



December 10, 2021

Welkin Collins  
Regulatory Affairs Manager  
PERKINELMER, INC.  
68 Elm Street  
Hopkinton, MA 01748

Re: EUA200055/S011  
Trade/Device Name: PerkinElmer New Coronavirus Nucleic Acid Detection Kit  
Dated: October 22, 2021  
Received: October 22, 2021

Dear Welkin Collins:

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; (1) update the saliva sample stability claims based on additional stability testing performed to fulfill Condition R of the July 15, 2021 letter and (2) update the in silico inclusivity analysis, is granted. Upon review, we concur that the data and information submitted in EUA200055/S011 supports the requested updates for use with the PerkinElmer New Coronavirus Nucleic Acid Detection Kit. In addition, minor updates were made to the IFU 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 re-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