November 2, 2020

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

Device:	Color SARS-CoV-2 LAMP Diagnostic Assay
Company:	Color Genomics, Inc.
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal swabs, anterior nares swabs, mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirates, as well as bronchoalveolar lavage specimens collected from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to the authorized laboratories. This test is also for use with dry nasal swab specimens that are self-collected unsupervised at home or in a healthcare setting by individuals using the Color COVID-19 Self-Swab Collection Kit when determined to be appropriate by a healthcare provider based on results of a COVID-19 medical questionnaire.
Authorized Laboratories:	Testing is limited to Color Genomics, 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. Topper:

On May 18, 2020, based on your[1] request, the Food and Drug Administration (FDA) determined that the Color SARS-CoV-2 LAMP Diagnostic Assay met the criteria for issuance under section 564(c) of the Act to be eligible for authorization under the March 31, 2020, Emergency Use Authorization (EUA) for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (High Complexity LDT Umbrella EUA) for the qualitative detection of

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

nucleic acid from SARS-CoV-2 in respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). As authorized under the High Complexity LDT umbrella EUA, testing was limited to the single laboratory that developed the authorized test and that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests pursuant to the Scope of Authorization and Conditions of Authorization of that EUA.[2] On July 24, 2020, based on your request, FDA authorized use of the Color SARS-CoV-2 LAMP Diagnostic Assay with revisions incorporated.[3] Based on your request, FDA also granted updates to the authorized labeling on August 28, 2020[4] and September 22, 2020.[5]

On October 6, 2020, you requested to further revise this EUA to, among other revisions, update the name of the product. Based on these requests, and having concluded that revising the July 24, 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 July 24, 2020, letter in its entirety with the revisions incorporated.[6] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter,

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[2] In this case, testing was limited to your laboratory 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.

[3] On July 24, 2020, because the requested revision to include self collection of nasal swab specimens was beyond the Scope of Authorization of the High Complexity LDT Umbrella EUA, FDA authorized use pursuant to Section 564 of the Act and the Scope of Authorization and Conditions of Authorization of the July 24, 2020, letter. Thus, the indication for the Color SARS-CoV-2 LAMP Diagnostic Assay was for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal swabs, anterior nares swabs, mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirates, as well as bronchoalveolar lavage specimens collected from individuals suspected of COVID-19 by their healthcare provider. The test was also for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit specified in this EUA's authorized labeling when determined to be appropriate by a healthcare provider. Testing was limited to Color Genomics, 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.

[4] On August 28, 2020, your request was granted to update the Instructions for Use (Laboratory SOP) of your product to; (1) remove the ORFlab primer set from the procedure and reporting algorithm (2) update the assay interpretation protocol, (3) remove redundant plate controls, (4) make minor changes to the SOP to provide clearer instructions to the assay operator, (5) change the name of the assay from "Color SARS-CoV-2 LAMP Diagnostic Assay" to "Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay," (6) update language in the "Medical Oversight and Process to be Used for Unmonitored Nasal Swab Collection" section of the EUA summary and (7) update the clinical evaluation section to accurately reflect the comparator that was used to evaluate the assay's clinical performance.

[5] On September 22, 2020, your request was granted via email to update the EUA Summary of your product to add the results of testing the FDA SARS-CoV-2 Reference Panel Testing.

[6] The revisions to the July 24, 2020, letter and authorized labeling include: (1) revise the name of the test from "Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay" back to the original "Color SARS-CoV-2 LAMP Diagnostic Assay," (2) removal of the Color COVID-19 Unmonitored Collection Kit as part of the Color SARS-CoV-2 LAMP Diagnostic Assay due to it being authorized on its own under the Color COVID-19 Self-Swab Collection Kit EUA, (3) update the intended use to include use with dry nasal swab specimens that are self-collected unsupervised at home or in a healthcare setting by individuals using the Color COVID-19 Self-Swab Collection Kit when determined to be appropriate by a healthcare provider based on results of a COVID-19 medical questionnaire, (4) updates to the accessioning criteria to accurately reflect the dry swab stability claim of 56 hours, (5) revisions to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language more consistent with recent authorizations, and (6) revisions to the Conditions of Authorization as a result of the new intended use and for consistency with recent authorizations.

your product[7] 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. [8]

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, as described in the Scope of Authorization (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

3. There is no adequate, approved, and available alternative to the emergency use of your product for diagnosing COVID-19. [9]

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.

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

[8] 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).

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

Authorized Product Details

Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal swabs, anterior nares swabs, mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirates, as well as bronchoalveolar lavage (BAL) specimens collected from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with dry nasal swab specimens that are self-collected unsupervised at home or in a healthcare setting by individuals using the Color COVID-19 Self-Swab Collection Kit when determined to be appropriate by a healthcare provider based on results of a COVID-19 medical questionnaire. Testing is limited to Color Genomics, Inc., located at 863 Mitten Road, Burlingame, CA 94010, which is certified under CLIA and meets requirements to perform high-complexity tests.

The SARS-CoV-2 RNA is generally detectable in respiratory 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. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

To use your product, SARS-CoV-2 nucleic acid is first extracted from upper respiratory and BAL specimens 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 J. 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:

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

- No Template Extraction Control - 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.

- LAMP Positive Control (synthetic SARS-CoV-2 RNA) - should show positive signal for all three SARS-CoV-2 specific targets and no signal for RNase P. A lack of amplification of the SARS-CoV-2 targets would indicate reagent or process failure during LAMP.

- No Template LAMP Control - should not produce positive signal for any of SARS-CoV-2 targets or the internal RNase P target.

- 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.

The above described product 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/vitro-diagnostics-euas), and the following product information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Color Genomics, Inc.- Color SARS-CoV-2 LAMP Diagnostic Assay

- Fact Sheet for Patients: Color Genomics, Inc. - Color SARS-CoV-2 LAMP Diagnostic Assay

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and Color SARS-CoV-2 RT-LAMP Diagnostic Assay Standard Operating Procedure (collectively referenced as "authorized labeling"), is authorized to be 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 the 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 Genomics, Inc. (You)

A. Your authorized test 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 will inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your authorized product and/or authorized labeling.

C. You will notify the relevant public health authorities of your intent to run your product.

D. You will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. You will 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 will make available on your website(s), the authorized labeling.

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 will use your product as outlined in the authorized labeling. Deviations from the authorized labeling, 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. You will 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.

J. 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..

K. You will evaluate the analytical limit of detection and assess traceability[10] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the date 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.

L. You will have a process in place in accordance with 21 CFR Part 803 to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

M. 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 test procedure.

N. You 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.

[10] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study if we receive reports of adverse events concerning your authorized test.

O. You will additionally track adverse events associated with the Color COVID-19 Self-Swab Collection Kit, or any other home specimen collection kit authorized for use 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-EUA-Reporting@fda.hhs.gov).

P. You will make available all instructions related to the self-collection of dry nasal swab specimens using the Color COVID-19 Self-Swab Collection Kit, or any other home specimen collection kit authorized for use with your product on your website.

Conditions Related to Printed Materials, Advertising and Promotion

Q. 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.

R. 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.

S. No descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests 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 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 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