CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

FOR *IN VITRO* DIAGNOSTIC USE ONLY
FOR PRESCRIPTION USE ONLY

DPP® Zika IgM System Control Pack

62-1001-1

For Use with the DPP® Zika IgM System

Read this Product Insert and the DPP Zika IgM 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 in accordance with US blood donation requirements and restrictions 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.

STORAGE: Store at -20°C (-4°F) or colder.

INTENDED USE

The Chembio DPP Zika IgM System Control Pack is an external quality control kit for use with the DPP Zika IgM System only. The performance characteristics of the DPP Zika IgM System 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
- Once per week (if the kit is used for longer than a week)
- Whenever a new shipment of test kits is received
- At periodic intervals as indicated by the user facility

It is the responsibility of each site using the DPP Zika IgM 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 site's standard quality control procedures.

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

SUMMARY AND EXPLANATION OF ZIKA REACTIVE AND NON-REACTIVE CONTROLS

Chembio DPP Zika IgM System Control Pack Reactive/Non-Reactive Controls and Diluent 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 System.

MATERIALS PROVIDED

- 1 DPP Zika Reactive Control (300 µL): This vial contains ready-to-use, undiluted, naturally occurring Zika IgM positive plasma samples.
- 1 DPP Zika Non-Reactive Control (300 µL): This vial contains ready-to-use undiluted, naturally occurring Zika IgM negative plasma samples.
- 1 DPP Zika Diluent (300 µL): This vial contains naturally occurring Zika IgM negative plasma samples used for diluting the DPP Zika Reactive Control to make a Zika low-reactive control.
- 1 Product Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- DPP Zika IgM System (Catalog #: 65-9560-0)

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 10 µL Microsafe® Tubes
- 20 Sample vials
- 20 Transfer Pippettes (100 µL)
- 1 DPP Zika IgM Buffer (7.5 mL)– YELLOW CAP
  - 7.5 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

- Chembio DPP® Micro Reader (Catalog # 70-1064-0)

Each kit contains:

- DPP Micro Reader with Zika IgM RFID Sticker
  - 3 Lithium-ion, type CR2032 (3 V/230 mAh), coin cell batteries (installed)
- Custom power adapter cable (USB to 2.0 mm jack)
- Power plug adaptor
- DPP Cartridge Holder
- Microfiber cloth
- User Manual

- Clock, watch, or other timing device
- Calibrated Pipettor capable of delivering 10-100 µL of sample may be used in lieu of the disposable 10 µL Microsafe pipette or 100 µL transfer pipettes supplied with the kit (for use with serum, potassium-EDTA plasma, and potassium-EDTA venous whole blood specimens or with the Chembio DPP Zika IgM System Control Pack)
- Microcentrifuge Tubes
- 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

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)**.

WARNINGS AND PRECAUTIONS

1. For *In Vitro* Diagnostic Use only.
2. Read the DPP® Zika IgM System product insert completely before testing control kit specimens. Follow the instructions carefully as not doing so may result in inaccurate test results.
3. The DPP Zika IgM System is to be operated between 13 to 27°C (55 to 81°F).
4. 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.
5. Controls are kit lot specific and must not be interchanged between different DPP® Zika IgM System lots.
6. Use of this product is limited to personnel working in CLIA moderately complex sites and/or personnel who have been trained in the techniques of serology and *in vitro* diagnostic procedures on cleared instruments.
7. Laboratory biosafety guidance for working with Zika virus specimens is provided at http://www.cdc.gov/zika/state-labs/index.html. The Zika virus is considered a pathogen that can be safely worked with in a biosafety level 2 (BSL-2) laboratory.
8. Material may be infectious. Use universal precautions[1,2] when using control materials and performing the assay.
9. 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.
10. 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.
11. 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]
12. 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.
13. Do not use kits or components beyond the expiration date given on the label.
14. Aliquots of the concentrated controls are recommended to AVOID multiple freeze-thaw cycles. If freeze-thaw is still needed, DO NOT EXCEED 3 thaws. Discard diluted aliquots after use. DO NOT STORE diluted aliquots at 2-8°C.

