March 29, 2023

Barbara-Ann Conway-Myers, Ph.D.
Principal, Regulatory Affairs, North America
LumiraDx Inc.
On behalf of: LumiraDx UK Ltd.
Dumyat Business Park, Bond Street
Alloa, GRB FK10 2PB

Re: EUA2202314/S012
Trade/Device Name: LumiraDx SARS-CoV-2 Ag Test
Dated: November 16, 2022
Received: November 16, 2022

Dear Dr Conway-Meyers:

This is to notify you that your request to update the authorized labeling of the LumiraDx SARS-CoV-2 Ag Test; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, and (2) include results of additional reactivity studies, is granted. Upon review, we concur that the information submitted in EUA2202314/S012 supports the requested updates for use with the LumiraDx SARS-CoV-2 Ag Test and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. T The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

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 Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the LumiraDx SARS-CoV-2 Ag Test re-issued on July 21, 2022.

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