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

LAURA ROSE, REGULATORY AFFAIRS TEAM LEAD,
DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS December 6, 2016
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
1600 CLIFTON RD. NE,
MS-C18 DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS,
ATLANTA, GA 30333 US

Re: EUA160004/A004
Trade/Device Name: Zika MAC-ELISA
Dated: November 21, 2016
Received: November 22, 2016

Dear Ms. Rose:

This is to notify you that your request to modify the Fact Sheets authorized with the Zika MAC-ELISA to combine the Fact Sheet for Patients and the Fact Sheet for Pregnant Women into one Fact Sheet for Patients and to include updated language to align with the latest CDC Zika Laboratory Guidance, implemented in November 2016, 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 Zika MAC-ELISA issued June 29, 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