March 24, 2020

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

Re: EUA200010/A001
Trade/Device Name: TaqPath COVID-19 Combo Kit
Dated: March 21, 2020
Received: March 19, 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 manual sample extraction procedures using the MagMAX Viral/Pathogen Nucleic Acid Isolation Kit, (2) add the Applied Biosystems 7500 Fast system that utilizes DCS versions 1.5.1 and 2.3, (3) add Applied Biosystems COVID-19 Interpretive Software v1.1, and (4) include some format changes and minor edits to the IFU for clarification, is granted. In addition, FDA concurs with your request to include an abbreviated package insert with the product and include reference to the full TaqPath COVID-19 Combo Kit IFU available on-line. 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
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health