March 20, 2023

Stacy Drakousis
Sr. Regulatory Affairs Manager
Thermo Fisher Scientific
200 Oyster Pt. Blvd
South San Francisco, CA 94080

Re: EUA202953/S004
Trade/Device Name: TaqPath COVID-19, FluA, FluB Combo Kit
Dated: September 02, 2022
Received: September 02, 2022

Dear Ms. Drakousis:

This is to notify you that your request to update the authorized labeling of the TaqPath COVID-19, FluA, FluB Combo Kit to; (1) update the amount of MS2 phage control provided with each test, (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 updates, is granted. Upon review, we concur that the data and information submitted in EUA202953/S004 supports the requested updates for use with the TaqPath COVID-19, FluA, FluB Combo Kit. 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 reissued letter authorizing the emergency use of the TaqPath COVID-19, FluA, FluB Combo Kit issued on August 3, 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