



November 20, 2020

Natalie Damrau
Sr. Regulatory Affairs Specialist
Thermo Fisher Scientific
5823 Newton Way
Carlsbad, CA 92008

Re: EUA200010/S008
Trade/Device Name: TaqPath COVID-19 Combo Kit and TaqPath COVID-19 Combo Kit Advanced
Dated: October 6, 2020
Received: October 7, 2020

Dear Natalie Damrau:

This is to notify you that your request to update the Instructions for Use (IFU) of the “TaqPath COVID-19 Combo Kit and TaqPath COVID-19 Combo Kit Advanced” to; (1) add use of additional PCR instrument systems with the TaqPath COVID-19 Combo Kit Advanced “high volume” workflows; (2) make updates to the Applied Biosystems COVID-19 Interpretive Software; and (3) update the device labelling for clarity and consistency with the requested modifications including some minor updates requested by FDA, is granted. Upon review, we concur that the data and information submitted in EUA200010/S008 supports the requested updates for use with the “TaqPath COVID-19 Combo Kit and TaqPath COVID-19 Combo Kit Advanced”. 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 Combo Kit and TaqPath COVID-19 Combo Kit Advanced” re-issued on October 9, 2020.

Sincerely yours,

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