U.S. FOOD & DRUG ADMINISTRATION

September 26, 2018

WENDI L. KUHNERT-TALLMAN, Ph.D.,
ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE
NATIONAL CENTER FOR EMERGING AND ZOONOTIC DISEASES
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
1600 CLIFTON RD. NE,
ATLANTA, GA 30333, US

Re: EUA160004/A008
Trade/Device Name: Zika MAC-ELISA
Dated: September 21, 2018
Received: September 24, 2018

Dear Dr. Kuhnert-Tallman:

This is to notify you that your request to modify the Instructions for Use of the Zika MAC-ELISA to include a minor update to improve clarity has been granted. 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 Zika MAC-ELISA issued on June 29, 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