



August 31, 2022

Ian McGill
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5791 Van Allen Way
Carlsbad, CA 94080

Re: EUA200010/S014
Trade/Device Name: TaqPath COVID-19 Combo Kit
Dated: July 28, 2022
Received: July 28, 2022

Dear Mr. McGill:

This is to notify you that your request to; (1) extend shelf-life claims for the TaqPath COVID-19 Combo Kit box reagents and TaqPath COVID-19 Control Dilution Buffer box to 18 months from the date of manufacture when stored at -30°C to -10°C , (2) extend the shelf-life claim for the TaqPath COVID-19 Control box (included in the TaqPath COVID-19 Combo Kit) to 18 months from the date of manufacture when stored at $\leq -70^{\circ}\text{C}$, (3) revise the Instructions for Use (IFU) with updated inclusivity *in silico* analysis data, (4) revise the IFU with updates made to the firmware and the QuantStudio Design and Analysis Desktop Software specific for the Applied Biosystems QuantStudio 5 Real-Time PCR Instrument, and (5) provide additional minor clarify edits, is granted. Upon review, we concur that the data and information submitted in EUA20010/S014 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 issued on May 18, 2022.

Sincerely yours,

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