August 28, 2020

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

Re: EUA200539/S004
Trade/Device Name: Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay
Dated: August 7, 2020
Received: August 8, 2020

Dear Dr. Topper:

This is to notify you that your request to update the Instructions for Use (IFU) of the Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay 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, is granted. Upon review, we concur that the data and information submitted in EUA200539/S004 supports the requested updates for use with the Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay. We have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Color Genomics SARS-CoV-2 RT-LAMP Diagnostic Assay issued on July 24, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health