November 16, 2017

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

Re: EUA170005/A001
Trade/Device Name: ADVIA Centaur Zika test
Dated: October 31, 2017
Received: November 1, 2017

Dear Mr. Gee:

This is to notify you that your request to update the Instructions for Use for the ADVIA Centaur Zika test to improve the overall clarity, make some minor editorial modifications and to correct some typographical errors has 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 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