CHEMBIO DIAGNOSTIC SYSTEMS, INC.

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For *In Vitro* Diagnostic Use Only

DPP® ZCD IgM/IgG System

For Detection of Zika, Chikungunya, Dengue IgM and IgG Antibodies in Blood, Serum and Plasma

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.

STORAGE: Store at 2 to 30°C (36 to 86°F)

NAME AND INTENDED USE

The DPP® ZCD IgM/IgG (Zika/Chikungunya/Dengue IgM/IgG) System is a single-use rapid immunochromatographic test intended for the detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to Zika Virus (ZIKV); the detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to chikungunya Virus (CHIKV); and the detection and differentiation of Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibodies to dengue Virus (DENV) in fingerstick whole blood, EDTA venous whole blood, serum, or EDTA plasma samples. The DPP ZCD IgM/IgG System is intended for use in clinical and point-of-care (POC) settings to aid in the diagnosis of infection with ZIKV and/or CHIKV and/or DENV only in patients with clinical symptoms consistent with these arboviruses; a recent history of travel to geographic regions during a period of active arbovirus virus transmission at the time of travel; and/or other epidemiologic criteria for which arbovirus testing may be indicated as part of public health response. This test is intended to provide a preliminary result. 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 evidence. Results must be confirmed using local guidelines for diagnosis of these arboviral diseases.

SUMMARY AND EXPLANATION

Zika, dengue and chikungunya are arboviruses. The primary route of infection for humans is through the bite of a mosquito within the genus *Aedes*. Symptoms of arbovirus infection generally occur 3–15 days after exposure to the virus and last 3 or 4 days. The most common clinical features of infection are fever, headache, and malaise.

ZIKV is an RNA virus that is a member of the *Flaviviridae* family and the genus *Flavivirus*.[1] It is transmitted to humans by mosquitoes belonging to the *Aedes* genus[2] and can also be transmitted through sexual transmission,[10] and possible transfusion-transmission.[11] ZIKV was first identified in 1947 in the Zika Forest of Uganda, then propagated into many areas of Africa, Southeast Asia and Pacific Islands. In May 2015, the first locally acquired cases of ZIKV infection in the Americas were confirmed in Brazil.[6,7] As of early 2016, ZIKV had spread to other countries in South America, Central America, Mexico, and the Caribbean, including the U.S. territories of Puerto Rico and the Virgin Islands.[7]
In humans, ZIKV infection is typically associated with mild flu-like symptoms, but more recently, with serious and sometimes fatal cases of Guillain-Barré syndrome[8] and with microcephaly and other birth defects in infants born to infected mothers.[9]

DENV is also an RNA virus that is a member of the *Flaviviridae* family and the genus *Flavivirus*. Dengue fever is caused by any one of the four dengue virus serotypes (DEN-1, DEN-2, DEN-3 and DEN-4). It is transmitted by several species of mosquito within the genus *Aedes*, principally *A. aegypti*. DENV is a leading cause of illness and death in the tropics and subtropics. As many as 400 million people are infected yearly.

The diagnosis of dengue and the differentiation between primary and secondary infections are important for monitoring the spread of the epidemic and identifying the risk of severe forms of the disease. Diagnosis is typically made clinically, based on reported symptoms (Fever, as high as 106°F (41°C), headaches, muscle, bone and joint pain) and physical examination; this applies especially in endemic areas.[16] Early disease can be difficult to differentiate from other viral infections.[17] Serologic detection of IgM and IgG antibodies is the main laboratory technique for diagnosing dengue.[20] Confirmation by microbiological laboratory testing[16,18] includes virus culture, nucleic acid detection (PCR), viral antigen (e.g. NS1) or specific antibodies detection (serology).[16,19] Primary dengue infection is characterized by a slow rise of and low antibody titer. IgM antibody appears first, followed by IgG, detectable at low titer after the first week of illness, and slowly increasing. In contrast, upon secondary infection, antibody titers rise extremely rapidly, and antibody reacts broadly with many flaviviruses. High levels of IgG are detectable even in the acute phase and rise dramatically over the following two weeks. The kinetics of the IgM response is more variable. IgM levels are significantly lower in secondary dengue infections and thus some anti-dengue IgM false-negative reactions are observed during secondary infections. Rapid IgM/IgG antibody detection can assist in the diagnosis of dengue and could greatly enhance public health efforts to decrease the spread of this infection.

