U.S. FOOD & DRUG ADMINISTRATION

May 9, 2020

Faith Du,
Regulatory Affairs Manager,
Thermo Fisher Scientific, Inc.
5781 Van Allen Way,
Carlsbad, CA 92008 US

Re: EUA200010/A003
Trade/Device Name: TaqPath COVID-19 Combo Kit
Dated: April 22 and 29, 2020
Received: April 23, 2020

Dear Ms. Du:

This is to notify you that your request to update the Instructions for Use (IFU) of the TaqPath COVID-19 Combo Kit to; (1) add Applied Biosystems QuantStudio 7 Flex Real-Time PCR system, 384-well (RUO) and Applied Biosystems QuantStudio 5 Real-Time PCR system 384-well (ROU) instruments, (2) add Applied Biosystems COVID-19 Interpretive Software v2.2, (3) add extraction procedure for MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit for manual extraction using 400µl specimen input, (4) add protocols for the new real-time PCR instruments and extraction methods and revise some of the existing procedures for clarification, (5) add additional products as an alternative to the KingFisher 96 KF microplate for automated RNA extraction, (6) update specimen storage recommendations, (7) update limitations section regarding nasal and mid-turbinate swabs, (8) include additional minor edits in the IFU for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200010/A003 supports the requested updates for use with the TaqPath COVID-19 Combo Kit. 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 TaqPath COVID-19 Combo Kit issued on March 13, 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
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Center for Devices and Radiological Health

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