DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 12, 2017

Jeff Zinza, RAC
Manager, Regulatory Affairs
Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121

Re: EUA160011/A002
Trade/Device Name: Aptima® Zika Virus assay
Dated: April 7, 2017
Received: April 10, 2017

Dear Mr. Zinza:

This is to notify you that your request to modify the Instructions for Use for the Aptima® Zika Virus assay to (1) extend the stability of processed urine specimens, (2) clarify storage and stability of serum and plasma specimens, and (3) improve the overall clarity and accuracy of the document has been granted. The minor updates to the authorized Aptima® Zika Virus assay Fact Sheets requested by FDA have also been granted. By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Aptima® Zika Virus assay issued June 17, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., PhD.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure