March 4, 2022

Kiran Sorathia
Regulatory Affairs Specialist III
Thermo Fisher Scientific
180 Oyster Point Boulevard
South San Francisco, CA 94080

Re: EUA202953/S002 and S003
Trade/Device Name: TaqPath COVID-19 FluA/FluB Combo Kit
Dated: August 9, 2021 and September 24, 2021
Received: August 10, 2021 and September 28, 2021

Dear Kiran Sorathia:

This is to notify you that your request to update the Instructions for Use (IFU) of the TaqPath COVID-19 FluA/FluB Combo Kit to; (1) add the QuantStudio 7 Flex (QS7) PCR instrument, (2) add in-use freeze/thaw stability information for the TaqPath COVID-19 FluA/FluB assay reagent, (3) add in-use Positive Control stability information for refrigerated conditions, (4) update the in silico analysis, (5) add the MicroAmp Optical Film Compression Pad for use with the QuantStudio 5 Real Time PCR Instrument, (6) add specimen transport stability information, (7) add prospective clinical evaluation data, and (8) provide minor corrections and formatting updates, is granted. Upon review, we concur that the data and information submitted in EUA202953/S002 and EUA202953/S003 support the requested updates for use with the TaqPath COVID-19 FluA/FluB 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 FluA/FluB Combo Kit reissued on August 3, 2021.

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