U.S. FOOD & DRUG ADMINISTRATION

September 15, 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/S010/A001
Trade/Device Name: LumiraDx SARS-CoV-2 RNA STAR Complete
Dated: August 25, 2022 and September 8, 2022
Received: August 25, 2022 and September 8, 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 results of the additional pooling performance evaluation performed to fulfill Condition of Authorization Q. from the February 18, 2022 Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA202584/S010/A001 supports the requested updates for use with the LumiraDx SARS-CoV-2 RNA STAR Complete and fulfills Condition of Authorization Q. from the February 18, 2022, letter. 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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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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