CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

REF 62-1001-0
20 Test Kit

For use under Emergency Use Authorization (EUA) Only.

DPP® Zika IgM Assay Control Pack
FOR I*N VITRO* DIAGNOSTIC USE
FOR PRESCRIPTION USE ONLY
STORAGE: store at -20 °C or colder.

Read this Product Insert and the DPP® Zika IgM Assay System Product Insert completely before using this product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate Test Results. Users of this test MUST follow Universal Precautions[1,2,]. The units that make up this panel were tested and found negative for Dengue Virus IgM antibodies, anti-HIV 1/2, HBsAg and anti-HCV. This does not ensure the absence of these or other human pathogens.

NAME AND INTENDED USE
The Chembio DPP® Zika IgM Control Pack is an external quality control kit for use with the DPP® Zika IgM Assay System only. The performance characteristics of the DPP® Zika IgM Control Pack have not been established for any other assay or instrument different from the DPP® Micro Reader.

RUN THE KIT CONTROLS UNDER THE FOLLOWING CIRCUMSTANCES:

- **Each new operator prior to performing tests on patient samples**
- **When opening a new test kit lot**
- **Whenever a new shipment of test kits is received**
- **If the temperature of the test storage area falls outside of 2 to 8 °C (36 to 46 °F)**
- **If the temperature of the testing area falls outside of 18 to 30 °C (64 to 86 °F)**
- **At periodic intervals as indicated by the user facility**

It is the responsibility of each laboratory using the DPP® Zika IgM Assay System to establish an adequate quality assurance program to ensure the performance of the device under its specific locations and conditions of use. Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

If the Zika Control reagents do not produce the expected results, contact Chembio Diagnostic Customer Service at 1-844-CHEMBIO (844-243-6246).

SUMMARY AND EXPLANATION OF ZIKA REACTIVE AND NONREACTIVE CONTROLS
Chembio DPP® Zika IgM Assay Control Pack Reactive/Nonreactive Controls are human, plasma-based reagents. The controls are specifically formulated and manufactured to ensure performance of the test, and are used to verify the user's ability to properly perform the test and interpret the results. Use of control reagents manufactured by another source may not produce the required results, and therefore, may not meet the requirements for an adequate quality assurance program for the DPP® Zika IgM Assay System.

MATERIALS PROVIDED
Each Kit contains the items to perform 25 tests**:**

- 1 DPP Zika Reactive Control (250 µl): undiluted, naturally occurring Zika IgM positive plasma samples.
- 1 DPP Zika Nonreactive Control (250 µl): undiluted, naturally occurring Zika IgM negative plasma samples.
- 1 Product Insert

All reagents are supplied ready to use.

Controls are not kit lot specific and may be safely interchanged between different DPP® Zika IgM Assay System lots.

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MATERIALS REQUIRED BUT NOT PROVIDED

- DPP® Zika IgM Assay System (Catalog #: 65-9555-0)

Each kit contains the reagents and tools to perform 20 tests:
20 individually pouched DPP® Zika IgM Test Devices, each containing:
  - 1 DPP Zika Test Device (membrane immobilized with recombinant Zika NS-1 antigen in the TEST (T) area and Protein A in the CONTROL (C) area.
  - 1 Desiccant Pouch

20 Disposable 10µL Microsafe® Tubes
20 Sample vials
20 Transfer Pipets (100 µl)
1 DPP Zika IgM Sample Buffer- BLUE Cap
  - 4.5 mL, contains sodium phosphate, sodium chloride, EDTA, NP-40, Tween 20, Urea, Tru Block™3, chicken serum, goat-anti human IgG antibodies, gentamicin, streptomycin, and sodium azide as preservative.

1 DPP Zika IgM Running Buffer (4.5 mL)– YELLOW Cap
  - 4.5 mL, contains sodium phosphate, sodium chloride, EDTA, NP-40, Tween 20, Urea, chicken serum, gentamicin, streptomycin, and sodium azide as preservative.

