August 21, 2024

Barbara-Ann Conway-Myers, Ph.D.
Principal, Regulatory Affairs, North America
Global Quality & Regulatory
LumiraDx UK Ltd.
3 More London Riverside,
London, SE1 2AQ, United Kingdom
Re: Revocation of EUA202169

Dear Dr. Conway-Myers:
This letter is in response to the request from LumiraDx UK Ltd., in an email dated August 12, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the LumiraDx SARS CoV-2 RNA STAR issued on August 11, 2020, and amended on November 28, 2020, September 23, 2021, February 24, 2023, and July 18, 2023. LumiraDx UK Ltd. indicated that they have ceased manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable LumiraDx SARS CoV-2 RNA STAR reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because LumiraDx UK Ltd. has requested that FDA revoke the EUA for the LumiraDx SARS CoV-2 RNA STAR, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202169 for the LumiraDx SARS CoV-2 RNA STAR, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the LumiraDx SARS CoV-2 RNA STAR is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Michelle Tarver, M.D., Ph.D.
Acting Center Director
Center for Devices and Radiological Health
Food and Drug Administration