February 17, 2022

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

Re: EUA202314/S007/S008
Trade/Device Name: LumiraDx SARS-CoV-2 Ag Test
Dated: S007: December 21, 2021
S008: December 29, 2021
Received: S007: December 21, 2021
S008: December 29, 2021

Dear Dr. Lindner:

This is to notify you that your request to update the LumiraDx SARS-CoV-2 Ag Test to (1) extend the shelf-life expiration date of the LumiraDx SARS-CoV-2 Ag Test strips to 13 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies, (2) provide the additional temperature and humidity flex study data to fulfill Condition of Authorization R. of the Letter of Authorization re-issued on October 29, 2021, and (3) update the acceptable operating conditions in the Instructions For Use and QRI to reflect a maximum relative humidity of 75%, based on the results of the additional temperature and humidity flex study, is granted. Upon review, we concur that the data and information submitted in EUA202314/S007/S008 support the requested updates for the LumiraDx SARS-CoV-2 Ag Test. FDA has also updated the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to be consistent with 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 Ag Test re-issued on October 29, 2021.

Sincerely yours,

_____

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