U.S. FOOD & DRUG ADMINISTRATION

May 18, 2018

ESTELA RAYCHAUDHURI, PRESIDENT,
INBIOS INTERNATIONAL, INC.
562 1ST AVE. S. SUITE 600
SEATTLE, WA 98104

Re: EUA160013/A002
Trade/Device Name: ZIKV Detect IgM Capture ELISA
Dated: May 10, 2018
Received: May 11, 2018

Dear Ms. Raychaudhuri:

This is to notify you that your request to modify the ZIKV Detect IgM Capture ELISA to (1) replace the original Ready-To-Use ZIKV Recombinant Antigen for IgM with an updated version of the reagent, (2) remove the use of horseradish peroxidase-labeled monoclonal anti-Flavivirus antibody (Conjugate for ZIKV IgM reagent) and replace with a secondary antibody targeting flavivirus antigens (Ready-To-Use Secondary Antibody reagent) and a horseradish peroxidase-labeled anti-mouse antibody (Conjugate for ZIKV IgM reagent) for the detection of human anti-ZIKV IgM, (3) update the ZIKV IgM Positive Control reagent, and (4) update the result interpretation has been granted. Your request to modify the name from ZIKV Detect IgM Capture ELISA to ZIKV Detect 2.0 IgM Capture ELISA has also been granted.

Upon review, we concur that the clinical and analytical data submitted in EUA160013/A002 supports the modifications to the ZIKV Detect IgM Capture ELISA as outlined above. We also concur with the related updates of the Instructions for Use and the Fact Sheets for the ZIKV Detect 2.0 IgM Capture ELISA that reflect the modifications granted in this letter.

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 ZIKV Detect IgM Capture ELISA issued on August 17, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director
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