U.S. FOOD & DRUG ADMINISTRATION

September 21, 2022

Ashley Vu
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5781 Van Allen Way
Carlsbad, CA 92008

Re: EUA210403/S005
Trade/Device Name: TaqPath COVID-19 RNase P Combo Kit 2.0
Dated: September 8, 2022
Received: September 8, 2022

Dear Ms. Vu:

This is to notify you that your request to revise the Instructions for Use for the TaqPath COVID-19 RNase P Combo Kit 2.0 with; (1) updated inclusivity *in silico* analysis data, (2) updated cross-reactivity analysis, (3) 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 (4) provide additional minor clarify edits, is granted. Upon review, we concur that the data and information submitted in EUA210403/S005 supports the requested updates for use with the TaqPath COVID-19 RNase P Combo Kit 2.0. 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 RNase P Combo Kit 2.0 reissued on May 2, 2022.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health