March 22, 2021

Tim Blicharz, Ph.D.
VP, Quality & Regulatory Affairs
LumiraDx UK Ltd.
3 More London Riverside
London, SE1 2AQ GBR

Re: EUA202584/S004
Trade/Device Name: LumiraDx SARS-CoV-2 RNA STAR Complete
Dated: February 19, 2021
Received: February 19, 2021

Dear Dr. Blicharz:

This is to notify you that your request to update the Instructions for Use (IFU) of the LumiraDx SARS-CoV-2 RNA STAR Complete to include an RUO instrument qualification protocol and RUO label, is granted. Upon review, we concur that the information submitted in EUA202584/S004 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 9, 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