August 8, 2020

Irma Barr,
Principal Regulatory Affairs Specialist
Cepheid
904 Caribbean Drive,
Sunnyvale, CA 94089-1189

Re: EUA200035/S003
Trade/Device Name: Xpert Xpress SARS-CoV-2
Dated: May 15, 2020
Received: May 16, 2020

Dear Irma Barr:

This is to notify you that your request to update the Instructions for Use (IFU) labeling for the Xpert Xpress SARS-CoV-2 test run on the GeneXpert Dx and GeneXpert Infinity systems (laboratory) and on the GeneXpert Xpress System (Tablet and Hub Configurations - point-of-care system) to; (1) update the Limit of Detection and Clinical data in the Performance Characteristics section to reflect a change in one of the cartridge reagent sources, (2) update the number of transfer pipettes supplied with the kit, (3) update the *in silico* inclusivity information, (4) update to the limitations section to remove reference to symptomatic population testing with nasal and mid-turbinate swabs, (5) add assay cutoff information and (6) make some additional minor clarifications and edits, is granted. Upon review, we concur that the data and information submitted in EUA200035/S003 supports the requested update for use with the Xpert Xpress SARS-CoV-2 test. We have also updated the Healthcare Provider and Patient Fact Sheets to reflect more recent authorizations. By submitting these EUA revisions 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 test issued on March 20, 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
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Center for Devices and Radiological Health

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