March 3, 2022

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

Re: EUA210257/S003
Trade/Device Name: Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit
Dated: January 24, 2022
Received: January 24, 2022

Dear Ms. Srivastava:

This is to notify you that your request to update the Instructions for Use (IFU) of the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit to; (1) revise the existing limitation regarding S-gene drop-outs to reference the Omicron variant, (2) update the Limit of Detection section to reflect additional study data, (3) update inclusivity study data, (4) revise test instruction information related to various software and hardware features to improve the ease-of-use and serviceability, as well as to reduce the frequency of user errors, (5) update the in-use reagent stability section to reflect additional study data, and (6) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA210257/S003 supports the requested updates for use with the Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit. 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 Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit issued on October 12, 2021.

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