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
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
1600 CLIFTON RD. NE,
MS-C18 DIVISION OF PREPAREDNESS AND EMERGING INFECTIONS,
ATLANTA, GA 30333 US

May 3, 2017

Re: EUA160004/A005
Trade/Device Name: Zika MAC-ELISA
Dated: April 17, 2017
Received: April 18, 2017

Dear Ms. Spies:

This is to notify you that your request to modify the Instructions for Use labeling for the CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) to (1) add the Dynex Technologies, Inc.'s Agility® and DSX® systems as acceptable automated instruments for use with the Zika MAC-ELISA, (2) add language recommending an additional negative human serum control be run once daily, (3) include a limitation concerning the use of the Hennessey detecting antibody conjugate 6B6C-1 in conjunction with the Vero E6 antigen when testing infant serum, and (4) update contact information, has been granted. The minor updates to the authorized Zika MAC-ELISA Fact Sheet for Healthcare Providers requested by FDA have also been granted. Upon review, we concur that the analytical data submitted in EUA160004/A005 supports the addition of Dynex Technologies, Inc.'s Agility® and DSX® systems as acceptable automated instruments for use with the Zika MAC-ELISA. 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 -S

Uwe Scherf, M.Sc., Ph.D.
Director
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Office of In Vitro Diagnostics
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Enclosure