August 31, 2020

Niall J. Lennon, Ph.D.
Institute Scientist and Sr. Director
Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard
320 Charles Street
Cambridge, MA 02141

Re: EUA200147/S001
Trade/Device Name: CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay
Dated: August 2, 2020
Received: August 2, 2020

Dear Dr. Lennon:

This is to notify you that your request to update the authorized labeling of the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay to add use of spun polyester swabs placed into empty, sterile tubes (termed dry swabs) for collection of anterior nares specimens tested using version 2 of the assay, is granted. Upon review, we concur that the data and information submitted in EUA200147/S001 supports the requested updates for use with the CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay. FDA have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. 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 CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay issued on July 8, 2020.

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