March 31, 2023

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

Re: EUA210403/S007
Trade/Device Name: TaqPath COVID-19 RNase P Combo Kit 2.0
Dated: December 05, 2022
Received: December 05, 2022

Dear Ms. Drakousis:

This is to notify you that your request to update the Instructions for Use (IFU) of the TaqPath COVID-19 RNase P Combo Kit 2.0 to; (1) support a shelf-life claim of up to 12 months when stored at the recommended conditions in the IFU, based on the results of real-time stability studies, (2) correct a typo in the asymptomatic screening clinical validation data from samples run on the QuantStudio 7 instrument and recalculate the corresponding Positive Percent Agreement and Negative Percent Agreement statistics, and (3) provide minor updates, is granted. Upon review, we concur that the data and information submitted in EUA210403/S007 supports the requested updates for use with the TaqPath COVID-19 RNase P 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 reissued letter authorizing the emergency use of the TaqPath COVID-19 RNase P Combo Kit 2.0 issued 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