July 17, 2020

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

Re: EUA200010/A004
Trade/Device Name: TaqPath COVID-19 Combo Kit
Dated: June 23, 2020
Received: June 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) extend the expiration dating for reagents based on the results from an Accelerated Stability Study, (2) update the *in silico* analysis of inclusivity, (3) revise the TaqPath COVID-19 Combo Kit interpretive software to address the potential for false-negative results and Positive Control failures, (4) update the device labelling for clarity and consistency with the modifications authorized under this amendment, in addition to some minor updates requested by FDA, is granted. Upon review, we concur that the data and information submitted in EUA200010/A004 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