CHIKV is a member of the *alphavirus* genus, and *Togaviridae* family. Yet, similar to Zika and dengue, chikungunya is also transmitted by mosquitoes such as *Aedes aegypti* and *Aedes albopictus*, both present in the Americas. It also shares some clinical signs with these other two arboviruses (high fever, joint and muscle pain, and headache) and is often misdiagnosed in areas where dengue is common. Chikungunya must be distinguished from dengue. While with both diseases patients may have diffuse body pain, the pain resulting from having chikungunya is much more intense and localized in the joints and tendons than dengue. The joint pain may last for months or years and may become a cause of chronic pain and disability. There is no specific treatment for chikungunya infection, nor any vaccine to prevent it. Since 2004, chikungunya virus has caused massive and sustained outbreaks in Asia, Africa and the Indian subcontinent, infecting more than 2 million people, with attack rates as high as 68% in some areas.[21] In 2007, disease transmission was reported for the first time in Europe, in a localized outbreak in northeastern Italy.[21] This situation can put a sudden and heavy burden on health services.

BIOLOGICAL PRINCIPLES OF THE TEST

The DPP ZCD IgM/IgG System employs Chembio's patented DPP technology (Dual Path Platform-US/7189522, Brazil PI0600759-7 and WO/2006/099191) and consists of a sample path that distributes sample onto two test strips. The top test strip (window labeled 1, 2, 3) is for the detection of IgM antibodies to DENV, ZIKV and CHIKV and the bottom test strip (window labeled 1, 2, 3) is for the detection of IgG antibodies to DENV, ZIKV and CHIKV. To initiate the test, a 10 µL specimen is diluted with buffer and applied to the SAMPLE+BUFFER Well located in the middle of the sample transfer strip of the DPP ZCD IgM/IgG Test Device. The sample flows in both directions along the sample path membrane and is delivered to the Top and Bottom TEST (1, 2, 3) and CONTROL areas. DENV, ZIKV and CHIKV antibodies, if present in the sample, bind to the immobilized viral antigens on the TEST (1, 2, 3) areas, while non-specific antibodies bind to the Protein A in the CONTROL (C) area. Five minutes after adding the sample/buffer mix, 250 µL DPP IgM/IgG Buffer is added to the BUFFER Well, located in the middle of the buffer pad. The buffer flows onto both assay strips, hydrates the two dried antibody-binding colored conjugates, which migrate to the two TEST areas. If the sample contains DENV, ZIKV or CHIKV antibodies, the conjugate binds to the antibodies (IgM or IgG or both if present) captured in the TEST (1, 2, 3) areas. If only one of the two species of antibodies is present (IgM or IgG), the conjugate will be captured only at the location of the IgM (top strip) or IgG (bottom strip) test line. The liquid continues to flow through the membranes and is captured in the CONTROL (C) area in both windows. This procedural control serves to demonstrate that specimen and reagents have been properly applied, the sample and conjugate released and migrated through the device.

At the time of reading the results, the DPP Micro reader and cassette adapter MUST BE USED to obtain the test results, as the order of the test lines in the readout windows may be different than the order of the letters Z, C and D in the product name. Also, the reader helps the user to obtain accurate results by providing numerical values proportional to the intensity of the test lines, and removes subjectivity in interpreting test results.

