U.S. FOOD & DRUG ADMINISTRATION

February 22, 2022

Barbara-Ann Conway Myers
Principal, Regulatory Affairs, North America
LumiraDx UK Ltd.
3 More London Riverside
London, SE1 2AQ

Re: EUA202584/S011
Trade/Device Name: LumiraDx SARS-CoV-2 RNA STAR Complete
Dated: January 24, 2023
Received: January 24, 2023

Dear Barbara-Ann Conway Myers:

This is to notify you that your request is granted to; (1) update the authorized labeling of the LumiraDx SARS-CoV-2 RNA STAR Complete to alternative catalogue numbers for the assay kit to reflect different formulations of the Negative Control Media (Phosphate Buffered Saline or Molecular Grade Water), and (2) extend the shelf-life of the LumiraDx SARS-CoV-2 RNA STAR Complete kit to 12 months when stored according to the authorized labeling. Upon review, we concur that the data and information submitted in EUA202584/S011 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 re-issued 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health