



January 26, 2022

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

Re: EUA202423/S005
Trade/Device Name: Color COVID-19 Self-Swab Collection Kit
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 to; (1) include additional usability study data on 2-4 year-olds using the modified collection instructions to partially fulfill Condition O of the September 3, 2021 letter, and (2) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA202423/S005 supports the requested updates for use with the Color COVID-19 Self-Swab Collection Kit. 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 issued on September 3, 2021.

Sincerely yours,

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