July 21, 2022

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

Re: EUA202791/S005
Trade/Device Name: PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1
Dated: June 17, 2022
Received: June 20, 2022

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; (1) update the clinical performance section with results from the prospective clinical study performed to fulfill Condition of Authorization R. of the October 6, 2021 letter, and (2) provide minor edits, is granted. Upon review, we concur that the data and information submitted in EUA202791/S005 supports the requested updates for use with the PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 and fufills Condition of Authorization R. of the October 6, 2021 letter. FDA have 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 PKamp Respiratory SARS-CoV-2 RT-PCR Panel 1 issued on October 6, 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