August 31, 2022

Tim Blicharz, Ph.D.
Vice President, Quality and Regulatory Affairs, North America
LumiraDx UK Ltd.
Dumyat Business Park, Bond Street
Alloa, FK10 2PB
United Kingdom

Re: EUA202735/S002/A001
Trade/Device Name: LumiraDx SARS-CoV-2 Ab Test
Dated: August 19, 2022
Received: August 19, 2022

Dear Dr. Tim Blicharz:

This is to notify you that your request to update the authorized labelling for LumiraDx SARS-CoV-2 Ab Test with results from the Independent Evaluation Testing by the National Cancer Institute (NCI/FNLCR), is granted. Upon review, we concur that the data and the information provided in EUA202735/S002/A001 support the requested updates. FDA has also updated the Instructions for Use, Factsheet for Healthcare Provider and Recipient Factsheet to reflect language used in more recent authorizations. By submitting this information for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of LumiraDx SARS-CoV-2 Ab Test issued on August 2, 2021.

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