



August 3, 2018

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

Re: EUA170006/A002
Trade/Device Name: DPP Zika IgM Assay System
Dated: July 23, 2018
Received: July 25, 2018

Dear Mr. Ippolito:

This is to notify you that your request to modify the Instructions for Use labeling for Chembio Diagnostic system, Inc.'s DPP Zika IgM Assay System to correct some typographical and formatting errors has been granted. 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