March 1, 2022

Palwasha Basir
Regulatory Affairs Manager
Life Technologies (a part of Thermo Fisher Scientific Inc.)
5781 Van Allen Way
Carlsbad, CA 92008

Re: EUA210403/S003
Trade/Device Name: TaqPath COVID-19 RNase P Combo Kit 2.0
Dated: December 23, 2021
Received: December 24, 2021

Dear Palwasha Basir:

This is to notify you that your request to (1) update the TaqPath COVID-19 RNase P Combo Kit 2.0 authorized labelling (the Instructions for Use (IFU) and Fact Sheet Healthcare Providers) in response to Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (2) update the IFU to provide more concise language for the instructions, and (3) update the results of the in silico inclusivity analysis, is granted. Upon review, we concur that the data and information submitted in EUA210403/S003 supports the requested updates for use with the TaqPath COVID-19 RNase P Combo Kit 2.0. FDA have also updated the Healthcare Provider and Patient Fact Sheets to reflect 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 RNase P Combo Kit 2.0 re-issued on September 1, 2021 and the Viral Mutation Revision Letter issued on September 23, 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
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