



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  
OHT7: Office of In Vitro Diagnostics and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health