February 23, 2021

Natalie Damrau
Regulatory Affairs Manager
Thermo Fisher Scientific
5781 Van Allen Way
Carlsbad, CA 92008 USA

Re: EUA200010/S011
Trade/Device Name: TaqPath COVID-19 Combo Kit
Dated: February 10, 2021
Received: February 12, 2021

Dear Ms. Damrau:

This is to notify you that your request to update the Instructions for Use (IFU) and EUA of the TaqPath COVID-19 Combo Kit to: (1) add the MicroAmp EnduraPlate as an additional plastic reaction plate, and (2) add additional assay distributors is granted. Upon review, we concur that the data and information submitted in EUA200010/S011 supports the requested updates for use with the TaqPath COVID-19 Combo Kit. By submitting this EUA revision 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 reissued on October 9, 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