July, 24, 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 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.
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) issued a letter determining that your product[2] met the criteria for issuance under section 564(c) of the

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Color Genomics, Inc.
[2] 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.

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 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 of your test was limited to the single laboratory that developed the authorized test and that is certified under 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.[3]

On June 22, 2020, FDA received a request from you to revise the Scope of Authorization, and thus the test's intended use as originally specified by the High Complexity LDT Umbrella EUA, to include self-collection of nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using the Color COVID-19 Test Unmonitored Collection Kit, or other authorized home-collection kit specified in this EUA's authorized labeling, when determined to be appropriate by a healthcare provider. In response to that request, because the requested revision is beyond the Scope of Authorization of the High Complexity LDT Umbrella EUA, FDA is hereby authorizing the use of the Color SARS-CoV-2 LAMP Diagnostic Assay used for the indication identified above pursuant to Section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this letter of authorization.

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]

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:

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

[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).

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.[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

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 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 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 Color COVID-19 Test Unmonitored Collection Kit enables the self-collection of a nasal swab specimen (unobserved) that is transported in dry conditions in a sterile collection container to Color Genomics, Inc. for testing when determined to be appropriate by a healthcare provider. Healthcare providers (HCP) at specific institutions use a COVID-19 eligibility questionnaire. Patients should follow all specimen collection and mailing instructions provided in the kit. The Color COVID-19 Test Unmonitored Collection Kit consists of a sterile packaged spun polyester swab, collection tube, biohazard bag, cardboard box, barcode card, instructions for use, and a bag with a prepaid return label.

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-

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

infection with other viruses.

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 (refer to Condition P), 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/emergency-situations-medical-devices/emergency-use-authorizations), 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 SARS-CoV-2 LAMP Diagnostic Assay
- Fact Sheet for Patients: 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, Standard Operating Procedures (SOP) for the Color SARS-CoV-2 LAMP Diagnostic Assay and Sample Accessioning, Color COVID-19 Test Unmonitored Collection Kit Eligibility Questionnaire, Color COVID-19 Test Unmonitored Collection Kit instruction booklet for in-office collection, and Color COVID-19 Test Unmonitored Collection Kit instruction booklet for at-home collection (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 for the qualitative detection of SARS-CoV-2 and 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 test, authorized labeling and authorized Fact Sheets.

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), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients and the Color COVID-19 Test Unmonitored Collection Kit instruction booklet for in-office and at-home collections.

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 the Scope of Authorization (Section II in this letter) of

your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

K. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. You may request the addition of other extraction methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition and/or substitution of primers or probes for use with your authorized test. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You may request the addition and/or substitution of home specimen collection kits for use with your product, that will be named in the authorized labeling. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You will evaluate the analytical limit of detection and assess traceability of your authorized test with any FDA-recommended reference material(s), if requested by FDA[6]. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, FDA will update the EUA summary to reflect the additional testing. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

[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 if we receive reports of adverse events concerning your authorized test.

T. You will track adverse events, including any occurrence of false results with your authorized test and report any such events to FDA pursuant to 21 CFR Part 803.

U. 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.

V. 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.

W. You will additionally track adverse events associated with the Color COVID-19 Test Unmonitored 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).

X. You will make available all instructions related to the self-collection of nasal swab specimens using the Color COVID-19 Test Unmonitored Collection Kit, or any other home specimen collection kit authorized for use with your product, both in the shipped kit and on your website.

Y. You will notify FDA of any changes to the patient qualification criteria used by the healthcare provider to determine eligibility of an individual to receive the Color COVID-19 Test Unmonitored Collection Kit, or any other home specimen collection kit authorized for use with your product.

Z. You will submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using nasal swab specimens collected with the Color COVID-19 Test Unmonitored Collection Kit during that timeframe, including how many kits were requested and granted for unmonitored collection, how many kits were shipped and returned, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the Color COVID-19 Test Unmonitored Collection Kit.

Conditions Related to Advertising and Promotion

AA. 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.

BB. 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.

CC. All 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 diagnostics for detection and/or diagnosis of COVID-19 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 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