MATERIALS PROVIDED

Each kit contains the items to perform 20 tests:

- 20 Individually Pouched DPP ZCD IgM/IgG Test Devices, each containing:
  - 1 DPP ZCD IgM/IgG Test Device
  - 1 Desiccant Pouch
- 20 Disposable 10 µL Sample Loops- BLUE
- 20 Sample Vials/Tubes
- 20 Transfer Pipets (100 µL)
- 20 Sterile Safety Lancets (for fingerstick whole blood specimens)
- 20 Bandages
- 1 DPP IgM/IgG Buffer – (9.5 mL) **BLUE Cap** (contains: sodium phosphate, NP-40, sodium chloride, EDTA, Tween 20, avidin, chicken serum and urea, gentamicin, streptomycin, and sodium azide as a preservative)
- 1 Product Insert for the DPP ZCD IgM/IgG System
- 1 Quick Reference Guide for the DPP ZCD IgM/IgG System

ACCESSORIES AVAILABLE AND REQUIRED

DPP Micro Reader Kit for use with DPP ZCD IgM/IgG System (Catalog 70-1058-0)
Each kit contains:

- 1 DPP Micro Reader (includes 3 batteries)
- 1 Holder for use with DPP Test Device
- 1 Adapter Cable (5 V / 1000 mA)
- 1 Microfiber Cloth
- 1 RFID Card for use with DPP ZCD IgM/IgG System
- 1 Certificate of Analysis
- 1 User Manual

For problems or questions, please read the DPP MICRO READER manual.

MATERIALS REQUIRED BUT NOT PROVIDED

- 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 Sample Loops supplied with the Kit (for other than fingerstick whole blood specimens) and 100 µL Transfer Pipets
- Disposable gloves
- Sterile gauze (for fingerstick whole blood specimens)
- Antiseptic wipes
- Biohazard disposal container
- Collection devices (for venous whole blood, serum, plasma)

WARNINGS

For *IN VITRO* diagnostic use

1. Read the Product Insert completely before using this assay. Follow the instructions carefully as not doing so may result in inaccurate test results.
2. Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.
3. This test should be performed at 18 to 30°C (64 to 86°F). If stored refrigerated, ensure that the pouch and buffer are brought to operating temperature before performing testing.
4. This test has not been evaluated for newborn screening, cord blood specimens, or testing blood or plasma donors.

PRECAUTIONS

SAFETY PRECAUTIONS

1. Specimens may be infectious. Use Universal Precautions[12,13] when performing this assay.
2. Use routine laboratory precautions. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.
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. 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.

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 ZCD IgM/IgG Test Devices should be stored in unopened pouches at 2 to 30°C (36 to 86°F). Do not freeze. Do not open 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 IgM/IgG Buffer should be stored at 2 to 30°C (36 to 86°F) in its original container.

SPECIMEN COLLECTION

The DPP ZCD IgM/IgG System can be performed on fingerstick whole blood, EDTA venous whole blood, serum, or EDTA plasma samples.

1. Transfer 5 drops (~150 µl) of the DPP IgM/IgG Buffer (**Blue cap**) into the supplied Sample Vial.

FINGERSTICK WHOLE BLOOD

2. Prepare to perform the fingerstick collection procedure. 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 just 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.

   Collect the sample from the second drop, laying the disposable Sample Loop provided against the drop of blood until the Sample Loop is full as shown in Figure 1.

Figure 1.

3. Immerse the end of the loop filled with blood into the buffer in the sample vial; mix the contents well with the loop; remove and discard the empty loop in the biohazardous waste container. Test immediately following Test Procedure instructions.

FOR MATRICES OTHER THAN FINGERSTICK

VENOUS WHOLE BLOOD:

Draw blood following laboratory procedure for obtaining venous blood. Collect sample in a tube containing EDTA. Be sure the tube of blood is well mixed before sampling.

Use a laboratory pipet to withdraw 10 µL of the blood. Transfer sample into the sample vial containing buffer and mix the contents by swirling the vial in a circular motion. Test immediately, following Test Procedure instructions.

If tested the same day, venous whole blood may be kept at room temperature. Venous whole blood may be stored for up to 3 days between 2 and 8°C (36 to 46°F) before testing.

