February 6, 2018

THOMAS IPPOLITO
VICE PRESIDENT, CLINICAL AND REGULATORY AFFAIRS
CHEMBIO DIAGNOSTIC SYSTEM, INC.
3661 HORSEBLOCK ROAD,
MEDFORD, NY 11763, US

Re: EUA170006/A001
Trade/Device Name: DPP Zika IgM Assay System
Dated: January 31, 2018
Received: February 2, 2018

Dear Mr. Ippolito:

This is to notify you that your request to 1) replace the liquid form of the goat anti-human IgG antibodies and heterophilic antibody (HA) interference blocker for treatment of the specimen with the dehydrated form of the reagents placed in the DPP Zika IgM Assay System device, 2) expand the kit storage range from 2 to 8 °C to 2 to 30 °C, and 3) replace the DPP Zika IgM Sample Buffer and DPP Zika IgM Running Buffer vials by a single vial that is labeled DPP Zika IgM Buffer has been granted.

Upon review, the analytical and clinical data submitted in EUA170006/A001 support the three changes listed above. We also concur with the related updates to the Instructions for Use for the DPP Zika IgM Assay System that reflect the requested design change.

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 Chembio Diagnostic system, Inc.'s DPP Zika IgM Assay System issued September 27, 2017.

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov