July 21, 2022

Brandon Johnson
Head of R&D
Nexus Medical Labs, LLC.
313 Pleasant Street, 1st Floor
Watertown, MA 02472

Re: EUA220198/S001
Trade/Device Name: Nexus High Throughput SARS-CoV-2 Assay
Dated: June 8, 2022
Received: June 8, 2022

Dear Alicia Y. Zhou:

This is to notify you that your request to add an additional set of the Rhinostics Nasal Swab Collection Kit for Nexus High Throughput SARS-CoV-2 Assay On-site Instructions" and the "Rhinostics Nasal Swab Collection Kit for Nexus High Throughput SARS-CoV-2 Assay Mail-in Instructions," specific to Color Health, Inc. for the Harvard University community-based distribution network for kit assembly 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 Color Health, Inc. specific distribution. Upon review, we concur that the information submitted in EUA220198/S001 supports the requested updates for use with the Nexus High Throughput SARS-CoV-2 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 Nexus High Throughput SARS-CoV-2 Assay issued on May 17, 2022.

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