Dear Customer,

You are receiving this letter because you have expressed interest in using the DPP Zika IgM Assay (cat. No. 65-9555-0) 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. 65-9555-0) is authorized for the presumptive detection of Zika Virus IgM antibodies in 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 collected from individuals meeting the CDC Zika Virus clinical criteria and/or CDC Zika virus epidemiological criteria.

- The DPP® Zika IgM Assay System has been authorized by the FDA under an EUA for use by laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendment (CLIA) to perform high or moderate complexity tests.

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

- The DPP® Zika IgM Assay System has been authorized for the presumptive detection of Zika virus infection between 8 days and 12 weeks.

- 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 presumptive detection of Zika virus under section 564(b)(1)(C) of the 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 but authorized as described above.

Additional terms and conditions for the usage of the DPP® Zika IgM Assay System can be found listed below as in the manufacturer's Product Insert and 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.

We confirm that we have received the authorized DPP® Zika IgM Assay System Fact Sheet for Health Care Providers and the authorized DPP® Zika IgM Assay System Fact Sheet for Patients.

We have also been informed about the terms and conditions for the usage of the DPP® Zika IgM Assay System. In addition, we agree to comply with the following:

1. We will include with reports of the results of the DPP® Zika IgM Assay System, the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients, and any additional DPP Zika IgM Assay System Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

2. We will perform the DPP Zika IgM Assay System 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.

3. We will be responsible for collecting the patient specimen must collect a patient matched serum specimen for all authorized non-serum specimen types to facilitate any additional testing that may be required, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, to confirm Zika virus infection.

4. We will read the results of the DPP Zika IgM Assay System on the DPP Micro Reader or on other authorized instruments and will not attempt to interpret the results of the DPP Zika IgM Assay System visually.

5. Within the United States and its territories, we will report all reactive results (i.e., presumptive Zika IgM positive) to Chembio.

6. We will have a process in place to assure that, for reactive results (i.e., presumptive Zika IgM positive), additional testing (as described in the Instructions for Use document) is performed and/or test results for other patient-matched specimens, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, are considered.

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

8. We will collect information on the performance of the assay, and report to DMD/OIR/CDRH (via email CDRH-EUA-Reporting@fda.hhs.gov) and to Chembio Diagnostic Systems, Inc. any suspected occurrence of false-positive or false-negative results and significant deviations from the established performance characteristics of the assay as we become aware.

9. All laboratory personnel using the assay must be appropriately trained in performing and interpreting immunochromatographic techniques, use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the DPP Zika IgM Assay System.

10. We will maintain all records associated with this EUA, including device usage, until notified by FDA. Such records will be made available to FDA for inspection upon request.

We hereby certify that our use of this assay conforms to the limitations described above. We further agree to notify Chembio Diagnostic Systems, Inc. should there be any change in our laboratory status or use.

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 complete the EUA Certification Statement and 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.