



July 21, 2022

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

Re: EUA202423/S006
Trade/Device Name: Color COVID-19 Self-Swab Collection Kit
Dated: June 17, 2022
Received: June 17, 2022

Dear Alicia Y. Zhou:

This is to notify you that your request to add an additional set of the “Color COVID-19 Self-Swab Collection Kit On-site Instructions” specific for the Massachusetts Institute of Technology (MIT) community-based distribution network, for on-site unsupervised specimen collection, using the MIT Atlas mobile application for patient registration, pre-test kit activation, and post-test access to results, is granted. FDA has updated the EUA Summary accordingly, to outline details of the MIT-specific distribution and remove reference to the Summary Report requested under Condition O. of the September 3, 2021, re-issued Letter of Authorization which has been fulfilled based on recent data and information provided to FDA for review. Upon review, we concur that the information submitted in EUA202423/S006 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 letter authorizing the emergency use of the Color COVID-19 Self-Swab Collection Kit re-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