August 24, 2023

Bryce Dzialo, JD
Regulatory Affairs Specialist Diagnostics
Hologic Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Re: EUA160011/A004
Trade/Device Name: Aptima Zika Virus assay
Dated: June 23, 2023
Received: July 3, 2023

Dear Bryce Dzialo:

This is to notify you that your request to update the Instructions for Use (IFU) of the Aptima Zika Virus assay; (1) in response to FDA's request, and (2) to include some additional minor edits and clarifications, is granted. Upon review, we concur that the information submitted in EUA160011/A004 supports the requested updates for use with the Aptima Zika Virus Assay. 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 Aptima Zika Virus assay issued on June 17, 2016.

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