STORAGE AND STABILITY

The Chembio DPP Zika controls should arrive frozen and should be stored at -20 °C or colder. Chembio recommends that the controls be divided into smaller aliquots upon receipt and avoid multiple freeze-thaw cycles.

If the control material appears thawed upon arrival or if the package appears damaged, contact Chembio Diagnostic Systems Customer Service at **1-844-CHEMBIO (844-243-6246)**. If turbidity or particulate matter is observed, the samples should be centrifuged in accordance with the test kit manufacturer's instructions for sample preparation.

TEST PROCEDURE

All components for the DPP Zika IgM System are ready to use as supplied. Instructions for use are given in the Chembio DPP Zika IgM 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 13 to 27°C (55 to 81°F) prior to testing.

In order to verify the DPP Zika IgM System, the Non-reactive control, the Reactive control and a low-positive control must be performed.

TO RUN THE DPP ZIKA NON-REACTIVE CONTROL ON THE DPP ZIKA IgM SYSTEM

1. Open the DPP Zika Non-Reactive Control containing the Zika Non-Reactive control reagent.
2. Remove the Chembio DPP Zika IgM 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 Buffer from the YELLOW CAP bottle to the supplied sample vial by holding the bottle vertically.
6. Using a calibrated Pipettor capable of delivering 10-100 µL, transfer 10 µL of the control sample into sample vial containing the Buffer. Mix it well by gently swirling the vial in a circular motion.
7. Attach a new tip to a calibrated Pipettor capable of delivering 10-100 µL. 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 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 15 minutes after the addition of the Running Buffer to Well 2 as per STEP 9. Do not read the test before 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 pipette tips, Test Device and any other test materials into a biohazard waste container.
12. If an aliquot was used as suggested, **discard any remaining concentrated non-reactive control material** into a biohazard waste container.

TO RUN THE DPP ZIKA REACTIVE CONTROL ON THE DPP ZIKA IgM SYSTEM

1. Open the DPP Zika Reactive Control containing the Zika Reactive control reagent.
2. Remove the Chembio DPP Zika IgM 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 Buffer from the YELLOW CAP bottle to the supplied sample vial by holding the bottle vertically.
6. Using a calibrated Pipettor capable of delivering 10-100 µL, transfer 10 µL of the control sample into sample vial containing the Buffer. Mix it well by gently swirling the vial in a circular motion.
7. Attach a new tip to a calibrated Pipettor capable of delivering 10-100 µL. 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 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 15 minutes after the addition of the Running Buffer to Well 2 as per STEP 9. Do not read the test before 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 pipette tips, Test Device and any other test materials into a biohazard waste container.
12. If an aliquot was used as suggested, **discard any remaining concentrated reactive control material** into a biohazard waste container.

TO RUN THE DPP ZIKA LOW-REACTIVE CONTROL ON THE DPP ZIKA IgM SYSTEM

A. MAKE YOUR LOW-REACTIVE CONTROL SAMPLE

1. Open the DPP Zika Diluent containing the Zika diluent.
2. Using a calibrated laboratory pipette capable of delivering 10-100 µL, transfer 20 µL of the diluent into a microcentrifuge tube.
3. Open the DPP Zika Reactive Control containing the Zika Reactive control reagent.
4. Using a calibrated laboratory pipette capable of delivering 10-100 µL, transfer 10 µL of the Zika Reactive control into the microcentrifuge tube containing the 20 µL of the diluent. Mix it well by pipetting it up and down at least 3 times.

