**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

November 15, 2016

LAURA ROSE, REGULATORY AFFAIRS TEAM LEAD,
DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS
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/A003
Trade/Device Name: Zika MAC-ELISA
Dated: October 24, 2016
Received: October 25, 2016

Dear Ms. Rose:

This is to notify you that your request to modify the algorithm for results confirmation of the Zika MAC-ELISA as outlined in the draft updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection (revised) 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