January 30, 2024

Lisa Vershave
Regulatory Affairs Manager
Revvity, Inc.
940 Winter Street
Waltham, MA 02451

Re: Revocation of EUA202494

Dear Lisa Vershave:

This letter is in response to the request from Revvity, Inc., on behalf of Revvity Omics (a Revvity, Inc. company that was a rebranding of PerkinElmer Genomics) in an email dated January 19, 2024, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit issued on April 12, 2021, and amended on September 23, 2021. Revvity, Inc. indicated that as of the date of this letter they have discontinued use of the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit at the Revvity Omics (formally PerkinElmer Genomics) laboratory located in Pittsburgh.

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 Revvity, Inc. has requested that FDA revoke the EUA for the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202494 for the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration