

For Use Under Emergency Use Authorization (EUA) Only

DPP® Zika IgM Assay System
FOR *IN VITRO* DIAGNOSTIC USE
FOR PRESCRIPTION USE ONLY
STORAGE: Store at 2 to 30°C (36 to 86°F)

Read this product insert completely before using the product. Follow the instructions carefully when performing the test as not doing so may result in inaccurate test results.

NAME AND INTENDED USE

The Chembio DPP® Zika IgM Assay System is intended 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 (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated). *Specimens from symptomatic patients or returning travelers from endemic areas should not be collected prior to 8 days after onset of symptoms or risk of exposure, respectively.* The assay is intended for use in laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories, consistent with the latest CDC guidance for the diagnosis of Zika virus infection.

Assay results are for the presumptive detection of IgM antibodies to Zika virus (ZIKV). Reactive results are not definitive for the diagnosis of Zika virus infection. False positive results are possible in patients with a history of infection with other Flaviviruses. Confirmation of the presence of anti-Zika IgM antibodies in presumptive positive specimens requires additional testing according to the latest CDC guideline for the diagnosis of Zika virus infection. Within the United States and its territories, laboratories are required to report presumptive positive results to the appropriate public health authorities.

Results of this test cannot be used as the sole basis of patient management decisions and must be combined with clinical observations, patient history, epidemiological information, and other laboratory evidences. Zika IgM levels over the course of illness are not well characterized. IgM levels are variable, may be detectable from near day two post onset of symptoms and persist up to approximately 12 weeks following initial infection.

Negative results do not preclude the possibility of Zika virus infection, past or present. Negative results may be seen in specimens collected before day four post onset of symptoms or after the window of detectable IgM closes.

The Chembio DPP® Zika IgM Assay System is intended for use by trained laboratory personnel who are proficient in performing and interpreting immunoassays. The assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

Zika virus (ZIKV) is a member of the virus family *Flaviviridae* and the *Flavivirus* genus, and is thus related to the dengue, yellow fever, Japanese encephalitis, and West Nile viruses. As with other flaviviruses, Zika virus is an enveloped, single-stranded, positive sense RNA virus approximately 50nm in size¹.

Zika virus is primarily transmitted by mosquitoes, including *Aedes aegypti*. *Aedes aegypti* is the same mosquito that transmits dengue, chikungunya and yellow fever. In addition, human-to-fetus and sexually transmitted infections have been documented. Most cases of Zika virus infection (approximately 80%) are asymptomatic; however, when symptoms occur, they are generally mild and flu-like². Fever is usually low grade and accompanied with muscle and joint pain². Non-purulent conjunctivitis (pink-eye) has frequently been described². Recent reports of unusually high rates of Guillain-Barré syndrome (GBS) and primary microcephaly in countries that have experienced Zika outbreaks have raised concerns that

the Zika virus circulating in these regions represents an additional public health threat with neuropathic and teratogenic outcomes². However, the U.S. Center for Disease Control and Prevention (CDC) is continuing to investigate the link between GBS and Zika to learn more².

During the first 14 days after onset of symptoms, Zika virus disease can be diagnosed by performing reverse transcriptase-polymerase chain reaction (RT-PCR) in samples of symptomatic patients. Anti-Zika IgM is typically detectable starting soon after onset of symptoms and is reliably detectable for approximately 12 weeks following infection. If Zika virus infection is suspected based on CDC's published clinical and/or epidemiological criteria, the DPP® Zika IgM Assay System may be ordered for patients whose blood specimen was collected 8 days from likely risk of Zika virus exposure or post-onset of symptoms and should be performed according to the CDC-issued guidance (<http://cdc.gov/zika/laboratories/lab-guidance.html>)³. The algorithms included within the guidance illustrate the appropriate Zika testing approach based on the presence of signs and symptoms, pregnancy status, and the time between onset of symptoms or suspected exposure and specimen collection³.

There is currently no available vaccine or anti-viral drug treatment for Zika virus.

BIOLOGICAL PRINCIPLES OF THE TEST

The Chembio DPP® Zika IgM Assay System is a qualitative immunochromatographic assay for the presumptive detection of IgM antibodies to Zika virus. The Chembio DPP® Zika IgM Assay System includes the DPP Zika Test Device and the DPP® Micro Reader. The device employs Chembio's patented DPP (Dual Path Platform) technology and consists of a sample path that distributes sample onto a reagent strip containing a TEST (T) area and a CONTROL (C) area in the test-control window of the test device. The reagent strip is for the detection of ZIKV IgM antibodies. To initiate the test, a 10 µL specimen is collected, diluted with buffer and applied to the SAMPLE+BUFFER Well#1 of the DPP Zika Test Device. The specimen migrates along the sample path membrane and is delivered to the TEST (T) area of the reagent strip, where Zika NS1 antigens are immobilized. Zika-specific antibodies, if present in the sample, bind to the immobilized NS1 antigens in the TEST (T) area, while non-specific antibodies bind to the Protein A in the CONTROL (C) area. Successful sample application is indicated by the disappearance of soluble dye lines in the TEST and CONTROL areas. Five minutes after adding the sample, buffer is added into the BUFFER Well #2. The buffer hydrates the dried antibody-binding colored conjugate, which migrates to the TEST area. Detection is performed by using the Chembio DPP® Micro Reader, a portable, battery-powered instrument that uses assay-specific algorithms to verify the presence of the control line and measure color intensity at the TEST (T) line position; it interprets the results using assay-specific cut-off values, and reports a reactive, nonreactive, or invalid result along with a numerical intensity value for the IgM test line after approximately 3 seconds. The results are presented through a 14-segment liquid crystal display (LCD) on the top of the instrument. The DPP® Micro Reader has been developed to minimize human interpretation errors, therefore the results must not be visually interpreted by the operator. The DPP® Micro Reader is maintenance-free, not configurable by the user and is operated by a single, multi-function button.

MATERIALS PROVIDED

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 Pipets (100 µl)

1 DPP® Zika IgM Buffer– 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 Authorized Product Insert for the DPP® Zika IgM Assay System

1 Quick Reference Guide for the DPP® Zika IgM Assay System

Fact Sheet for Health Care Providers

Fact Sheet for Patients

MATERIALS REQUIRED BUT NOT PROVIDED

- 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)
 - Custom power adapter cable (USB to 2.0 mm jack)
 - 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).

- Chembio DPP Zika IgM Rapid Test Control Pack (Catalog #62-1001-1)
 - 1 DPP Zika Reactive Control (volume of 250 µL; enough to perform 25 tests): undiluted, naturally occurring Zika IgM positive plasma sample.
 - 1 DPP Nonreactive Control (volume of 250 µL; enough to perform 25 tests): undiluted, naturally occurring Zika IgM negative plasma sample.
 - 1 Product Insert
- Clock, watch, or other timing device
- Pipettor capable of delivering 10-100µL of sample may be used in lieu of the disposable 10µL MicroSafe® Tube and 100µL Transfer Pipets 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

1. For *In Vitro* Diagnostic Use under Emergency Use Authorization only.
2. 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.
3. Laboratory biosafety guidance for working with Zika virus specimens is provided at <http://www.cdc.gov/zika/statelabs/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.
4. Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate test results.
5. Use of the DPP® Zika IgM Assay System with sample types other than those specifically approved for use with this device may result in inaccurate test results.
6. This test should be performed at 18 to 30 °C (64 to 86°F). If the kit is stored refrigerated, ensure that the pouch and buffers are brought to operating temperature before performing the test.

PRECAUTIONS

SAFETY PRECAUTIONS

1. All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Use Universal Precautions^{4,5} when performing this assay.
2. Use routine laboratory precautions. Do not eat, drink, smoke or apply cosmetics in the area where samples and kit reagents are handled. Avoid any contact between skin, eyes or mucous membranes.
3. 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.
4. Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach (0.5% sodium hypochlorite) and disposed of as though potentially infectious.
5. 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.⁶

HANDLING PRECAUTIONS

1. If Desiccant Packet is missing, DO NOT USE. Discard test device and use a new test device.
2. Do not use any test device if the pouch has been perforated.
3. Each test device is for single use only.
4. Do not use the test beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
5. Do not mix reagents from different lot numbers of kits.

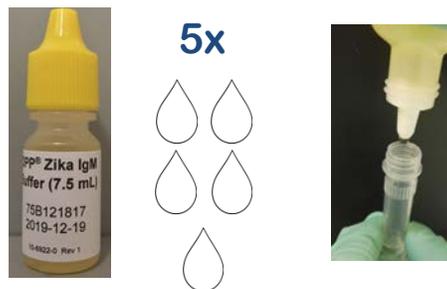
STORAGE AND STABILITY

The DPP Zika Test Devices should be stored in unopened pouches at 2 to 30°C (36 to 86°F). Do not freeze. Do not open the pouch until you are ready to perform a test. When stored as indicated, test devices are stable until the expiration date marked on the pouch. The DPP Zika IgM Buffer should be stored at 2 to 30°C (36 to 86°F) in the original container.

