



September 27, 2021

Ashley Vu
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5781 Van Allen Way
Carlsbad, CA 92008
Re: Revocation of EUA210447

Dear Ms. Vu:

This letter is in response to Thermo Fisher Scientific, Inc.'s request on behalf of Life Technologies Corporation (a part of Thermo Fisher Scientific, Inc.) dated September 22, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA210447) for the TaqPath COVID-19 MS2 Combo Kit 2.0 issued on August 2, 2021. Thermo Fisher Scientific, Inc. indicated that it has decided to not commercially support the TaqPath COVID-19 MS2 Combo Kit 2.0 at this time "due to the current public clinical needs being met by our other EUA assays that are available and on market."

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 notified FDA that it is longer commercially supporting the TaqPath COVID-19 MS2 Combo Kit 2.0 and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210447 for the TaqPath COVID-19 MS2 Combo Kit 2.0, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TaqPath COVID-19 MS2 Combo Kit 2.0 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration