April 13, 2023

Colleen Watson
Senior Director Regulatory Affairs
Fisher Diagnostics
Part of Thermo Fisher Scientific Inc.
8365 Valley Pike
Middletown, VA 22645

Re: Revocation of EUA202212

Dear Colleen Watson:

This letter is in response to the request from Thermo Fisher Scientific Inc., in a letter received April 10, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the OmniPATH COVID-19 Total Antibody ELISA Test issued on October 2, 2020 and revised on September 23, 2021. Thermo Fisher Scientific Inc. indicated that they are no longer manufacturing or producing the authorized product and requested that the EUA be withdrawn. FDA understands that, as of the date of this letter, there are no viable OmniPATH COVID-19 Total Antibody ELISA Test 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 withdraw the EUA for OmniPATH COVID-19 Total Antibody ELISA Test, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA202212 for the OmniPATH COVID-19 Total Antibody ELISA Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the OmniPATH COVID-19 Total Antibody ELISA Test 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