SPECIMEN COLLECTION

The Chembio DPP® Zika IgM Assay System must be performed on fingerstick whole blood, or EDTA venous whole blood, or serum (plain or separation gel), or EDTA plasma samples. However, confirmatory testing requires the use of serum samples. If fingerstick whole blood, or EDTA venous whole blood, or EDTA plasma samples are used with the Chembio DPP® Zika IgM Assay System, a patient-matched serum specimen should also be collected, or if this is not possible, an additional serum specimen should be collected soon after the original specimen.

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1. Add 5 drops of buffer from the DPP® Zika IgM Buffer Bottle (Yellow cap) into the supplied sample tube, which will be used to process the specimen.



2. *For Fingertick Whole Blood specimen Collection:*

Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using a sterile lancet, puncture the skin slightly off the center of the finger and wipe away the first drop of blood with sterile gauze. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid. Without squeezing the bulb, touch the end of the Microsafe® Tube horizontally (Figure 1) to the blood specimen (Figure 2). Capillary action automatically draws the specimen to the black fill line and stops (10 µL). Be sure the tube is completely filled to the black line and there are no air bubbles (Figure 2).

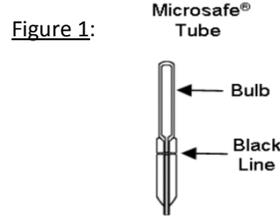
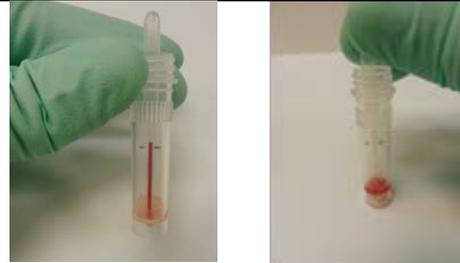


Figure 2: Blood Filled Microsafe® Tube

CAUTION: When drawing sample with the Microsafe® Tube DO NOT squeeze the bulb at the top of the tube. Capillary action will draw the sample to the black fill line.

3. Transfer the blood held in the Microsafe® Tube to the sample vial containing the DPP Zika IgM Buffer and squeeze the bulb to dispense the specimen into the buffer. Discard the Microsafe® Tube in the biohazardous waste container. Mix the contents in the tube by swirling in a circular motion.

CONTINUE ON TO TEST PROCEDURE



FOR MATRICES OTHER THAN FINGERSTICK

VENIPUNCTURE WHOLE BLOOD

Using the standard venous phlebotomy procedures, collect a whole blood specimen in a tube containing EDTA (lavender top).

If not testing at the time of specimen collection, whole blood specimens may be stored up to 3 days between 2 and 8°C (36 to 46°F). Prior to testing, mix the blood by gentle inversion several times. Do not heat or freeze whole blood specimens. Allow refrigerated sample to reach room temperature and mix gently before testing.

Using a calibrated laboratory pipet, transfer 10 µL of the whole blood into the sample vial containing 5 drops of the DPP® Zika IgM Buffer and pipette up and down 3x. Discard the pipette tip in the biohazardous waste container. Mix the contents in the tube by swirling in a circular motion and test immediately, following test procedure instructions for whole blood, serum, plasma samples.

SERUM OR PLASMA

Using the standard venous phlebotomy procedures, collect a whole blood specimen in a tube without anticoagulant for serum, or in a tube containing EDTA (lavender top) for plasma. Other anticoagulants have not been validated to be used with this device.

Serum and Plasma specimens may be tested immediately after collection. If specimens are not tested immediately, refrigerate them at 2 to 8°C (36 to 46°F) following collection. These specimens should be tested within 3 days of collection. If specimens are not tested within 3 days of collection, serum or plasma specimens should be frozen at -20°C (-4°F) or colder.

Using a calibrated laboratory pipet, transfer 10 µL of the serum or plasma specimen into the sample vial containing 5 drops of the DPP Zika IgM Buffer and pipette up and down 3x. Discard the pipette tip in the biohazardous waste container. Mix the contents in the tube by swirling in a circular motion and test immediately, following test procedure instructions for whole blood, serum, plasma samples.

SPECIMEN SHIPPING

If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents. Venous whole blood and plasma specimens should be shipped refrigerated with cold packs or wet ice.

TEST PROCEDURE

All components for the Chembio DPP® Zika IgM Assay System are ready to use as supplied. Follow directions as indicated. If the sample and/or kit components have been refrigerated, remove them from the refrigerator and allow them to come to a temperature of 18 to 30 °C (64 to 86°F) prior to testing.

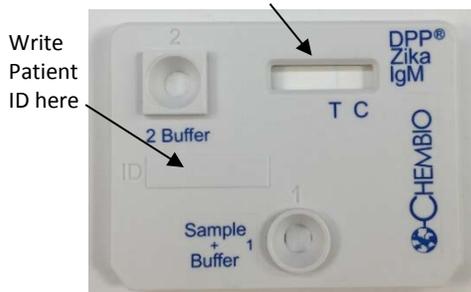
1. Remove the DPP® Zika IgM Assay System device from its pouch and place it on a flat surface.

Note: If desiccant packet is missing, DO NOT USE, discard test device and use a new test device.

Label the test device with patient ID or identification number.

Note: There are 2 colored lines in the test window; do not use the device if these lines are not visible.

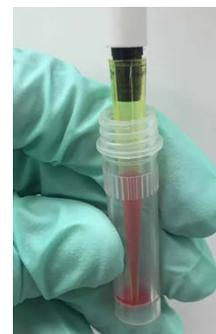
Test Window- IgM detection



- 2a. For a Fingerstick sample, using the supplied transfer pipette, fill up to the black line (100 µL).

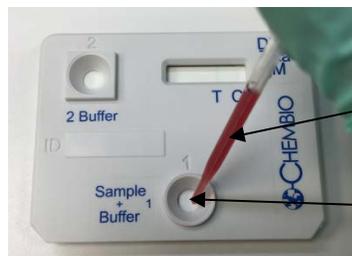


For Whole blood, serum or plasma sample, use a laboratory pipette to fill to 100 µL.

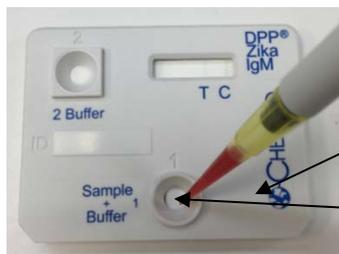


2b. Transfer 100 μ L of the specimen/buffer mixture from the sample vial into SAMPLE + BUFFER Well 1.

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100 μ L Specimen + Buffer
Well 1

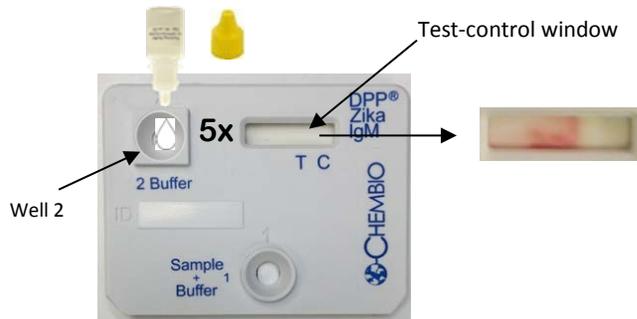


100 μ L Specimen + Buffer
Well 1

3. **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.

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.

Within 2-3 minutes, you should see a diffused reddish color moving across the test-control window.



4. **Fingerstick, Venous Whole Blood, Serum or Plasma**

Test Results are read using the DPP Micro Reader between 10 and 15 minutes after the addition of the Buffer to Well 2 as per STEP 3. Do not read the test before 10 minutes or after 15 minutes of addition of the Buffer to Well 2. **DO NOT ATTEMPT TO INTERPRET THE RESULTS VISUALLY. ALWAYS USE THE DPP MICRO READER TO OBTAIN ACCURATE RESULTS.** Record results manually.

5. Using the DPP® Micro Reader

The DPP Micro Reader has 4 components: The DPP Micro Reader with a DPP Zika IgM-specific RFID sticker, the holder for use with DPP® Zika IgM Assay System Test Device, a power plug adaptor and a USB adaptor. It also provides a microfiber cloth and a user manual.

DPP Micro Reader



Zika IgM RFID Sticker

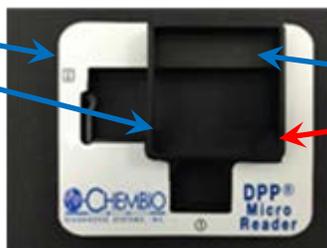
Assemble the DPP® Micro Reader (Catalog # 61-1070-0):

- a) Check to make sure that the window at the bottom of the reader is clean of finger marks and dust or lint before using the reader. Use enclosed microfiber cloth to wipe free of marks, dust or debris following the DPP® Micro Reader User Manual instructions.
- b) Place the DPP® Micro Reader holder on a flat surface. Align the angled edge in the bottom of the DPP® Micro Reader with the corresponding angled corner of the holder socket and place the DPP® Micro Reader in the holder socket.



DPP® Micro Reader

Openings for Wells 1 and 2



Reader Opening

Angled Corner

Holder for Reader



DPP Micro Reader in Holder

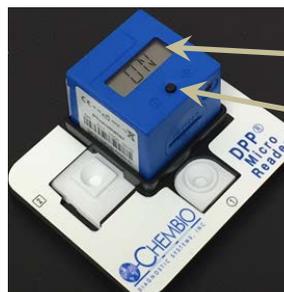
- c) To read a test, place the DPP® Micro Reader-holder assembly on top of the testing device. Make sure the rectangular test window on the testing device is aligned with the reading window of the reader. At the end of assembly, the black button, battery compartment and Buffer Well 1 on the test device should be facing the user and Buffer Well 2 should be to the left of the user.



DPP Micro Reader with holder on top of testing device

6. Reading a test:

- a) Between 10 to 15 minutes after the addition of the Buffer to Well 2 as per STEP 3, push the operating button. "ON" should appear in the reading window.



Reading Window

Push this Button

- b) Press the Operating Button again; the display will read “RFID”.



- c) “TEST” will appear in the display window.



- d) Press the Operating Button and “RUN” will appear in the display window.



After approximately 3 seconds, a numerical value for the IgM result is displayed followed by either “R” for Reactive or “NR” for Non-reactive. **Record the IgM result according to the laboratory policy (refer to INTERPRETATION OF TEST RESULTS) as the reader does not record results.**

If the DPP Micro Reader does not detect a line in the IgM CONTROL (C) area, then it will display “INV”, indicating that the test is INVALID. An invalid result indicates a problem with running the test, either related to the specimen, the device, or the procedure followed. An invalid test cannot be interpreted; it is recommended that the invalid test be repeated with a new device.

The reader will turn off automatically after approximately 50 seconds of inactivity. There is no active function to shut off the DPP Micro Reader or to recall the last test results.

NOTE: Discard the used Microsafe Tube, Sample Vial, Test Device, and any other test materials into a biohazard waste container.

QUALITY CONTROL

The DPP® Zika IgM Assay System provides two types of controls: a built in control feature in the DPP® Zika IgM testing device and an external quality control (Chembio DPP® Zika IgM Rapid Test Control Pack; Catalog #62-1001-1)

Built-in Control Feature

The control line in the DPP Zika IgM testing device serves as a built-in internal control and verifies that the assay procedure was followed and that the reagents were added or released, and migrated as intended. A numerical value will be displayed for the specimen if the test has been performed correctly and the device is working properly. (Please see: Interpretation of Test Results section).

External Quality Control

Chembio DPP® Zika IgM Control Pack (Catalog #:62-1001-1) is available separately for use with the Chembio DPP® Zika IgM Assay System (Catalog #: 65-9555-0). The assay controls are used to verify and assess the assay performance and verify the user’s ability to properly perform the test and to interpret the results. Use of control reagents manufactured by

another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance program for the DPP® Zika IgM Assay System. The DPP® Zika IgM Reactive Control is expected to produce a reactive test result on the DPP® Zika IgM Assay and the DPP® Zika IgM Nonreactive Control is expected to produce a nonreactive test result on the DPP® Zika IgM Assay. Run the controls as described in the Test Procedure section for a plasma sample and follow the directions in the Interpretation of Results section of this product insert.

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 30 °C (36 to 86 °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 facility using the Chembio DPP® Zika IgM Assay System to establish an adequate quality assurance program to ensure the performance of the device under 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).

INTERPRETATION OF TEST RESULTS

INTERPRETATION

NON-REACTIVE

If the numerical result displayed for IgM is less than 20, the specimen test result is interpreted as NON-REACTIVE.

A NON-REACTIVE Test Result means that Zika IgM antibodies were not detected in the specimen.

The Test Result is interpreted as NON-REACTIVE (i.e., negative); however, this does not rule out Zika virus infection, particularly if testing is conducted prior to 8 days post-onset of symptoms (before anti-Zika IgM antibodies levels are expected to become detectable by the assay) or more than 12 weeks after the infection is thought to have occurred (as anti-Zika IgM antibodies levels are expected to drop).

As with any test, providers must consider the patient's likelihood of exposure and the possibility of false laboratory results when making treatment or other patient management decisions.

Negative results with specimens collected before 8 days after onset of symptoms should be repeated with a later bleed taken at least **7 days** from the first specimen.

In the case of pregnant women please follow the latest CDC guidance for healthcare providers regarding clinical management of negative results.

Please also refer to the Fact Sheet for Health Care Providers for More Information.

**THE FOLLOWING WILL SCROLL
ACROSS THE READER DISPLAY**



IgM REACTIVE

If the numerical result displayed for IgM is greater than or equal to 20, the specimen test result indicates a REACTIVE Zika IgM Antibody Test Result.

A REACTIVE test result (i.e., presumptive Zika IgM positive) from the DPP® Zika IgM Assay System indicates that anti-Zika IgM antibodies were detected in the patient's specimen.

The result should be confirmed by the latest CDC testing algorithms. For information regarding Zika testing algorithm, please refer to CDC guidance for state and local public health laboratories:

<https://www.cdc.gov/zika/laboratories/index.html>.

Laboratory test results should always be considered in the context of clinical observations, epidemiological information, and travel history in making a final diagnosis and patient management decisions. For guidance on Zika virus, please refer to <http://www.cdc.gov/zika/hc-providers/index.html>.

Please also refer to the Fact Sheet for Health Care Providers for More Information.

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: The magnitude of the reported Index value is not indicative of the amount of Zika virus antibodies present in the patient sample.

LIMITATIONS OF THE PROCEDURE

1. Specimens from symptomatic patients or travelers to endemic areas should not be collected prior to 8 days after onset of symptoms or risk of exposure, respectively.
2. Recent Zika virus infection cannot be ruled out if test results from specimens collected more than 12 weeks after symptom onset or risk of exposure are negative by the DPP® Zika IgM Assay System.
3. Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.
4. Negative results do not preclude infection with Zika virus and should not be the sole basis of a patient treatment/management or public health decision.
5. A skillful technique and strict adherence to the instructions are necessary to obtain reliable results.
6. Improper collection, storage, or transport of specimens may lead to false negative results.
7. The test is not validated as a quantitative test for treatment monitoring.
8. Performance of this DPP® Zika IgM Assay System has only been established for capillary (fingerstick) or EDTA venous whole blood, serum, or EDTA plasma. Performance with other specimen types has not been evaluated.
9. Do not heat or inactivate serum.
10. Do not freeze whole blood.
11. Ensure finger is completely dry before performing fingerstick.
12. Reading test results using the DPP Micro Reader earlier than 10 minutes after the addition of the Buffer to Well 2 may yield erroneous results.
13. Do not open the sealed foil pouch until just prior to use.
14. Do not use kit contents beyond labeled expiration date.
15. Screening of the general population should not be performed.



16. The Chembio DPP Zika IgM Assay System has not been evaluated in a pediatric population.

CONDITIONS FOR AUTHORIZATION FOR THE LABORATORY

The DPP® Zika IgM Assay System Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website: <https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>. Use of the DPP Zika IgM Assay System must follow the procedures outlined in these manufacturer's Instructions for Use and the conditions of authorization outlined in the Letter of Authorization. Deviations from the procedures outlined are not permitted under the Emergency Use Authorization. To assist clinical laboratories running the DPP Zika IgM Assay System, the relevant Conditions of Authorization are listed verbatim below.

- Authorized laboratories will include with reports of the results of the DPP Zika IgM Assay System, the authorized Fact Sheet for Healthcare 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.
- Authorized laboratories will perform the DPP Zika IgM Assay System on only 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.
- If non-serum specimens are used with the DPP Zika IgM Assay System, authorized laboratories responsible for collecting the patient specimen must collect a patient-matched serum specimen, or if this is not possible, an additional serum specimen must be collected soon after the original specimen. This is 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.
- Authorized laboratories must read the results of the DPP Zika IgM Assay System on the DPP Micro Reader or on other authorized instruments. Authorized laboratories must not attempt to interpret the results of the DPP Zika IgM Assay System visually.
- Within the United States and its territories, authorized laboratories will report all reactive results (i.e., presumptive Zika IgM positive) to Chembio.
- Authorized laboratories 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.
- Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.^[1]
- Authorized laboratories will collect information on the performance of the DPP Zika IgM Assay System and report to DMD/OIR/CDRH (via email CDRH-EUA-Reporting@fda.hhs.gov) and Chembio any suspected occurrence of false negative and false positive results and significant deviations from the established performance characteristics of which they become aware.
- 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.

^[1] For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Chembio and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition (see <http://www.cdc.gov/zika/>).

- Chembio, its authorized distributor(s), and authorized laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

PERFORMANCE CHARACTERISTICS

The DPP Zika IgM Assay System contains goat anti-human IgG antibodies and heterophilic antibody (HA) interference blocker for treatment of the specimen. The current version of DPP Zika IgM Assay System (REF 65-9560-0) contains these materials as dehydrated reagents in the test device that were in liquid form in the earlier version of the DPP Zika IgM Assay System (REF 65-9555-0). The current version of the DPP Zika IgM Assay System was evaluated for cross-reactivity, potentially interfering substances, matrix equivalency and performance with clinical samples; the results of the testing demonstrated equivalent performance for the two versions of the DPP Zika IgM Assay System. The following sections contain the original performance data obtained with the earlier version of the DPP Zika IgM Assay System (REF 65-9555-0).

Assay Cut-Off: LoB

The assay cut off value of 20 was determined through the testing of

- 184 natural plasma samples sourced from a non-endemic population from the United States (n=95) and an endemic population from Peru (n= 89)
- 569 natural serum samples sourced from a non-endemic population from the United States and Mexico.
- 215 natural venous whole blood samples sourced from a non-endemic population from the United States.
- 102 natural capillary whole blood samples sourced from a non-endemic population from the United States.

The approach was based on CLSI document EP17-12¹ describing the calculation of the Limit of Blank (LoB), using a non-parametric method based on the % cumulative frequency of the results. The cut-off was set at 20 to optimize the sensitivity of the assay while also covering at minimum 98% of negative samples

Hook Effect

Chembio's proprietary DPP® technology differs from classical lateral flow tests by operating in a manner similar to that of the sequential ELISA format which is not sensitive to the "Hook Effect". On the primary flow path of DPP® devices, the sample migrates towards the immobilized immunoreagents on the horizontal strip that captures the analyte of interest, if present. Following a brief incubation to maximize analyte binding efficiency, the detector nanoparticles are released from the conjugate pad via the secondary flow path. This sequential approach resembles the traditional ELISA assay process and minimizes the potential of the prozone (or hook) effect.

Matrix Equivalency

To determine if all matrices are equivalent in performance regarding non-reactive results, matched fresh EDTA whole blood, EDTA plasma and serum collected in tubes without anticoagulant from one-hundred (100) individual, asymptomatic, U.S. blood donors not expected to have been infected with Zika virus, were evaluated on the DPP Zika IgM Assay System. Each matrix resulted in 100% Negative Percent Agreement and therefore, 100% concordance between matrices (Table 1).

¹ Clinical Laboratory and Standards Institute (CLSI) published EP12-A2 guideline, "EP12-A2: User Protocol for Evaluation of Qualitative Test Performance"

Table 1. Specificity Matrix Equivalency of the DPP Zika IgM Assay System with Matched Specimens from Asymptomatic U.S. Blood Donors

U.S. Blood Donor Samples	Matrix	Zika IgM NPA (95%CI)
	EDTA Whole Blood	100/100 100% (96.3-100%)
	EDTA Plasma	100/100 100% (96.3-100%)
	Serum	100/100 100% (96.3-100%)

To determine if all matrices are equivalent in performance regarding reactive results, matched frozen EDTA whole blood, EDTA plasma and serum collected in tubes without anticoagulant from eleven (11) individuals positive either by Authorized PCR or serological assays from the Dominican Republic were evaluated simultaneously on the DPP Zika IgM Assay System. When tested on the DPP Assay, all three matrices were equivalent in performance; 9 specimens were reactive for all three matrices and 2 were non-reactive for all three matrices.

In addition, 49 samples (serial bleeds over days from symptom onset) from 7 individuals residing in the Dominican Republic (DR) were tested via a plasma replacement study. All subjects were confirmed positive for Zika virus by nucleic acid testing and were positive for Zika IgM antibodies in at least one of the serial bleeds by a reference Zika IgM assay. Negative EDTA whole blood specimens from 49 individuals obtained from a U.S. blood bank were centrifuged. Each plasma portion from the negative specimens was removed and the corresponding pellet was carefully suspended in an equal volume of Zika IgM antibody positive EDTA plasma from one of the 49 Zika positive plasma samples. The process was repeated until the plasma from all 49 samples from the DR individuals was mixed with pellets from the negative individuals. Results for all 49 plasma-replaced whole blood samples were reactive for Zika IgM antibodies on the DPP Zika IgM Assay System. Therefore, the positive agreement between plasma and whole blood was 49/49 (PPA=100%, CI 92.7%-100%).

To further demonstrate matrix equivalency for serum, 5 individual negative sera and plasma were spiked with positive plasma specimens to obtain high negative, low positive, and 4 values across the dynamic range of the DPP assay. These individual negative matrices were then tested for each concentration of analyte in duplicates and the results between the matrices was compared at each level. Of the 30 combinations of antibody levels and negative individual matrix, agreement between plasma and serum was observed for 27 of the 30 combinations; disagreement was observed only for 3 high negative specimens.

Class Specificity

To determine if reactivity with Zika specific IgG is a potential assay interferent, a study where the reducing agent Dithiothreitol (DTT) was added to the sample buffer* was performed. Sample buffer with 10mM DTT resulted in nonreactive DPP® Zika IgM assay results when tested with three clinical Zika IgM positive samples suggesting that the IgM antibody reactivity was abolished. In contrast, standard Zika IgM sample buffer formulation resulted in the expected reactive DPP Zika IgM assay results when tested with the same three clinical Zika IgM positive samples (Table 2).

Table 2. Class Specificity of the DPP Zika IgM Assay System

	Specimens		
	A EDTA PLASMA IgM+/IgG+	B (neat) EDTA PLASMA IgM/IgG+	B (1:64) EDTA PLASMA IGM+/ IgG+
	DPP Zika IgM Assay Results		
Standard Sample buffer	140 (R)	320 (R)	330 (R)
Sample buffer with 10 mM DTT	9 (NR)	3 (NR)	1 (NR)

*DPP® Zika IgM Sample Buffer

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.

Positive Agreement

Positive agreement was evaluated using serial EDTA plasma samples collected from symptomatic subjects. All subjects confirmed positive for Zika virus by nucleic acid testing and were positive for Zika antibodies in at least one of the serial bleeds by the DPP® Zika IgM Assay System and the FDA authorized Zika IgM assay. The positive population consisted of 50 subjects from the Dominican Republic, from whom 400 specimens were drawn. The 50 subjects included 11 pregnant women. Three specimens did not have days post symptoms listed and were excluded from the calculations.

Table 3: Positive Agreement – by number of samples

Days Post onset of Symptoms	FDA Authorized Assay: Zika IgM Nonreactive [#]		FDA Authorized Assay: Zika IgM Reactive ^{##}		Total (n)
	DPP®Zika IgM Assay System Positive (P)	DPP®Zika IgM Assay System Negative (N)	DPP®Zika IgM Assay System Positive (P)	DPP®Zika IgM Assay System Negative (N)	
0-7	11	31	6	5	53
8-14	1	0	39	0	40
15-28	7	0	82	0	89
29-42	11	0	78	0	89
43-56	24	0	59	0	83
57-70	12	1	19	0	32
71-84	3	0	8	0	11
Total	69	32	291	5	397*

[#]Nonreactive samples include Negative and Presumptive Other Flavivirus Positive specimens.

^{##}Reactive samples include Possible and Presumptive Zika Positive Specimens.

*Three specimens did not have days post symptoms and were excluded from the calculations.

Table 4: Positive Agreement – by percentage agreement

Days Post onset of Symptoms	FDA Authorized Assay: Zika IgM Nonreactive	FDA Authorized Assay: Zika IgM Reactive
	Negative Percent Agreement	Positive Percent Agreement
0-7	31/42=73.8%	6/11=54.55%*
8-14	0/1=0%	39/39=100%
15-28	0/7=0%	82/82=100%
29-42	0/11=0%	78/78=100%
43-56	0/24=0%	59/59=100%
57-70	1/13=7.7%	19/19=100%
71-84	0/3=0%	8/8=100%

*This time frame is not supported by the authorization.

Performance was also evaluated for EDTA venous whole blood, serum and additional plasma specimens. A summary of the results obtained from testing all of the specimens is presented in Table 5.

Table 5: Summary Positive Agreement Specimens from Flavivirus Endemic Regions – by percentage agreement

Matrix	IgM PPA (95% CI)
EDTA Venous Whole Blood	49/51=96.1% (86.8 – 99.0%)
Plasma	301/307=98.0% (95.8 – 99.1%)*
Serum	39/41=95.1% (83.9 – 98.2%)

*Serial bleeds including the three specimens without day post symptoms were evaluated for total plasma performance. The value also includes 7/8 positives from a commercial panel, which upon repeat gave 8/8 positives.

Negative Agreement

Flavivirus Endemic Region: Asymptomatic Individuals

The specificity of the DPP® Zika IgM Assay System was evaluated using 50 presumed negative EDTA plasma specimens collected from asymptomatic individuals from Peru before the Zika outbreak. The resulting negative agreement of the DPP® Zika IgM Assay System for IgM when tested with EDTA plasma from asymptomatic individuals from Peru is 100% (50/50 = 100% with 95% CI: 92.9-100%) as shown in Table 6.

Non-Endemic Flavivirus Endemic Region: Asymptomatic Individuals

The specificity of the DPP® Zika IgM Assay System was evaluated using 566 presumed negative specimens. The specimens were a combination of serum (n= 100) specimens, EDTA plasma (n = 120) specimens, EDTA venous whole blood specimens (n = 244), and fingerstick capillary specimens (n=102), collected from asymptomatic apparently healthy donors within the United States, which is a non-endemic region for Zika infection. These samples did not come from patients who were symptomatic or at risk for exposure to Zika virus at the time of donation either through travel or through locally-acquired mosquito-borne Zika virus infection. The resulting negative agreement of the DPP® Zika IgM Assay System for IgM when tested with these specimens was 100% (100/100=100% with 95% CI 96.3-100%), 100% (120/120=100% with 95% CI 96.9-100%), 98.0% (239/244=98.0% with 95% CI 95.3-99.1%) and 100% (102/102=100% with 95% CI 96.4-100%) respectively (Table 6).

Pregnant Women

Flavivirus Endemic Region: The specificity of the DPP® Zika IgM Assay System was evaluated using 39 EDTA presumed negative plasma specimens from pregnant women (all trimesters) from Peru. Of the 39 specimens tested, no samples were positive for IgM on the DPP® Zika IgM Assay System. The resulting specificity of the DPP® Zika IgM Assay System on these specimens was 100% (39/39=100% with 95% CI 90.0-100%) as shown in Table 6.

Non-Endemic Flavivirus Endemic Region: The specificity of the DPP® Zika IgM Assay System was evaluated using 300 presumed negative serum samples from pregnant women (all trimesters) from Mexico (obtained during a time when Mexico was classified as a non-endemic region for Zika infection) and 194 serum samples from pregnant women (all trimesters) from the continental United States. The resulting specificity of the DPP® Zika IgM Assay System on these samples was 97.8% (483/494=97.8% with 95% CI 96.1-98.8%) as shown in Table 6.

Table 6: Negative Agreement

Pregnant	Population		Positive	Negative	Total	Negative Agreement (95% CI)
No	Endemic	EDTA Plasma	0	50	50	100% (92.9-100%)
	Non-Endemic	Serum	0	100	100 ²	100% (96.3-100%)
		EDTA Plasma	0	120	120 ²	100% (96.9-100%)
		EDTA Venous Whole Blood	5 ¹	239	244 ²	98.0% (95.3-99.1%)
		Fingerstick Whole blood	0	102	102	100% (96.4-100%)
Yes	Endemic	EDTA Plasma	0	39	39	100% (90.1-100%)
	Non-Endemic	Serum	11 ³	483	494	97.8% (96.1-98.8%)

¹Upon further testing with EIA, one sample was found to be reactive for Zika Virus IgG antibodies and IgG antibodies to West Nile Virus.

²Includes 100 whole blood-EDTA plasma-serum matched specimens from asymptomatic U.S. blood donors.

³Upon further testing with EIA, one sample was found to be reactive for Chikungunya IgG antibodies only. A second sample was found to be reactive for Dengue IgG antibodies only and Flavivirus IgM positive by the Comparator. Two other samples were each found to be reactive for Dengue IgG antibodies and IgG antibodies to West Nile Virus.

Interfering Substances

Controlled studies of potentially interfering substances performed on 3 negative and 3 positive plasma samples near the clinical decision point showed no interference on the DPP® Zika IgM Assay System at the highest concentration for each substance listed below in Table 7. Testing was performed as per CLSI guidelines EP7-A2.

Table 7: Interfering Substances for the DPP® Zika IgM Assay System

Interfering Substance	Concentration Tested
Hemoglobin	20 g/dL
Bilirubin	20 mg/dL
Serum Proteins	11 g/dL
HAMA	81 ng/mL
Sodium Citrate	4000 mg/dL
Lithium Heparin	2000 mg/dL
Sodium Heparin	2000 mg/dL

Cross Reactivity

The cross reactivity study for the DPP® Zika IgM Assay System was designed to evaluate potential interference from antibodies against other closely related viruses as well as organisms whose infection produces symptoms similar to those

observed during Zika virus infection. Samples that were seropositive for the cross reactant were used to test for potentially cross-reactive antibodies.

Table 8: Cross Reactivity of the DPP® Zika IgM Assay System

	Organism/Condition	N	DPP® Zika IgM Assay System		
			Positive	Negative	% Cross-reactivity
Flaviviruses	Anti-Dengue virus (IgM)	78	7 ¹	71	9%
	Anti-Dengue virus (IgG)	35	2 ²	33	5.7%
	Anti-West Nile Virus (IgM)	22	3 ³	19	13.6%
	Anti-West Nile Virus (IgG)	8	1 ³	7	12.5%
	Yellow fever virus post-immunization	12	0	12	0%
Other Viruses/diseases	Anti-Chikungunya virus	9	0	9	0%
	Anti-Varicella zoster virus (VZV) IgM	3	0	3	0%
	Anti-Cytomegalovirus (CMV) IgM	43	4	39	9.3%
	Anti-Cytomegalovirus (CMV) IgG	13	0	13	0%
	Anti-Epstein Barr Virus (EBV) IgM	8	0	8	0%
	Anti-Epstein Barr Virus (EBV) IgG	9	0	9	0%
	Anti-Parvovirus B19 (IgM)	3	0	3	0%
	Anti-nuclear Antibodies (ANA)	10	0	10	0%
	Anti- Malaria/anti- <i>plasmodium falciparum</i> ⁴	3	0	3	0%
Rheumatoid Factor	10	0	10	0%	

¹Four (4) specimens were Zika IgM+ on both the DPP Zika IgM Assay System and the Comparator Assay. Four (4) samples were also found to be positive for West Nile Virus IgM antibodies by EIA.

²Also positive for Zika by the Comparator Assay. The two (2) specimens gave equivocal results when tested for West Nile Virus IgM antibodies by EIA and equivocal results with an FDA cleared Dengue IgM EIA.

³Negative by the Comparator Zika Assay and by an FDA cleared Dengue IgM EIA.

⁴Specimens were confirmed positive for Malaria infection by Giemsa and Microscopy but serological status is not known.

REFERENCES

- Musso D, Gubler DJ. 2016. Zika Virus. Clin Microbiol Rev. Jul;29(3):487-524.
- <https://www.cdc.gov/zika/healtheffects/gbs-ga.html> accessed on June 27 2017; Content source: Centers for Disease Control and Prevention; Page last reviewed: August 9, 2016; Page last updated: August 9, 2016
- <http://cdc.gov/zika/laboratories/lab-guidance.html>; accessed on June 27 2017; Content source: Centers for Disease Control and Prevention; Page last reviewed: May 8, 2017; Page last updated: May 8, 2017
- <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
- 29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens; current version.
- Clinical and Laboratory Standards Institute. 2011. Clinical Laboratory Waste Management. CLSI Document GP5-A3.

ORDERING INFORMATION

- REF 65-9560-0 Chembio DPP® Zika IgM Assay System
- REF 61-1070-0 Chembio DPP® Zika IgM Micro Reader
- REF 62-1001-1 Chembio DPP® Zika IgM Control Pack

For Product Information, Literature and/or SDS please email info@chembio.com

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MEDFORD, NY 11763 USA

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Web Site: www.chembio.com

SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	WARNING
	DO NOT RE-USE
	FOR USE WITHIN TEMPERATURE LIMITS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE
	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	USE BY DATE
	CONTAINS SUFFICIENT FOR 20 TESTS
Rx Only	PRESCRIPTION DEVICE

DPP® Zika IgM Assay System Quick Reference Instructions

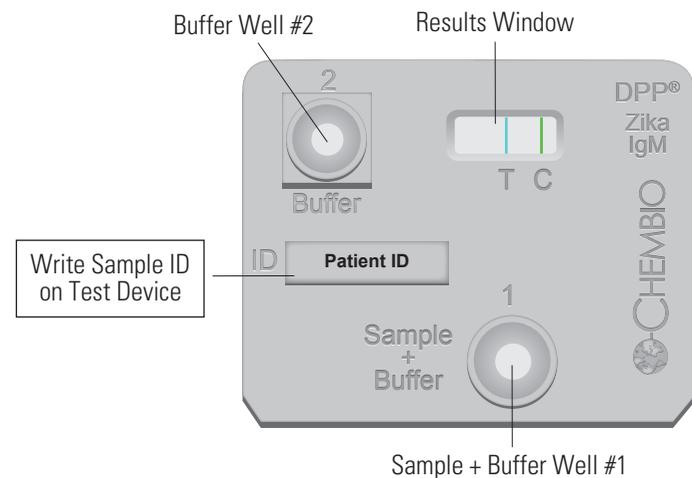


Product Part No. REF 65-9560-0

**For use under the Emergency Use Authorization (EUA) only
For prescription use only
For In vitro Diagnostic Use Only**

ASSAY COMPONENTS

DPP® Zika Test Cartridge



BEFORE YOU BEGIN

These instructions are only a reference guide. Read the complete Product Instructions and the Reader User Manual before performing the test.

- Gather the material you will need.
- Cover work station with a clean, disposable absorbent workplace cover.
- Wear disposable gloves, gown (fluid resistant or impermeable), and eye protection (goggles or face shield).
- Let the test reach room temperature (between 18-30°C or 64-86°F) before opening the pouch.
- Remove the DPP® Zika IgM Assay System test device from pouch and become familiar with it.

MATERIALS INCLUDED

The DPP Zika IgM Assay System kit contains the following items to perform 20 tests:

- 20 Individually Pouched DPP® Zika IgM Assay System Test Devices
- 20 Disposable 10µl Microsafe® Tubes
- 20 Sample Vials/Tubes
- 20 Transfer Pipets (100 µl)
- 1 DPP Zika IgM Buffer (7.5 mL)- YELLOW Cap
- 1 Product Insert for the DPP Zika IgM Assay System
- 1 Quick Reference Instructions for the DPP Zika IgM Assay System

MATERIALS REQUIRED BUT NOT PROVIDED

- Chembio DPP Zika IgM Rapid Test Control Pack (Catalog #62-1001-1)
- Clock, watch, or other timing device
- Pipettor capable of delivering 10-100 µl of sample may be used in lieu of the disposable 10 µl MicroSafe® Tube and 100 µl Transfer Pipets 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

Each kit contains:

- 1 DPP Micro Reader with Zika IgM RFID sticker (includes 3 batteries)
 - CR2031 3V Lithium Batteries: CR2032 (3 V / 230 mAh)
- 1 Holder for use with DPP Test Device
- 1 User Manual for the DPP Micro Reader
- 1 Custom power adapter cable (USB to 2.0 mm jack)
- 1 Microfiber Cloth
- 1 Power plug adapter

USING THE DPP® MICRO READER

Before you begin, ensure that the reader and components are clean. Remove any dust or debris from bottom camera window using the enclosed microfiber cloth.

- A** Connect DPP® Micro Reader to holder as shown. Insert base of reader so slanted edge meets corresponding slanted corner in holder cavity. Reader should lay flat in holder, and button and battery compartment should face sample well and the user.



DPP® Micro Reader



Cartridge Holder



Micro Reader with Holder and Test Device

- B** At the time indicated for reading test results, place reader and holder onto top of the cassette and push the button. "ON" should appear in the display window.



- C** Press the Operating Button again; Display will read "RFID."
Display will read "TEST".



Press the Operating Button one more time and the display will read "RUN."

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.

After approximately 3 seconds, a numerical value for the IgM result followed by "R" for reactive or "NR" for nonreactive will scroll across the reading window. Record the IgM result, then refer to the INTERPRETING THE RESULTS section on the reverse side.

NOTE: Once manual data recording is completed, the reader will turn off automatically after approximately 50 seconds of inactivity. There is no active function to shut off the DPP Micro Reader or to recall the last test results.

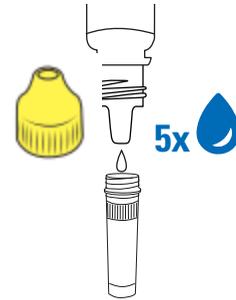
DPP® Zika IgM Assay System Quick Reference Instructions

INSTRUCTIONS FOR VENOUS BLOOD/PLASMA/SERUM

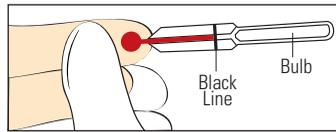
INTERPRETING THE RESULTS

INSTRUCTIONS FOR FINGERSTICK WHOLE BLOOD

1 Add Buffer to Vial
Holding vertically the DPP® Zika IgM Buffer (**yellow cap**), deliver 5 drops of solution into supplied sample vial.

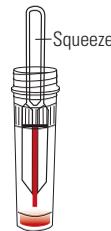


2 Collect Sample
Perform a fingerstick per standard procedures.

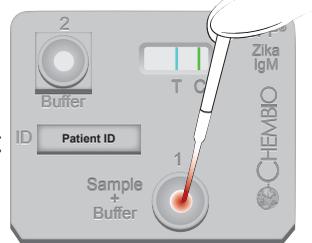


Without squeezing bulb, hold Microsafe® Tube in a horizontal position and touch tip of tube to blood sample. Capillary action will draw sample to black fill line (~10 µl). Be sure tube is filled to black line and there are no air bubbles.

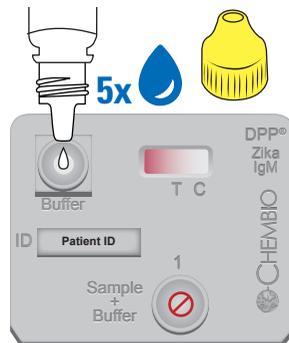
3 Prepare Sample
Immerse end of Microsafe® Tube with blood into buffer in sample vial and squeeze bulb to dispense specimen. Mix the contents of sample vial by swirling in a circular motion. Discard empty tube in biohazardous waste container.



4 Transfer Sample
Fill supplied transfer pipette to black fill line and deliver into Well 1. Colored lines in test area will start to disappear. If they do not, discard test device and repeat procedure with a new device. **Wait 5 minutes** after Step 4 before moving to Step 5.

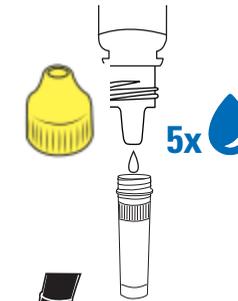


5 Add Buffer
Invert DPP® Zika IgM Buffer bottle (**yellow cap**) and hold VERTICALLY (not at an angle) over Well 2. Slowly add 5 DROPS of Buffer into Well 2.

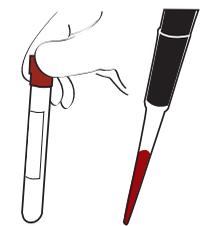


6 Read test results between **10 and 15 minutes** after addition of **Buffer** to Well 2 in Step 5.

1 Add Buffer to Vial
Holding vertically the DPP® Zika IgM Buffer (**yellow cap**), deliver 5 drops of solution into supplied sample vial.



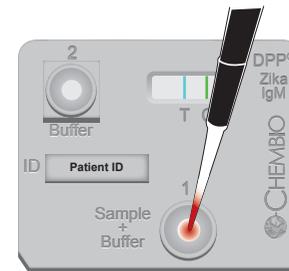
2 Collect Sample
Use standard venous phlebotomy procedures. Using a calibrated pipette, collect 10 µl of sample.



3 Add Sample to Buffer
Transfer sample into sample vial containing the Buffer. Pipet up and down 3x. Mix the contents of sample by swirling in a circular motion.

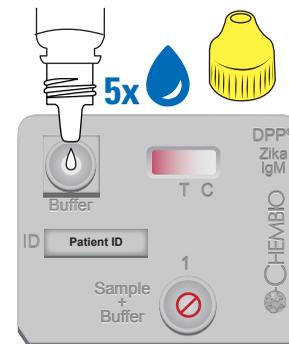


4 Transfer Sample
Using calibrated pipette, transfer 100µl to Well 1. Colored lines in test area will start to disappear. If they do not, discard test device and repeat procedure with a new device.



Wait 5 minutes after Step 4 before moving to Step 5.

5 Add Buffer
Invert DPP® Zika IgM Buffer bottle (**yellow cap**) and hold VERTICALLY (not at an angle) over Well 2. Slowly add 5 DROPS of Buffer into Well 2.



6 Read test results between **10 and 15 minutes** after addition of **Buffer** to Well 2 in Step 5.

DO NOT ATTEMPT TO INTERPRET RESULTS VISUALLY. ALWAYS USE THE DPP® MICRO READER TO OBTAIN RESULTS

TEST RESULT	INTERPRETATION
ZIGM <20 NR	NON-REACTIVE. A NON-REACTIVE test result means that Zika IgM antibodies were not detected in the specimen. The test result is interpreted as NON-REACTIVE if the value is <20; however, this does not exclude possible infection with Zika virus. If a sample is collected just after a person becomes ill (less than 8 days) or more than 12 weeks after infection is thought to have occurred, the level of Zika IgM antibodies may not be enough for the test to measure, resulting in a false negative.
ZIGM ≥20 R	IgM REACTIVE. A REACTIVE test result means that Zika IgM antibodies have been detected in the specimen. The patient is PRESUMED POSITIVE for Zika infection if the value is ≥20 as serological evidence of possible recent Zika virus infection has been identified. CONFIRMATION of the presence of anti-Zika IgM antibodies in presumptive positive specimens requires additional testing by qualified laboratories using the latest CDC-issued algorithm.
INV	INVALID. An INVALID result cannot be interpreted and it is recommended that test be repeated with a new device.

All test controls should be examined prior to interpretation of patient results. If controls are not valid, patient results cannot be interpreted.

Chembio DPP® Zika Reactive and Non-Reactive Controls (Catalog #62-1001-1) are available separately for use with the Chembio DPP® Zika IgM Assay System. The Zika Controls are used to verify operator's ability to properly perform test and interpret results. The Reactive Control will produce a reactive test result and has been manufactured to produce a faint line in the TEST (T) area. The Non-Reactive Control will produce a Non-Reactive test result. Run controls as described in the Test Procedure section for a plasma sample and follow directions in the Interpreting The Results section of this product insert. It is the responsibility of each facility using the Chembio DPP® Zika Assay System to establish an adequate quality assurance program to ensure performance of device under specific locations and conditions of use. If Zika Control reagents do not produce the expected results, do not proceed to evaluate clinical specimens and contact Chembio Diagnostic Customer Service at 1-844-243-6246.

**CHEMBIO DIAGNOSTIC SYSTEMS, INC. 3661 HORSEBLOCK ROAD
MEDFORD, NY 11763 USA
1 844-CHEMBIO (844 243-6246) | Fax: (631) 924-2065**

DPP® Micro Reader

Read this User Guide completely before using the product.

Storage conditions: Store between -20 to 80°C (-4 to 176°F)

For use under Emergency Use
Authorization (EUA) only.

For *In Vitro* Diagnostic Use.

NAME AND INTENDED USE

The DPP® Micro Reader –is for use with the DPP® Zika IgM Assay System Devices.

