



May 31, 2023

Stacey Moltchanoff  
Regulatory Affairs Manager  
Genetic Testing Solutions  
Thermo Fisher Scientific Inc.  
5781 Van Allen Way  
Carlsbad, CA 92008

Re: EUA202924/S001  
Trade/Device Name: TaqPath COVID-19 Pooling Kit  
Dated: May 12, 2023  
Received: May 12, 2023

Dear Ms. Moltchanoff:

This is to notify you that your request to update the TaqPath COVID-19 Pooling Kit to (1) provide an updated *in silico* inclusivity analysis protocol, and (2) update the *in silico* inclusivity results in the Instructions for Use to reflect more recent SARS-CoV-2 sequences based on the most recent *in silico* inclusivity analysis protocol, is granted. Upon review, we concur that the data and information submitted in EUA202924/S001 supports the requested updates for use with the TaqPath COVID-19 Pooling 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 letter authorizing the emergency use of the TaqPath COVID-19 Pooling Kit issued on May 25, 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