August 17, 2022

Tim Blicharz, Ph.D.
Vice President, US Regulatory and Quality Affairs
LumiraDx UK Ltd.
Unit 50 Yorkshire Way,
Doncaster, DN3 3FT, United Kingdom

Re: EUA202584/S009
Trade/Device Name: LumiraDx SARS-CoV-2 RNA STAR Complete
Dated: May 18, 2022
Received: May 18, 2022

Dear Dr. Blicharz:

This is to notify you that your request to update the authorized labeling of the LumiraDx SARS-CoV-2 RNA STAR Complete to include; (1) revised instrument settings and analysis parameters for use with the Analytik Jena qTOWER^3 G, (2) revised formulation of the Negative Control Media from molecular grade water to phosphate buffered saline (PBS), (3) extension of the claimed shelf-life of the LumiraDx SARS-CoV-2 RNA STAR Complete to 9 months at -25 to -15 °C, and (4) other minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA202584/S009 supports the requested updates for use with the LumiraDx SARS-CoV-2 RNA STAR Complete. 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 RNA STAR Complete reissued on February 18, 2022.

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

Cc: Barbara-Ann Conway-Myers, PhD, Senior Regulatory Affairs Specialist, North America