May 28, 2025

Sharmin Bhathena
Senior Manager, Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
Re: Revocation of EUA200035

Dear Sharmin Bhathena:
This letter is in response to the request from Cepheid, in a letter dated May 21, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Xpert Xpress SARS-CoV-2 test issued on March 20, 2020, revised and reissued on January 7, 2021, and amended on April 10, 2020, April 28, 2020, August 8, 2020, September 16, 2020, September 23, 2021 and April 26, 2022. Cepheid indicated that all their U.S. customers have transitioned to the Xpert Xpress SARS-CoV-2 *plus* product that was authorized under EUA220187.

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 Cepheid has requested that FDA revoke the EUA for the Xpert Xpress SARS-CoV-2 test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200035 for the Xpert Xpress SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Xpert Xpress SARS-CoV-2 test 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