April 1, 2021

Brian Ciccariello
Head of Regulatory & Medical Affairs -Americas
PerkinElmer Inc.
940 Winter Street
Waltham, MA 02451

Re: EUA200055/S007
Trade/Device Name: PerkinElmer New Coronavirus Nucleic Acid Detection Kit
Dated: February 2, 2021
Received: February 2, 2021

Dear Mr. Ciccariello:

This is to notify you that your request to update the Instructions for Use (IFU) of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit to add instrument verification procedures is granted. Upon review, we concur that the data and information submitted in EUA200055/S007 supports the requested updates for use with the PerkinElmer New Coronavirus Nucleic Acid Detection Kit and fulfils the Condition of Authorization related to this update. FDA also requested the addition of a limitation to the IFU related to performance with circulating variants and has 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 PerkinElmer New Coronavirus Nucleic Acid Detection Kit issued on February 5, 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