January 26, 2021

Dr. Nigel Lindner
Chief Innovation Officer & Head of Care Solutions
LumiraDx UK Ltd.
Dumyat Business Park, Bond Street
Alloa, GBR Fk10 2PB

Re: EUA202314/S001
Trade/Device Name: LumiraDx SARS-CoV-2 Ag Test
Dated: October 30, 2020 and November 27, 2020
Received: October 30, 2020 and November 30, 2020

Dear Dr. Lindner:

This is to notify you that your request to update the Instructions for Use (IFU) and/or Quick Reference Instructions (QRI) of the LumiraDx SARS-CoV-2 Ag Test to; (1) add an additional alternative extraction buffer tube, (2) update the shelf-life, and (3) include minor updates and clarifications, is granted. We also concur with the requested updates to the Test Strip Foil Label and the additional labeling for the authorized LumiraDx Platform instrument. Upon review, we concur that the data and information submitted in EUA202314/S001 supports the requested updates for use with the LumiraDx SARS-CoV-2 Ag Test. 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 Ag Test issued on August 18, 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