December 20, 2021

Mohamed Shariff
Sr. Manager, Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089-1189
Re: Revocation of EUA202699

Dear Mohamed Shariff:

This letter is in response to a request from Cepheid, received December 17, 2021, that the U.S. Food and Drug Administration (FDA) revoke the EUA202699 for the Xpert Omni SARS-CoV-2 test issued on November 27, 2020 and amended on December 23, 2020, April 20, 2021 and September 23, 2021. Cepheid indicated that due to the current public clinical needs being met by Cepheid's other EUA tests that are available, Cepheid has not commercially distributed any of the authorized product.

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 notified FDA that Cepheid has not commercially distributed any of the Xpert Omni SARS-CoV-2 product due to the current public clinical needs being met by Cepheid's other EUA tests that are available and requested FDA revoke the EUA202699 for the Xpert Omni 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 EUA202699 for the Xpert Omni SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Xpert Omni SARS-CoV-2 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: Suzette Chance, Senior Director Regulatory Affairs, Cepheid