July 18, 2023

Samir Ghevariya
Sr. Regulatory Affairs Specialist
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Re: EUA210505/S003
Trade/Device Name: Xpert Xpress CoV-2/Flu/RSV *plus*
Dated: May 26, 2023
Received: May 26, 2023

Dear Mr. Ghevariya:

This is to notify you that your request to update the Instructions for Use of the Xpert Xpress CoV-2/Flu/RSV *plus* to; (1) update the limitation on freezing of samples based on newly provided VTM and eNAT frozen specimen stability study results from SARS-CoV-2 testing, (2) added a reference to the eNAT package insert along with safety warnings for handling of eNAT, (3) remove saline as an acceptable transport media, (4) include results of an additional clinical performance study provided to fulfill Condition P. of the September 10, 2021 Letter of Authorization, (5) revise the Assay Definition File (ADF) to mitigate the risk of false negative results for influenza A/B and RSV, (6) update results of all analytical and clinical studies using the revised ADF, (7) revise product labels to include a new manufacturing facility in Lodi, CA, (8) provide an updated flyer with instructions for using the new ADF, and (9) provide minor clarifying edits, is granted. Upon review, we concur that the data and information submitted in EUA210505/S003 supports the requested updates for use with the Xpert Xpress CoV-2/Flu/RSV *plus*. FDA has updated the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in 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 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
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