



June 15, 2022

Alicia Y. Zhou, Ph.D.  
Chief Science Officer  
Color Health, Inc.  
831 Mitten Road, Suite 100  
Burlingame, CA 94010

Re: EUA203116/S004  
Trade/Device Name: Color COVID-19 Self-Swab Collection Kit with Saline  
Dated: May 24, 2022  
Received: May 24, 2022

Dear Dr. Zhou:

This is to notify you that your request to update the Color COVID-19 Self-Swab Collection Kit with Saline EUA Summary and the "Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit with Saline" standard operating procedure (SOP) to extend the stability claims for transport of anterior nasal swab specimens in saline to 72 hours and testing within a maximum of 96 hours post collection, is granted. Upon review, we concur that the data and information submitted in EUA203116/S004 supports the requested updates for use with the Color COVID-19 Self-Swab Collection Kit with Saline and fulfills Condition of Authorization P from the September 15, 2021 letter. 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 reissued letter authorizing the emergency use of the Color COVID-19 Self-Swab Collection Kit with Saline issued on September 15, 2021.

Sincerely yours,

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For: 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