U.S. FOOD & DRUG ADMINISTRATION

April 28, 2020

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

Re: EUA200035/A002
Trade/Device Name: Xpert Xpress SARS-CoV-2
Dated: April 20, 2020
Received: April 20, 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) add an Early Assay Termination (EAT) feature to the Assay Definition File (ADF), (2) add saline as an alternative swab transport media, (3) add oropharyngeal swab specimen to the Intended Use for the moderate or high complexity assays, (4) include labeling changes to accommodate co-labeling with CE mark, and (5) some additional minor edits, is granted. Upon review, we concur that the data and information submitted in EUA200047/A001 supports the requested update for use with the Xpert Xpress SARS-CoV-2 test and associated updates were also made to the Healthcare Provider Fact Sheet. By submitting this amendment 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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health