SUMMARY AND EXPLANATION

The DPP® Micro Reader is a reflectance reader used to obtain test results from DPP® Zika IgM Assay System assay cassettes. The DPP Micro Reader minimizes human errors due to subjective visual interpretation; therefore, the results of DPP Zika IgM Assay System Devices made specifically to be read with a DPP Micro Reader must be read exclusively with the DPP Micro Reader.

PRINCIPLES OF THE PROCEDURE

The DPP Micro Reader is a portable, battery-powered instrument that captures an image of the test strip surface, verifies the presence and intensity of the control line and measures the line intensity at each of the test line positions; it interprets the results using a scoring algorithm, and reports a REACTIVE, NON-REACTIVE or INVALID result after approximately 3 seconds. A 14-segment liquid crystal display (LCD) on the top of the instrument shows the status of the instrument and displays the test results to the operator.

The DPP Micro Reader is maintenance-free, not configurable by the user and is operated with a single, multi-function button.

MATERIALS PROVIDED

Each kit contains:

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

WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use.
- Where indicated, DPP Zika IgM Assay System test results **must be read using the DPP Micro Reader** and cannot be visually interpreted.
- The DPP Micro Readers are calibrated and checked before shipping under strict quality control measures in order to guarantee a high degree of quality. **Do not attempt** to open, re-configure or re-calibrate the Micro Reader.
- Protection provided by this instrument may be impaired if the equipment is used in a manner not consistent with the instructions in this manual.
- The DPP Micro Reader requires three (3) CR2032 (3 V/230 mAh) batteries to operate or must be plugged in through the power cable using the port located above the battery compartment and connecting it to a powered USB adapter or a powered USB hub.
- Do not use the DPP Micro Reader in direct sunlight or exposed to bright light while reading results.
- The DPP Micro Reader is designed for use on a clean, flat, horizontal surface.
- Always ensure that the DPP Micro Reader is positioned correctly in the DPP holder. Incorrect positioning may lead to incorrect results.
- The DPP Micro Reader can be operated at temperatures between 10 and 35°C (50 to 95°F) and between 20% and 85% humidity. Ensure that the Micro Reader is brought to operating temperature before use.
- Protect the DPP Micro Reader from liquids. Any liquid entering the Micro Reader may damage it permanently.

- Please follow the instructions in the product insert provided with the test kit regarding the disposal of DPP devices containing hazardous or infectious material.
- The DPP Micro Reader itself contains no biological hazards. However, contamination during use with biological hazards is possible. For cleaning and maintenance, refer to section **CLEANING AND MAINTENANCE**.

STORAGE AND STABILITY

The DPP Micro Reader should be stored at temperatures between -20 and 80°C (-4 to 176°F) and between 20% and 85 % humidity. It can be operated at temperatures between 10 and 35°C (50 to 95°F) and between 20% and 85% humidity.

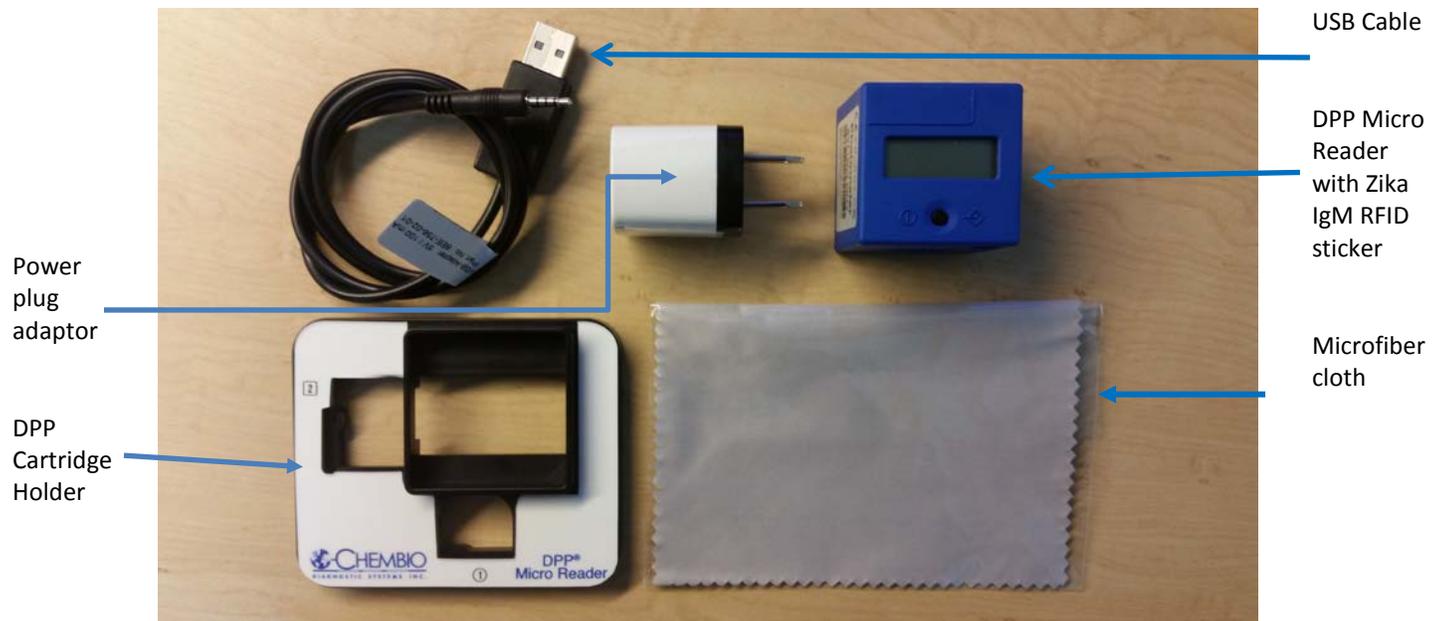
BATTERY LIFE

Under continuous use, one set of batteries will last for approximately 250- 300 reads (exact number may vary depending on battery quality, temperature, and length of storage between uses). The status of the batteries is being monitored and shown on the reader display every time the reader is turned ON. Verify that the battery symbol is not blinking nor has any bars left. Replace the batteries when the battery symbol starts to blink. The batteries cannot be recharged and have to be disposed according to local regulations. Always have a spare set of three batteries. Please see section on **BATTERY INSTALLATION** below. Alternatively, the DPP Micro Reader can be powered using the USB power cable connected to a power source.

UNPACKING AND SET-UP

1. Before using the DPP Micro Reader, visually inspect the contents for damage. If damage is apparent, contact Chembio Diagnostic Systems, Inc. (Figure 1).
2. Remove the reader from its protective wrapping. It is recommended that the packaging materials are retained for later use.
3. Ensure that the reader and components are clean. Remove any dust or debris with a smooth, dry cloth.

Figure 1: Package Content

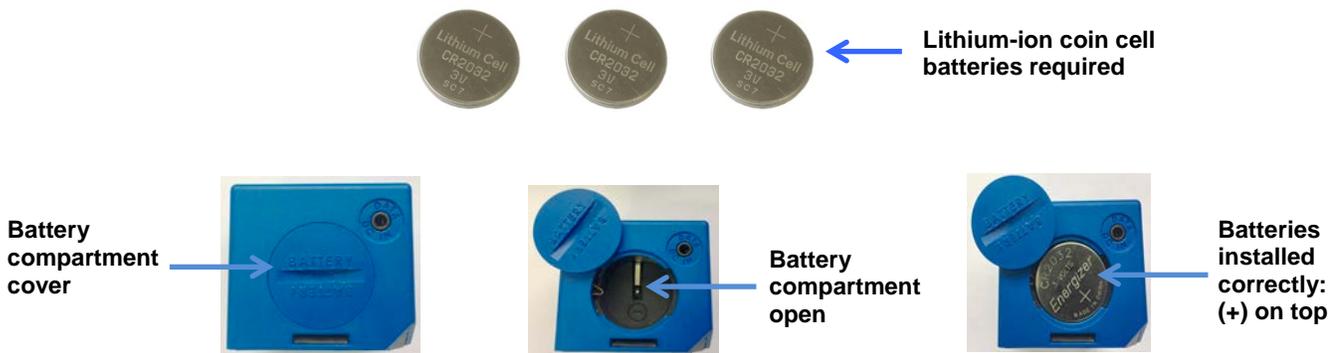


BATTERIES INSTALLATION AND REPLACEMENT

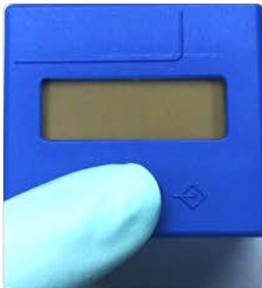
The reader requires three (3) CR2032 (3 V/230 mAh) batteries, Lithium-ion Coin Cell batteries such as Energizer™ ECR2032 3V LITHIUM; DURACELL DL2032B4 Battery, 2032, Lithium, 3V or equivalent. Replace the batteries when the battery symbol starts to blink. To replace the batteries, turn the battery cover with a smooth-edged coin ¼ turn counterclockwise until it stops. Tilt the side with the battery cover down so it falls into your hand, as well as the batteries inside. Place three new Lithium-ion Coin Cell batteries with correct polarity orientation ('+' sign outward, see Fig. 2) into the battery compartment one by one. Replace the battery cover by pressing slightly with a coin and turning ¼ turn clockwise until it stops.

