April 18, 2019

MATTHEW GEE, M.Sc.
SENIOR MANAGER, REGULATORY AFFAIRS
SIEMENS HEALTHCARE DIAGNOSTICS INC.
511 BENEDICT AVENUE,
TARRYTOWN, NY 10591, US

Re: EUA170005/A002
Trade/Device Name: ADVIA Centaur Zika test
Dated: November 30, 2018
Received: December 3, 2018

Dear Mr. Gee:

This is to notify you that your request to modify the ADVIA Centaur Zika test to include surfactant in the ADVIA Centaur Zika IgM assay reagent buffers has been granted. Upon review, we concur that the updated clinical and analytical data submitted in EUA170005/A002 supports this modification to the ADVIA Centaur Zika test. We also concur with the related revisions to the Instructions for Use for the ADVIA Centaur Zika test to (1) include the new clinical and analytical data collected to support the modification granted in this letter, (2) include updated recommendations for specimen storage based on recent specimen stability studies, and (3) correct some minor typographical errors to improve the overall clarity.

We also concur with the update to the Instructions for Use for the (1) Zika Ab (ZikaAb) Quality Control, and (2) Zika IgM (ZikaM) Quality Control to include the 60-day open vial storage claim.

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 ADVIA Centaur Zika test issued September 18, 2017.

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