January 27, 2021

Julie Purcell
Senior Manager, Regulatory Affairs
Cepheid
904 Caribbean Dr
Sunnyvale, CA 94089-1189

Re: EUA200453/S001
Trade/Device Name: Xpert Xpress SARS-CoV-2/Flu/RSV
Dated: October 21, 2020
Received: October 23, 2020

Dear Ms. Purcell:

This is to notify you that your request to update the Instructions for Use (IFU) of the Xpert Xpress SARS-CoV-2/Flu/RSV to: (1) add saline as an acceptable transport media, (2) include summary of post-authorization competitive interference studies, (3) add additional limitations, and (4) add minor edits for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200453/S001 supports the requested updates for use with the Xpert Xpress SARS-CoV-2/Flu/RSV. 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 Xpert Xpress SARS-CoV-2/Flu/RSV issued on September 24, 2020 (letter reissued for technical correction on October 1, 2020).

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
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