B. RUN YOUR LOW-REACTIVE CONTROL SAMPLE

5. Remove the Chembio DPP Zika IgM test device from its pouch and place it on a flat surface (It is not necessary to remove the desiccant from the pouch).
6. Label the test device with control reagent name or identification number.
7. 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.
8. Slowly add 5 drops of DPP Zika IgM Buffer from the YELLOW CAP bottle to the supplied sample vial by holding the bottle vertically.
9. Using a calibrated laboratory pipette capable of delivering 10-100 µL, transfer 10 µL of the low-positive sample (made in step A) into sample vial containing the Buffer. Mix it well by gently swirling the vial in a circular motion.
10. Attach a new tip to the laboratory pipette capable of delivering 10-100 µL. Transfer 100 µL of the sample/buffer mixture from the sample vial into SAMPLE + BUFFER Well 1 of the DPP Test Device.
11. 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.
12. When 5 minutes have passed after addition of the specimen/buffer mixture, slowly add 5 drops of DPP Zika IgM Buffer from the YELLOW CAP bottle to BUFFER Well 2 by holding the bottle vertically over the well.
13. Read the test result using the DPP Micro Reader 15 minutes after the addition of the Running Buffer to Well 2 as per STEP 9. Do not read the test before 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.
14. Discard the used pipette tips, Test Device and any other test materials into a biohazard waste container.
15. **Discard any remaining control material** into a biohazard waste container.

    DO NOT refreeze or store at 2-8°C the diluted low-reactive control.

INTERPRETATION OF TEST RESULTS

Please also refer to the DPP Zika IgM System Product Insert

External Control	DPP Micro Reader
NON-REACTIVE Control	**ZIGM ## NR,** Where ## will be a numerical value **0 to <20**
REACTIVE Control	**ZIGM ## R,** Where ## will be a numerical value **94 +/- 18***
Low-REACTIVE Control Dilution	**ZIGM ## R,** Where ## will be a numerical value **35+/-3** *
INVALID	**INV,** (Results cannot be interpreted)

***Kit controls are produced to result in average value of 94 +/- 18 for REACTIVE control and average value of 35 +/-3 for LOW REACTIVE Control Dilution. Refer to lot specific Kit Control Certification Sheet for actual results observed with DPP Zika IgM kit lot.**

EXPECTED RESULTS

NON-REACTIVE CONTROL

The Non-Reactive Control will produce a NON-REACTIVE Test Result, on the DPP Micro Reader, followed by the letter "NR" indicating a NON-REACTIVE Test Result if performed correctly.

ZIKA REACTIVE CONTROL

The Zika Reactive Control will produce a REACTIVE Test Result, on the DPP Micro Reader, followed by the letter "R" indicating a REACTIVE Test Result if performed correctly.

ZIKA LOW-REACTIVE CONTROL DILUTION

The Zika Low-Reactive Control Dilution will produce a REACTIVE Test Result, on the DPP Micro Reader, followed by the letter "R" indicating a REACTIVE Test Result if performed correctly.

If the result is NON-REACTIVE, on the DPP Micro Reader, followed by the letter "NR", it is recommended that a new dilution be prepared and the test be repeated with a new device.

If you are unable to obtain a REACTIVE result on the repeat test, do not continue testing with the DPP Zika IgM System. Contact Chembio Diagnostic Systems Customer Service at **1-844-CHEMBIO (844-243-6246)**.

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 any of the Zika Control Reagents do not produce the expected results, repeat the controls on a second device. If the zika control reagents do not produce the expected results and you are unable to obtain a correct control result upon repeat testing, contact Chembio Diagnostic Systems Customer Service at **1-844-CHEMBIO (243-6246)** for further instruction. If the external controls do not produce expected results, patient testing should not be performed.

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

Product	Catalog Number
Chembio DPP® Zika IgM System	65-9560-0
Chembio DPP® Micro Reader Kit for Use with DPP® Zika IgM System	70-1064-0
Chembio DPP® Zika IgM System Control Pack	62-1001-1

For Product Information, Literature and/or SDS please email:
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SYMBOL LEGEND	
	FOR USE WITHIN TEMPERATURE LIMITS
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
LOT	BATCH CODE
REF	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	USE BY DATE
Σ 20	CONTAINS SUFFICIENT FOR 20 TESTS
F	BIOLOGICAL RISKS
Rx Only	PRESCRIPTION DEVICE

For use with Chembio DPP Zika IgM System Lot: _____

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