Dear Customer,

You are receiving this letter because you have expressed interest in using the DPP Zika IgM Assay (cat. No. 65-9560-0) in your facility.

We want to inform you about the DPP® Zika IgM Assay System and the terms and conditions for use.

Information about DPP Zika IgM Assay System

- The DPP® Zika IgM Assay System (cat. no. 65-9560-0) has been authorized by the FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories for the presumptive qualitative detection of Zika Virus IgM antibodies in human "finger stick" whole blood, EDTA venous whole blood, serum or EDTA plasma samples collected from individuals meeting the CDC Zika Virus clinical criteria and/or CDC Zika virus epidemiological criteria.

- Use of the DPP® Zika IgM Assay System is limited to authorized laboratories and personnel trained in serology techniques and *in vitro* diagnostic procedures. .

- The DPP® Zika IgM Assay System has been authorized for the detection of Zika virus infection only and not for any other viruses or pathogens.

- The DPP® Zika IgM Assay System is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for the detection of Zika virus under section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360bbb-3(b)(1)(C)), unless the authorization is terminated or revoked sooner.

- The DPP® Zika IgM Assay System has not been FDA cleared or approved.

Additional terms and conditions for the use of the DPP® Zika IgM Assay System can be found on the FDA website: https://www.fda.gov/medicaldevices/safety/emergencysituations/ucm161496.htm

Please complete the attached Emergency Use Authorization (EUA) Certification Statement and return to customer service at Chembio Diagnostic Systems, Inc. either by fax to 1.631.868.7230 or by email to customerservice@chembio.com.

Sincerely,

Chembio Diagnostic System, Inc.

Emergency Use Authorization (EUA) Certification Statement

We, _____ located at _____

are certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. §263a, to perform high or moderate complexity tests, or are a similarly qualified non-U.S. laboratory, and hereby confirm that only clinical laboratory personnel specifically instructed and trained in the techniques of in vitro diagnostic immunoassay procedures will perform testing with the DPP® Zika IgM Assay System (the "Assay System").

We confirm that we have received the authorized DPP® Zika IgM Assay System Fact Sheet for Health Care Providers, the authorized DPP® Zika IgM Assay System Fact Sheet for Patients, the Instructions for Use/Package Insert for the Assay System, and a copy of FDA's Emergency Use Authorization ("EUA") letter.

We have also been informed of the terms and conditions for the usage of the Assay System contained in FDA's EUA letter for the Assay System and will comply with all applicable provisions of the EUA.

In addition, we agree to comply with the following:

1. We will include with reports of the results of the Assay System, the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

2. We will have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

3. We will perform the Assay System only on human serum (plain or separation gel) and fingerstick whole blood, EDTA venous whole blood, or EDTA plasma (each collected alongside a patient-matched serum specimen) specimens or with other authorized specimen types.

4. If a non-serum specimen is used with the Assay System, we will collect a patient-matched serum specimen at the time of collection or soon thereafter to facilitate any additional testing that may be required to confirm Zika virus infection.

5. We will read the results of the Assay System solely with the DPP Micro Reader. Test results will not be interpreted visually.

6. We will report all reactive results (i.e., presumptive Zika IgM positive) to Chembio Diagnostic Systems, Inc. ("Chembio") (via email to *info@chembio.com*).

7. We have a process in place to ensure that additional testing is performed, and/or test results for other patient-matched specimens (using the latest CDC testing algorithms) are considered, for reactive results.

8. We will collect information on the performance of the Assay System, and report to Chembio (info@chembio.com) and FDA (via email to CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false-positive or false-negative results, or significant deviations from the established performance characteristics, of which we become aware.

9. All of our laboratory personnel using the Assay System will be appropriately trained, will use appropriate laboratory and personal protective equipment when handling the Assay System, and will perform the test in accordance with the Instructions for Use/Package Insert.

10. We will maintain records concerning the use of the Assay System and make such records available to FDA for inspection upon request.

We hereby certify that our use of the Assay System will conform to the limitations described above. We further agree to notify Chembio Diagnostic Systems, Inc. should there be any change in our laboratory status,our use of the Assay System, or in the event that any of the above certifications are no longer accurate.

Institution: _____

CLIA License no.: _____ CLIA expiration date: _____

Phone: _____ Email: _____

Print name: _____ Title: _____

Signature: _____ Date: _____

The following section will be completed by Chembio Diagnostic Systems, Inc. customer service department on receipt of the completed form.

Customer ID:_____

Please return to the customer service department at Chembio Diagnostic Systems, Inc. either by fax to 1.631.868.7230 or by email to customerservice@chembio.com.