April 15, 2025

Justin Davis
Regulatory Affairs, U.S. Representative
LumiraDx UK Ltd.
Roche House Charles Avenue
Burgess Hill, England, RH15 9RY

Re: Revocation of EUA202584

Dear Justin Davis:

This letter is in response to the request from LumiraDx UK Ltd., in an email dated November 8, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete issued on October 14, 2020, revised and reissued on February 9, 2021, March 29, 2021, November 30, 2021, and February 18, 2022, and amended on March 22, 2021, April 13, 2021, September 23, 2021, April 25, 2022, August 17, 2022, September 15, 2022, February 22, 2023, and July 10, 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 Complete 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 Complete, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202584 for the LumiraDx SARS CoV-2 RNA STAR Complete, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the LumiraDx SARS CoV-2 RNA STAR Complete 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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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Technical Correction June 26, 2025: Edit to correct the date the EUA for the LumiraDx SARS CoV-2 RNA STAR Complete was originally issued.