March 7, 2023

Marie Louise Landry, M.D.
Director, Clinical Virology Laboratory, Yale New Haven Hospital
Professor, Laboratory Medicine and Medicine (Infectious Diseases)
Yale University School of Medicine
P.O. Box 208035
New Haven, CT 06520-8035 U.S.

Re: EUA200061/S002
Trade/Device Name: Yale New Haven SARS CoV-2 Assay
Laboratory: Clinical Virology Laboratory at Yale New Haven Hospital
Dated: September 27, 2021
Received: October 4, 2021

Dear Dr. Landry:

This is to notify you that your request is granted to update the authorized labeling of the Yale New Haven SARS CoV-2 Assay; (1) in response to Condition of Authorization (1) of the Viral Mutation Revision Letter dated September 23, 2021, and (2) to remove saliva collected in a sterile container as an acceptable specimen type. By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Viral Mutation Revision Letter dated September 23, 2021, and complied with the Conditions of Authorization stated in the November 15, 2021 reissued Letter of Authorization for Molecular Diagnostic Tests for SARS-CoV-2 Developed And Performed By Laboratories Certified Under CLIA To Perform High Complexity Tests for which the Yale New Haven SARS Co-V-2 Assay was added to Appendix A as an authorized test on March 31, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health