U.S. FOOD & DRUG ADMINISTRATION

April 7, 2021

Dr. Stefan Mitschke
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: EUA200571/S004
Trade/Device Name: FTD SARS-CoV-2
Dated: March 2, 2021
Received: March 3, 2021

Dear Dr. Mitschke:

This is to notify you that your request to update the Instructions for Use (IFU) of the FTD SARS-CoV-2 to include an appendix containing an RUO instrument label, is granted. Upon review, we concur that the information submitted in EUA200571/S004 supports the requested update for use with the FTD SARS-CoV-2 test. FDA has updated the FTD SARS-CoV-2 IFU to (1) clarify nasal swab to mean use of anterior nasal and mid-turbinate nasal swabs, and (2) add a general limitation statement regarding clinical performance with circulating variants. In addition, FDA updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect more recent authorizations. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the FTD SARS-CoV-2 re-issued on January 26, 2021.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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