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

KEN HOOD, MBA
SENIOR DIRECTOR, REGULATORY AFFAIRS,
HOLOGIC, INC.
10210 GENETIC CENTER DRIVE,
SAN DIEGO, CA 92121, US

September 7, 2016

Re: EUA160011/A001
Trade/Device Name: APTIMA® ZIKA VIRUS ASSAY
Dated: September 2, 2016
Received: September 6, 2016

Dear Mr. Hood:

This is to notify you that your request for the addition of processed urine (collected alongside a patient-matched serum or plasma specimen) as an authorized specimen type for use with the Aptima® Zika Virus assay has been granted. Upon review, the analytical and clinical data submitted in EUA160011/A001 supports the addition of processed urine (collected alongside a patient-matched serum or plasma specimen) as an authorized specimen type for testing using the Aptima® Zika Virus assay. We have also reviewed and we concur with the results of the analytical sensitivity evaluation that you submitted using the FDA Reference Material.

We are also concurring with updates made to the Instructions for Use and Fact Sheets for the Aptima® Zika Virus that reflect the addition of processed urine (collected alongside a patient-matched serum or plasma specimen) as an authorized specimen type and include your analytical sensitivity evaluation.

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 -S

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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and Radiological Health
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Enclosures