1 Product Insert for the DPP® Zika IgM System
1 Quick Reference Guide for the DPP® Zika IgM System
Fact Sheet for Health Care Providers
Fact Sheet for Patients

- Chembio DPP® Micro Reader (Catalog # 61-1070-0)
  Each kit contains:
  - DPP Micro Reader with Zika IgM RFID sticker
    - 3 Lithium-ion, type CR2032 (3 V/230 mAh), coin cell batteries (installed)
  - USB adaptor (will only transmit power)
  - Power plug adaptor
  - DPP Cartridge Holder
  - Microfiber cloth
  - User Manual

For problems or questions, please read the DPP Micro Reader manual, or contact Chembio Diagnostic Systems Customer Service at 1-844-CHEMBIO (844-243-6246)

- Clock, watch, or other timing device
- Calibrated Pipettor capable of delivering 10-100µL of sample may be used in lieu of the disposable 10µL Microsafe pipette or 100µL transfer pipettes supplied with the kit (for venous whole blood, serum or plasma specimens)
- Disposable gloves
- Antiseptic wipes
- Biohazard disposal container
- For fingerstick whole blood specimens:
  - Sterile gauze
  - Sterile Safety Lancets for fingerstick whole blood specimens
- For venous whole blood or serum/plasma specimens:
  - Collection devices

WARNINGS AND PRECAUTIONS

1. **For *In Vitro*** Diagnostic Use under Emergency Use Authorization only.
2. Read the DPP® Zika IgM Assay System product insert completely before testing control kit specimens. Follow the instructions carefully as not doing so may result in inaccurate test results.
3. Use of kit control reagents manufactured by another source may not produce the required results, and therefore, may not meet the requirements for an adequate quality assurance.
4. Use of this product is limited to specified laboratories and clinical laboratory personnel who have been trained in the techniques of serology and *in vitro* diagnostic procedures on authorized instruments.
5. Laboratory biosafety guidance for working with Zika virus specimens is provided at http://www.cdc.gov/zika/state-labs/index.html. It is recommended that laboratories perform a risk assessment when conducting new tests and safety precautions should be based on the laboratory's risk assessment. The Zika virus is considered a pathogen that can be safely worked with in a biosafety level 2 (BSL-2) laboratory.
6. Material may be infectious. Use universal precautions[1,2] when using control materials and performing the assay.
7. Use routine laboratory precautions. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact with hands, eyes or mouth during sample collection and testing.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient samples. Wash hands thoroughly after handling specimens and kit reagents.
9. Dispose of all samples and materials used in the test procedure in a biohazard waste container. Lancets should be placed in a puncture-resistant container prior to disposal. Proper handling and disposal methods should be established according to local regulations.[3]
10. Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach solution (containing 0.5% sodium hypochlorite) and disposed of as though potentially infectious.
11. Do not use kits or components beyond the expiration date given on the label.

STORAGE AND STABILITY

The Chembio DPP Zika controls should be stored at -20 °C or colder. Chembio recommends that the controls be divided into smaller aliquots and avoid multiple freeze-thaw cycles. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with each test kit manufacturer's instructions for sample preparation.

TEST PROCEDURE

All components for the DPP® Zika IgM Assay System are ready to use as supplied. Instructions for use are given in the Chembio DPP Zika IgM Assay System Product Insert and Quick Reference Instructions. Follow directions as indicated. If the specimen to be tested is frozen, remove it from the freezer and allow it to come to a temperature of 18 to 30°C (64 to 86°F) prior to testing.

