



January 31, 2022

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

Re: EUA203116/S003  
Trade/Device Name: Color COVID-19 Self-Swab Collection Kit with Saline  
Dated: November 16, 2021  
Received: November 17, 2021

Dear Alicia Y. Zhou:

This is to notify you that your request to update the EUA Summary of the Color COVID-19 Self-Swab Collection Kit with Saline to; (1) include additional usability study data on 2-4 year-olds using the modified collection instructions to fulfill Condition O of the September 15, 2021 letter, and (2) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA203116/S003 supports the requested updates for use with the Color COVID-19 Self-Swab Collection Kit with Saline. 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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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