U.S. FOOD & DRUG ADMINISTRATION

April 18, 2024

Oliver Jahnel
Regulatory Affairs Scientist, Molecular Diagnostics
Fast Track Diagnostics Luxembourg S.a.r.l.
A Siemens Healthineers Company
29, Rue Henri Koch
L-4354 Esch-sur-Alzette, Luxembourg
Re: Revocation of EUA200571

Dear Oliver Jahnel:

This letter is in response to the request from Fast Track Diagnostics Luxembourg S.?.r.l. (a Siemens Healthineers Company), in an email dated April 11, 2024, that the U.S. Food and Drug Administration (FDA) deregister the EUA for the FTD SARS-CoV-2 issued on May 5, 2020, amended on July 9, 2020, reissued on January 26, 2021, and amended on April 7, 2021, September 23, 2021, and January 19, 2022. Fast Track Diagnostics Luxembourg S.?.r.l. indicated that they have ceased United States distribution of the authorized product and requested that the EUA be deregistered. Communication with the company made clear that, based on their request, FDA would revoke the EUA. FDA understands that as of the date of this letter there are no viable FTD SARS-CoV-2 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 Fast Track Diagnostics Luxembourg S.?.r.l. has requested that FDA deregister the EUA for the FTD SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200571 for the FTD SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the FTD SARS-CoV-2 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