

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

OHT7: Office of In Vitro Diagnostics and Radiological Health Office of Product Evaluation and Quality

Center for Devices and Radiological Health