March 20, 2023

Palwasha Basir
Regulatory Affairs Manager
Thermo Fisher Scientific Inc.
5823 Newton Way
Carlsbad, CA 92008

Re: EUA210384/S002
Trade/Device Name: TaqPath COVID-19 Fast PCR Combo Kit 2.0
Dated: September 08, 2022
Received: September 08, 2022

Dear Ms. Basir:

This is to notify you that your request to update the Instructions for Use of the TaqPath COVID-19 Fast PCR Combo Kit 2.0 to; (1) incorporate protocol workflow stopping points that received FDA authorization under EUA210384/S001 and additional workflow stopping points based on in-use reagent stability data, (2) update in silico inclusivity analysis to reflect more recent SARS-CoV-2 sequences, (3) update the compatible firmware and software versions for the Applied Biosystems QuantStudio 5 Real Time PCR Instrument where listed, and (4) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA210384/S002 supports the requested updates for use with the TaqPath COVID-19 Fast PCR Combo Kit 2.0. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients 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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Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health