November 1, 2021

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

Re: EUA202791/S001
Trade/Device Name: PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1
Dated: October 11, 2021
Received: October 12, 2021

Dear Ms. Vershave:

This is to notify you that your request to update the Instructions for Use (IFU) of the PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 to add three additional RT-PCR instruments (QuantStudio Dx 96 and the Analytik Jena qTower platforms (both 96 and 384-well versions)) for use with the PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 test, is granted. Upon review, we concur that the data and information submitted in EUA202791/S001 supports the requested updates. 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 PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 issued on October 6, 2021.

Sincerely yours,

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For: 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