July 9, 2020

Matthew Gee, M.Sc.
Siemens Healthcare Diagnostics, Inc.
511 Benedict Avenue,
Tarrytown, NY 10591

Re: EUA200571/A001
Trade/Device Name: FTD SARS-CoV-2
Dated: June 19, 2020
Received: June 19, 2020

Dear Mr. Gee:

This is to notify you that your request to update the Instructions for Use (IFU) of the FTD SARS-CoV-2 to add the VERSANT kPCR Molecular System (Siemens Healthineers) as an additional extraction and amplification detection system for use with the FTD SARS-CoV-2 test, is granted. Upon review, we concur that the data and information submitted in EUA200571/A001 supports the requested updates for use with the FTD SARS-CoV-2 test. By submitting this amendment 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 issued on May 5, 2020.

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