NOTE: If the reader does not start after installing new batteries, clean the batteries with a dry cloth and make sure they are installed with the + side directed outwards. If it still does not start, try a set of fresh batteries.

Figure 2: Battery Installation/Replacement



After changing the batteries, perform the following steps. Note: the date that appears in step 3 (below) represents the manufacture date of the DPP® Micro reader.

- | | | | |
|---|--|--|--|
|  |  |  |  |
| <p>1. When the DPP® Micro Reader is off, the display is blank.</p> | <p>2. To turn on the device, press the button briefly (i.e. less than 1 second).</p> | <p>3. After activation, the buzzer sounds can be heard, and the display shows "Year – Date and time"</p> | <p>4. Press the button one more time (<1 second) and the display will show "ON" and is now ready to use</p> |

Using the DPP Micro Reader

The DPP Micro Reader has 3 components: The DPP Micro Reader with Zika IgM RFID sticker, the holder for use with DPP® Zika IgM Assay System Test Device, and a USB Cable.

Assemble the DPP® Micro Reader:

- a) Check to make sure that the window at the bottom of the reader is clean of finger marks and dust or lint before using the reader (see CLEANING AND MAINTENANCE Section below).
- b) Place the DPP Micro Reader holder on a flat surface. Align the angled edge in the bottom of the DPP Micro Reader with the corresponding angled corner of the holder socket and place the DPP Microreader in the holder socket.

DPP Micro Reader



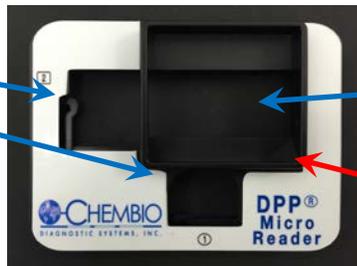
Zika IgM RFID Sticker



DPP Micro Reader

Openings for Wells 1 and 2

Angled Edge



Holder for Reader

Reader Opening

Angled Corner



DPP Micro Reader in Holder

- c) To read a test, place the DPP® Micro Reader-holder assembly on top of the testing device. Make sure the rectangular test window on the testing device is aligned with the reading window of the reader. At the end of assembly, the black button, battery compartment and Buffer Well 1 on the test device should be facing the user and Buffer Well 2 should be to the left of the user.



DPP Micro Reader with holder on top of testing device

Reading a test:

- a) Between 10 to 15 minutes after the addition of the Buffer to Well 2 as per STEP 3 in the TEST PROCEDURE, push the operating button. "ON" should appear in the reading window.



Reading Window

Push this Button

- b) Press the Operating Button again; the display will read “RFID”.



- c) “TEST” will appear in the display window.



- d) Press the Operating Button and “RUN” will appear in the display window.



After approximately 3 seconds, a numerical value for the IgM result is displayed followed by either “R” for Reactive or “NR” for Non-reactive. **Record the IgM result according to the laboratory policy (refer to INTERPRETATION OF TEST RESULTS) as the reader does not record results.**

If the DPP Micro Reader does not detect a line in the IgM CONTROL (C) area, then it will display “INV”, indicating that the test is INVALID. An invalid result indicates a problem with running the test, either related to the specimen, the device, or the procedure followed. An invalid test cannot be interpreted; it is recommended that the invalid test be repeated with a new device.

TURNING OFF THE READER

There is no active function to shut off the DPP Micro Reader; it will turn off automatically after approximately 50 seconds of inactivity.

CLEANING AND MAINTENANCE

The outer case and display may be cleaned with the enclosed microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA), 10% bleach solution, or mild soap solution. Do not introduce cleaning solution or any liquid into the unit. Do not use a saturated towel, which may leak liquid into the case or display seams. Ensure that the DPP Micro Reader is dry and the surface is free of fluid prior to returning to use.

Make sure that the window under the reader is clean of finger marks, dust and lint, which may interfere with the results. It can be wiped with the provided dry microfiber cloth, or the microfiber cloth lightly moistened with 70% isopropyl alcohol (IPA) to remove greasy or finger marks.

SERVICING AND RE-ORDERING

There are no user serviceable components in the unit with the exception of the replaceable batteries. For technical issues or questions, and to order a new reader, please contact Chembio Diagnostic Systems, Inc.

CUSTOMER SERVICE DEPARTMENT

Call: 1-844-CHEMBIO (844-243-6246)

Email: customerservice@chembio.com

DISPOSAL

As the DPP Micro Reader may be contaminated by infectious material, it should be disinfected according to the **CLEANING AND MAINTENANCE** section above before disposal. Remove the batteries before disposing of the expired device and dispose of the batteries in accordance with local regulations.

MESSAGES

Messages displayed by the DPP Micro Reader are described in the table below. For assay-specific messages, see the appropriate product insert.

Message	Type	Meaning	Action Recommended
ON	Status	Reader is ready for use.	None
RFID	Status	Reader is ready for RFID.	The RFID sticker is attached to the reader to allow the reader to obtain assay information. Press the button and the reader will show TEST.
TEST	Status	Reader is ready to run a DPP test device.	Press the button and the reader will show RUN.
RUN	Status	Reader is reading test results.	None.
OK	Status	Reader has recorded date and time information.	Press the button one more time, the reader will show 'ON' and is now ready for use.
ERR	Error	The device could not read the information from the RFID sticker.	(1) Press the button briefly (<1 second), the display will show 'ON'. (2) Make sure the RFID sticker is attached to the side of the reader. After you press the button when the RFID word is in the display, the reader should show TEST. If the error occurs again, please contact Chembio Diagnostic Systems, Inc.
DATE	Error	An expiry date appears to be exceeded.	Check the expiration date of the reader, RFID card and the test device in use.

SPECIFICATIONS

Dimensions: L x W x H: Approx. 1.6 x 1.6 x 1.6 in. (41 x 41 x 40 mm)
 Weight: Approx. 1.4 oz (40 g)
 Operation: One button operation
 Display: 14-segment LCD
 Storage capacity: None
 Device measurement period: Approx. 3 second
 Power supply: 3 batteries CR2032 (3 V/230 mAh)
 Or Micro-Reader specific power cord/USB cable
 Interface: 4 pole – 0.1 in. (2.5 mm) jack plug for power supply (instead of battery)
 Configuration: Specific configuration program; RFID technology
 Measuring field: Min. 0.2 in. (4 mm) width; Max. 0.7 in. (18 mm) length
 Lighting: Wavelength 525 nm
 Signaling device: Buzzer
 Operating conditions: Between 50°F (+10°C) and 95°F (+35°C); between +20 % and +85 % humidity
 Storage conditions: Between -22°F (-30°C) and 176°F (+80°C); between +20 % and 85 % humidity
 Degree of protection: IP 20
 Lifetime: 3,000

ORDERING INFORMATION

- REF 65-9560-0 Chembio DPP® Zika IgM Assay System
- REF 62-1001-1 Chembio DPP® Zika IgM Control Pack
- REF 61-1070-0 Chembio DPP® Micro Reader

For Product Information please email info@chembio.com



CHEMBIO DIAGNOSTIC SYSTEMS, INC.
3661 HORSEBLOCK ROAD
MEDFORD, NY 11763 USA

Tel: 1-844-CHEMBIO (844-243-6246)

Email: info@chembio.com
Web Site: www.chembio.com

SYMBOL LEGEND

	CONSULT THE MANUAL BEFORE USE
	CAUTION, CONSULT THE ACCOMPANYING DOCUMENTS
	FOR USE WITHIN TEMPERATURE LIMITS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	THIS DEVICE SHOULD BE TREATED AS WASTE EQUIPMENT AND DISPOSED OF AT DESIGNATED COLLECTION POINT
	READER POWER ACTUATION (ON/OFF)
	READER SERIAL NUMBER (13 DIGITS)
	PROTECTION CLASS OF ELECTRONIC EQUIPMENT

For use under Emergency Use Authorization (EUA) Only.

DPP® Zika IgM Assay Control Pack
FOR *IN 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 30 °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.

MATERIALS REQUIRED BUT NOT PROVIDED

- DPP® Zika IgM Assay 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 10µL Microsafe® Tubes

20 Sample vials

20 Transfer Pipets (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

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)
- Custom power adapter cable (USB to 2.0 mm jack)
- 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 Buffer from the YELLOW 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. Discard the pipette tip in the biohazardous waste container. Mix the contents in the tube by swirling in a circular motion.
8. 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.
9. 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.
10. 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.
 11. Read the test result using the DPP Micro Reader between 10 and 15 minutes after the addition of the Buffer to Well 2 as per STEP 9. Do not read the test before 10 minutes or after 15 minutes of addition of the 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.
 12. Discard the used pipet tips, Test Device and any other test materials into a biohazard waste container.
 13. 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 $0 \geq 20$
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 65-9560-0 Chembio DPP® Zika IgM Assay System
- REF 61-1070-0 Chembio DPP® Zika IgM Micro Reader
- REF 62-1001-1 Chembio DPP® Zika IgM Control Pack

For Product Information, Literature and/or SDS please email
info@chembio.com



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Web Site: www.chembio.com

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
	CONTAINS SUFFICIENT FOR 20 TESTS
F	Biological Risks
Rx Only	PRESCRIPTION DEVICE