March 8, 2018

JEFF ZINZA, RAC
MANAGER, REGULATORY AFFAIRS
HOLOGIC, INC.
10210 GENETIC CENTER DRIVE,
SAN DIEGO, CA 92121, US

Re: EUA160011/A003
Trade/Device Name: Aptima Zika Virus assay
Dated: January 10, 2018
Received: January 11, 2018

Dear Mr. Zinza:

This is to notify you that your request to modify the Intended Use of the Aptima Zika Virus assay to include processed whole blood K2EDTA (collected alongside a patient-matched serum or plasma specimen) as an authorized specimen type for detection of Zika virus has been granted.

Upon review, we concur that the data submitted in EUA160011/A003 supports the modification of the Intended Use to include processed whole blood K2EDTA (collected alongside a patient-matched serum or plasma specimen) as an authorized specimen type. We also concur with the related updates of the Instructions for Use and the Fact Sheets for the Aptima Zika Virus assay that reflect the addition of this authorized specimen type.

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 Aptima Zika Virus assay issued on June 17, 2016.

Sincerely yours,

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

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