June 13, 2023

Suzette Chance, Ph.D.
Sr. Director Regulatory Affairs
Global Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Re: EUA150002/A002
Trade/Device Name: Xpert Ebola Assay
Dated: July 31, 2019
Received: August 1, 2019

Dear Dr. Chance:

This letter is to notify you that your request to modify the authorized Instructions for Use of the Xpert Ebola Assay to; (1) include an additional limitation, (2) update the analytical reactivity section, (3) update some of the background information, and (4) add some clarification and formatting changes, has been granted. In addition, the updates requested by the Food and Drug Administration (FDA) to the; (1) Instructions for Use, including wording in the intended use, to improve the overall clarity and accuracy of the document, and (2) Healthcare Provider and Patient Fact Sheets, have been granted.

Upon review, we concur that the data and information submitted in EUA150002/A002 supports the requested updates for use with the Xpert Ebola Assay. By submitting this EUA Revision for review by the FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Xpert Ebola Assay issued on March 23, 2015.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Cc: Julie Purcell, Director, US Regulatory Affairs, Cepheid