April 17, 2023

Julie Purcell
Director, US Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Re: Revocation of EUA200453

Dear Julie Purcell:

This letter is in response to the request from Cepheid, in a letter received March 7, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Xpert Xpress SARS-CoV-2/Flu/RSV issued on September 24, 2020, reissued October 1, 2020, and revised on January 27, 2021, and September 23, 2021. Cepheid indicated that they have stopped sales of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable Xpert Xpress SARS/CoV-2/Flu/RSV 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 Cepheid has requested FDA revoke the EUA for the Xpert Xpress SARS-CoV-2/Flu/RSV, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200453 for the Xpert Xpress SARS-CoV-2/Flu/RSV, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Xpert Xpress SARS-CoV-2/Flu/RSV 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,

_____

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration