October 20, 2021

Julie Purcell
Director, US Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Re: EUA210505/S001
Trade/Device Name: Xpert Xpress CoV-2/Flu/RSV *plus*
Dated: October 8, 2021
Received: October 8, 2021

Dear Ms. Purcell:

This is to notify you that your request to update the Instructions for Use (IFU) of the Xpert Xpress CoV-2/Flu/RSV *plus* to: (1) update the competitive interference study data, and (2) update language in the limitations section related to circulating variants, and other updates for clarity is granted. Upon review, we concur that the data and information submitted in EUA210505/S001 supports the requested updates for use with the Xpert Xpress CoV-2/Flu/RSV *plus*. 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 CoV-2/Flu/RSV *plus* issued on September 10, 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
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