July 9, 2021

Alicia Y. Zhou, PhD
Chief Scientific Officer
Color Health, Inc.
831 Mitten Road, Suite 100
Burlingame, CA 94010

Re: EUA200539/S010
Trade/Device Name: Color SARS-CoV-2 RT-LAMP Diagnostic Assay
Dated: June 21, 2021
Received: June 22, 2021

Dear Dr. Zhou:

This is to notify you that your request to update the authorized labeling of the Color SARS-CoV-2 RT-LAMP Diagnostic Assay to change the assay format to include an initial screening assay followed by reflex testing for invalid results and "candidate" positive specimens, is granted. Upon review, we concur that the data and information submitted in EUA200539/S010 supports the requested updates for use with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay. By submitting this EUA revision 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 SARS-CoV-2 RT-LAMP Diagnostic Assay reissued on April 14, 2021.

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