June 30, 2023

Barbara-Ann Conway-Myers, Ph.D.
Principal, Regulatory Affairs, North America
LumiraDx UK Ltd.
Building 115, Bedford Technology Park,
Thurleigh
Bedford MK44 2YA, United Kingdom

Re: EUA220457/S001 and EUA220457/S002
Trade/Device Name: LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Assay
Dated: May 18, 2023 and May 23, 2023
Received: May 18, 2023 and May 23, 2023

Dear Dr. Conway-Myers:

This is to notify you that your request to update the authorized labeling of the LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Assay to; (1) update the manufacturer's address, and (2) extend the shelf-life expiration date to 9 months when stored at the recommended conditions in the authorized labeling, based on the results of ongoing stability studies, is granted. Upon review, we concur that the data and information submitted in EUA220457/S001 and EUA220457/S002 supports the requested updates for use with the LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Assay. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 LumiraDx SARS-CoV-2 & Flu A/B RNA STAR Complete Assay issued on February 3, 2023.

Sincerely yours,

_____

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