April 2, 2019

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

Re: EUA150007/A004
Trade/Device Name: DPP Ebola Antigen System
Dated: February 7, 2019
Received: February 8, 2019

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 Ebola Antigen System to update 1) the cross-reactivity performance for *Plasmodium malariae* and *Streptococcus pneumoniae* in whole blood, and 2) the endogenous interference data for Rheumatoid Factor, Glucose, unconjugated bilirubin, cholesterol and HAMA, has been granted.

Upon review, we concur that the analytical data submitted in EUA150007/A004 supports the updates of the afore mentioned data to the Instructions for Use for the DPP Ebola Antigen System. 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 Ebola Antigen System issued on November 9, 2018.

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