October 22, 2021

Ashley Vu
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5823 Newton Way
Carlsbad, CA 92008

Re: EUA210384/S001
Trade/Device Name: TaqPath COVID-19 Fast PCR Combo Kit 2.0
Dated: September 3, 2021
Received: September 8, 2021

Dear Ms. Vu:

This is to notify you that your request to update the Instructions for Use (IFU) of the TaqPath COVID-19 Fast PCR Combo Kit 2.0 to: (1) update saliva specimen stability claims to -70° C for up to seven weeks, (2) update reagent refrigerated storage conditions to seven hours and up to five freeze/thaw cycles, (3) addition of a limitation related to circulating variants, and (4) additional minor edits for clarity is granted. Upon review, we concur that the data and information submitted in EUA210384/S001 supports the requested updates for use with the TaqPath COVID-19 Fast PCR Combo Kit 2.0. FDA has updated the Healthcare Provider and Patient Fact Sheets and requested edits to the Product Information Card to reflect language used in more recent authorizations. 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 Fast PCR Combo Kit 2.0 issued on July 30, 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