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

STACEY SPIES, REGULATORY AFFAIRS TEAM LEAD,
LABORATORY PREPAREDNESS AND RESPONSE BRANCH July 31, 2017
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/A006
Trade/Device Name: Zika MAC-ELISA
Dated: July 28, 2017
Received: July 31, 2017

Dear Ms. Spies:

This is to notify you that your request to provide an interim update to the Instructions for Use labeling for the CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) to provide additional acceptance criteria designed to enhance the precision and accuracy of the assay across all testing laboratories, has been granted. The CDC communication to Zika Testing Laboratories has been appended to the front of the currently posted Zika MAC-ELISA IFU document. 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., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure