear Dr. Topper:

On August 31, 2020 based on your<sup>1</sup> request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Color COVID-19 Test Unmonitored Collection Kit, for use by individuals for unmonitored self-collection of nasal swab specimens at home or in a healthcare setting, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire, and for use only with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with the Color COVID-19 Test Unmonitored Collection Kit, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The August 31, 2020 letter authorizing emergency use of this test limited testing to laboratories designated by Color Genomics, 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 and that run the

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<sup>1</sup> For ease of reference, this letter will use the term “you” and related terms to refer to Color Genomics, Inc.

specimens collected from the Color COVID-19 Test Unmonitored Collection Kit on an IVD molecular test that is indicated for use with the Color COVID-19 Test Unmonitored Collection Kit.

On August 18, 2020, you requested to amend your Emergency Use Authorization (EUA) to change the device name of your product<sup>2</sup> from “Color COVID-19 Test Unmonitored Collection Kit” to “Color COVID-19 Self-Swab Collection Kit,” to update wording in the indication, as well as modify the components of the Color COVID-19 Self-Swab Collection Kit due to supply chain constraints. Based on that request, and having concluded that revising the August 31, 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 August 31, 2020 letter in its entirety with the revisions incorporated<sup>3</sup>. Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, this test 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<sup>4</sup>. 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.<sup>5</sup>

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;

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<sup>2</sup> For ease of reference, this letter will use the term “your product” to refer to the Color COVID-19 Self-Swab Collection Kit used for the indication identified above.

<sup>3</sup> The revisions to the August 31, 2020, letter include: (1) change of the device name from “Color COVID-19 Test Unmonitored Collection Kit” to “Color COVID-19 Self-Swab Collection Kit,” (2) change in the indication from “unmonitored self-collection” to “unsupervised self-collection,” and (3) modification of the components within the Color COVID-19 Self-Swab Collection Kit due to supply chain constraints to remove the outer cardboard shipping box and now include a push top closure tube and rigid biohazard bag.

<sup>4</sup> 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).

<sup>5</sup> 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)

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 self-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.<sup>6</sup>

## **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 unsupervised self-collection of nasal swab specimens at home or in a healthcare setting by individuals over 18 years of age when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire. Once collected, the human dry nasal swab specimen, which may include SARS-CoV-2 RNA, is maintained in the authorized product packaging and transported at ambient temperature to an authorized laboratory. The authorized laboratory then runs the specimen using an IVD molecular test that is indicated for use with dry nasal swab specimens collected with the Color COVID-19 Self-Swab Collection Kit. 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 includes the following materials or other authorized materials: FedEx soft shipping envelope with prepaid return label (at home collection), Rigid specimen biohazard bag, Sterile packaged spun polyester swab, Sterile collection tube with a push top closure, Barcode card, Instructions for self-collection (at home or healthcare setting (on-site) collection).

The above described product is authorized to be accompanied with authorized labeling (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>). Authorized labeling includes the following documents: EUA Summary, “Color COVID-19 Self-Swab Collection Kit At-home Instructions,” “Color COVID-19 Self-Swab Collection Kit On-site Instructions,” “COVID-19 Questionnaire (Screening SOP),” and the “Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit.”

The above described product, when accompanied by the authorized labeling (identified above) is authorized to be distributed to and used by individuals and authorized laboratories as set forth in this letter and pursuant to the conditions 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

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

the known and potential benefits of your authorized 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 self-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 Genomics, Inc. (You) and Authorized Distributor(s)<sup>7</sup>**

- 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

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<sup>7</sup> “Authorized Distributor(s)” are identified by you, Color Genomics, Inc., in your EUA submission as an entity allowed to distribute your device.

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) will make available on your website(s) the Color COVID-19 Self-Swab Collection Kit At-home Instructions and the Color COVID-19 Self-Swab Collection Kit On-site Instructions.
- C. You and authorized distributor(s) will 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) will maintain records of the numbers and locations to which your product is distributed.
- E. You and authorized distributor(s) will 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 Genomics, Inc. (You)**

- G. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- H. You will notify FDA of any authorized laboratories designated by Color Genomics, Inc. to use your product, including the name, address, and phone number of any authorized laboratories.
- I. You will provide authorized distributor(s) and 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.
- J. You may request 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. Such requests will be made in consultation with, and require concurrence of, 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).

- K. You will 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).
- L. 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.
- M. 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.
- N. 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.
- O. You will track adverse events associated with your product, including occurrences of false results and report 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](mailto:CDRH-EUAREporting@fda.hhs.gov)).
- P. You will make available all instructions related to the self-collection of nasal swab specimens using your product, both in the shipped kit and on your website.
- Q. You will notify FDA of any changes to the COVID-19 questionnaire used by a healthcare provider to determine eligibility of an individual to receive the Color COVID-19 Self-Swab Collection Kit.
- R. You will submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using nasal specimens collected with the Color COVID-19 Self-Swab Collection Kit during that timeframe, including how many kits were requested and sent for home collection to individuals, how many kits were shipped and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the first Color COVID-19 Self-Swab Collection Kit lot.

#### **Authorized Laboratories**

- S. Authorized laboratories testing nasal swab specimens self-collected using your product must follow the “Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit” standard operating procedure when accepting specimens for testing.
- T. Authorized laboratories using your product will use it only in conjunction with COVID-19 in vitro diagnostic (IVD) molecular tests that are authorized for use with your

product.

- U. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto: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 Genomics, Inc. (You), Authorized Distributors and Authorized Laboratories**

- V. You, authorized distributors, and authorized laboratories using your product 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.

**Conditions Related to Printed Materials, Advertising and Promotion**

- W. All descriptive printed matter, including 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 applicable requirements set forth in the Act and FDA regulations.
- X. No descriptive printed matter, including 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.
- Y. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:
- This self-sample collection kit has not been FDA cleared or approved;
  - This self-sample collection has been authorized by FDA under an EUA;
  - This self-sample collection kit has been authorized only for the self-collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
  - This self-sample collection kit is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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,

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Enclosure