June 4, 2020

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/A001
Trade/Device Name: Yale New Haven SARS CoV-2 Assay
Laboratory: Clinical Virology Laboratory at Yale New Haven Hospital

Dated: May 9, 2020
Received: May 9, 2020

Dear Dr. Landry:

This is to notify you that your request to update the Instructions for Use (IFU) of the Yale New Haven SARS CoV-2 Assay to add saliva collected in a sterile container as an acceptable specimen type to your EUA, is granted. Upon review, we concur that the data and information submitted in EUA200061/A001 supports the requested updates for use with the Yale New Haven SARS Co-V-2 Assay. FDA also made some minor changes to the EUA Summary. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the March 31, 2020 Letter of Authorization for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (Molecular LDT COVID-19 Authorized Test) 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,

_____

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