April 20, 2020

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

Re: EUA200010/A002
Trade/Device Name: TaqPath COVID-19 Combo Kit
Dated: April 6 and April 14, 2020
Received: April 6, 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 three real-time PCR instruments: Applied Biosystems 7500 Real-Time instrument, QuantStudio 5 with 0.1ml Block, and Quant Studio 5 with 0.2 ml Block, (2) add four extraction procedure modifications: automated extraction with MagMAX Viral/Pathogen Nucleic Acid Isolation Kit and 200 µl sample input volume, automated extraction with MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit and 200 or 400 µl sample input volume, manual extraction with MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit and 200 µl sample input volume (3) update the Applied Biosystems COVID-19 Interpretive Software to v1.2 and v2.0, (4) add oropharyngeal, nasal, and mid-turbinate swab specimen types to the Intended Use, and the associated limitation regarding the nasal and mid-turbinate swabs, (5) add endogenous interfering substances study (6) add protocols for the new real-time PCR instruments and extraction methods, and (7) include minor edits in the IFU for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200010/A002 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health