U.S. FOOD & DRUG ADMINISTRATION

April 16, 2018

WENDI L. KUHNERT-TALLMAN, Ph.D.,
DEPUTY ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE AND SAFETY (ACTING)
OFFICE OF THE ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE AND SAFETY
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/A007
Trade/Device Name: Zika MAC-ELISA
Dated: March 14, 2018
Received: March 16, 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; (1) include a standardized negative control serum and calibration control serum reagent set as one of the materials provided by CDC, (2) include use the Flavivirus group-specific conjugate MAB 6B6C-1/HRP with the Zika MAC-ELISA in CDC laboratories only, (3) integrate the previously granted test result acceptance criteria designed to enhance the precision and accuracy of the assay across all testing laboratories, (4) remove the Hennessey conjugate as a recommended detecting antibody conjugate, and (5) update the specimen handling and safety precautions has been granted.

Upon review, we concur that the data submitted in EUA160004/A007 supports the addition of a standardized negative control serum and calibration control serum reagent set as one of the materials provided by CDC, the addition of the Flavivirus group-specific conjugate MAB 6B6C-1/HRP with the Zika MAC-ELISA in CDC laboratories only, and the removal of the Hennessey conjugate as a recommended detecting antibody conjugate for use with the Zika MAC-ELISA. 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