Procedure for Using Controls with Chembio DPP® Zika IgM Assay System

To Run Controls on the DPP® Zika IgM Assay System:

1. Open a control vial containing the control reagent.
2. Remove the Chembio DPP® Zika IgM Assay test device from its pouch and place it on a flat surface (It is not necessary to remove the desiccant from the pouch).
3. Label the test device with control reagent name or identification number.
4. Note that the DPP test device has 2 colored lines in the Test Window. If the 2 colored lines are absent, DO NOT USE. Discard the test device and use a new test device.
5. Slowly add 5 drops of DPP® Zika IgM Sample Buffer from the BLUE CAP bottle to the supplied sample vial by holding the bottle vertically.
6. Using a calibrated laboratory pipette, transfer 10µL of the control sample into sample vial containing the Buffer. Mix it well by pipetting it up and down at least 3 times.
7. Attach a new tip to the laboratory pipette. Transfer 100 µl of the sample/buffer mixture from the sample vial into SAMPLE + BUFFER Well 1 of the DPP Test Device.
8. Within 5 minutes, the colored lines in the rectangular TEST and CONTROL window should have disappeared. If not, discard

the test device and repeat the procedure with a new DPP test device.

9. When 5 minutes have passed after addition of the specimen/buffer mixture, slowly add 5 drops of DPP® Zika IgM Running Buffer from the YELLOW CAP bottle to BUFFER Well 2 by holding the bottle vertically over the well.
10. Read the test result using the DPP Micro Reader between 10 and 15 minutes after the addition of the Running Buffer to Well 2 as per STEP 9. Do not read the test before 10 minutes or after 15 minutes of addition of the Running Buffer to Well 2. DO NOT ATTEMPT TO INTERPRET THE RESULTS VISUALLY. ALWAYS USE THE DPP MICRO READER TO OBTAIN THE RESULTS. For instructions on how to use the DPP Micro Reader, please see the DPP Micro Reader User Manual.
11. Discard the used pipet tips, Test Device and any other test materials into a biohazard waste container.
12. Reseal the Control Reagent Vials and store them in their original container at -20°C.

INTERPRETATION OF TEST RESULTS

Please also refer to the DPP® Zika IgM Assay System Product Insert

External Control	DPP® Microreader
NONREACTIVE Control	ZIGM ## NR, Where ## will be a numerical value 0 <20
REACTIVE Control	ZIGM ## R, Where ## will be a numerical value 0 ≥20
INVALID	INV (results cannot be interpreted)

EXPECTED RESULTS

Nonreactive Control:

The Nonreactive Control will produce a NONREACTIVE Test Result, i.e. a numerical result <20 on the DPP Micro Reader, followed by the letter “NR” indicating a NON-REACTIVE Test Result if performed correctly.

Zika Ractive Control:

The Zika Reactive Control will produce a REACTIVE Test Result, i.e. a numerical result ≥20 on the DPP Micro Reader, followed by the letter “R” indicating a REACTIVE Test Result if performed correctly.

INVALID:

If the reader returns an INVALID result, the test results cannot be interpreted. It is recommended that the INVALID test be repeated with a new device.

NOTE: If the test result for the Nonreactive Control or Zika Reactive Control is not as expected, the test should be repeated using a new test device and Control Specimen. If the Zika control reagents do not produce the expected results and you are unable to obtain a valid test result upon repeat testing contact Chembio Diagnostic Systems Customer Service at 1-844-CHEMBIO (844-243-6246).

REFERENCES

1. https://www.cdc.gov/zika/transmission/blood-transfusion.html; accessed on June 27 2017; Content source: Centers for Disease Control and Prevention; Page last reviewed: November 18, 2016; Page last updated: November 18, 2016
2. 29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens; current version.
3. Clinical and Laboratory Standards Institute. 2011. Clinical Laboratory Waste Management. CLSI Document GP5-A3.

ORDERING INFORMATION

REF 65-9555-0 Chembio DPP® Zika IgM Assay System

REF 61-1070-0 Chembio DPP® Zika IgM Micro Reader

REF 62-1001-0 Chembio DPP® Zika IgM Control Pack

For Product Information, Literature and/or SDS please email
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SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	WARNING
	DO NOT RE-USE
	FOR USE WITHIN TEMPERATURE LIMITS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
REF	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE
Σ 20	CONTAINS SUFFICIENT FOR 20 TESTS
Rx Only	PRESCRIPTION DEVICE

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