February 2, 2022

Lisa Vershave
Regulatory Affairs Manager
PerkinElmer Inc.
940 Winter Street
Waltham, MA 02451

Re: EUA200055/S012
Trade/Device Name: PerkinElmer New Coronavirus Nucleic Acid Detection Kit
Dated: January 11, 2022
Received: January 11, 2022

Dear Ms. Vershave:

This is to notify you that your request to update the Instructions for Use of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit to: (1) include use of the QuantStudio 12K Flex and QuantStudio 7 Flex RT-PCR instrument platforms and (2) add two collection media types (Mawi iSwab and saline), is granted. Upon review, we concur that the data and information submitted in EUA200055/S012 supports the requested updates for use with PerkinElmer New Coronavirus Nucleic Acid Detection. 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 PerkinElmer New Coronavirus Nucleic Acid Detection Kit issued on July 15, 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health