January 16, 2024

Stacy Drakousis,
Sr. Manager, Regulatory Affairs
Thermo Fisher Scientific, Inc.
5781 Van Allen Way
Carlsbad, CA 92008

Re: Revocation of EUA202924

Dear Stacy Drakousis:

This letter is in response to the request from Life Technologies Corporation (a legal entity of Thermo Fisher Scientific, Inc.), in a letter dated November 13, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the TaqPath COVID-19 Pooling Kit issued on May 25, 2021, and amended on September 23, 2021, and May 31, 2023. Thermo Fisher Scientific, Inc. indicated that they are no longer commercially supporting the TaqPath COVID-19 Pooling Kit and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable TaqPath COVID-19 Pooling Kit 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 Thermo Fisher Scientific, Inc. has requested that FDA revoke the EUA for the TaqPath COVID-19 Pooling Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202924 for the TaqPath COVID-19 Pooling Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TaqPath COVID-19 Pooling 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