DO NOT FREEZE WHOLE BLOOD! Allow refrigerated sample to reach room temperature and mix gently before testing.

SERUM OR PLASMA

Draw blood following laboratory procedure for obtaining serum or plasma samples. Collect samples in tubes that do not contain any anticoagulant (serum), or in a tube containing EDTA (plasma). Collect specimen in a clean container following standard laboratory procedures. Be sure that the tube of serum or plasma is well mixed before sampling.

Use a laboratory pipet to withdraw 10 µL of the serum/plasma. Transfer sample into the sample vial containing buffer and mix the contents by swirling the vial in a circular motion. Test immediately, following Test Procedure instructions.

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.

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, serum and plasma specimens should be shipped refrigerated with cold packs or wet ice.

TEST PROCEDURE

All components for the DPP ZCD IgM/IgG 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.

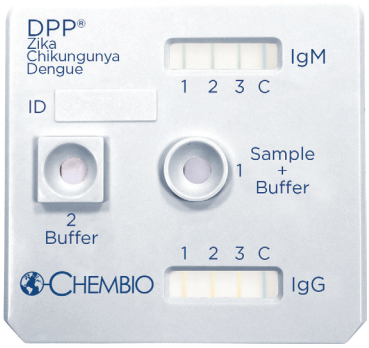
1. Remove the DPP ZCD IgM/IgG Test Device from its pouch and place it on a flat surface (it is not necessary to remove the Desiccant Packet from the pouch). Note: If Desiccant Packet is missing, DO NOT USE, discard Test Device and use a new Test Device.

   Label the Test Device with patient ID or identification number.

   Note: The DPP Test Device has 2 Test Windows. The top window is to detect IgM antibodies. The bottom window is to detect IgG antibodies.

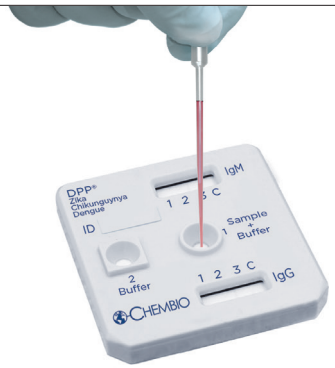
   There are 4 colored lines in each of the Test Windows; For IgM three are blue and the other is green. For IgG, three are yellow and the other is green.

   If any of the colored lines are absent from one or both windows, DO NOT USE, discard Test Device and use a new Test Device.



2a. If using a Fingerstick sample, fill the transfer pipette up to the black line (100 µL) ensuring there are no air bubbles in the pipette.

For **Whole Blood, Serum or Plasma** samples, use a laboratory pipette to draw 100 µL of the sample/ buffer mixture from the sample vial.



2b. With the transfer pipette, transfer 100 µL of the sample/buffer mixture from the sample vial into **Well 1 (Sample+Buffer)**. START THE TIMER.

Transfer the 100 µl of sample/buffer mixture into **Well 1 (Sample+Buffer)**. START THE TIMER.

3. Wait 5 minutes. The blue (IgM) and yellow (IgG) colored lines should have disappeared from the rectangular TEST and CONTROL windows. If not, DO NOT USE, discard Test Device and use a new Test Device.

The green colored line may or may not disappear.

Invert the DPP IgM/IgG Buffer bottle (**Blue Cap**) and hold it VERTICALLY (not at an angle) over **Well 2 (Buffer)**. Add 9 drops of Buffer (~250 µl) slowly, dropwise, into **Well 2 (Buffer)**.

A reddish color should begin to flow across the strip within 2-3 minutes. Otherwise, stop and repeat the test.

Read the test results using the DPP Micro Reader between 10 and 15 minutes from the addition of the DPP IgM/IgG Buffer to **Well 2 (Buffer)**.

4. Ensure that the reader and components are clean. Remove any dust or debris from bottom camera window. Insert DPP Micro Reader into the supplied holder as shown.

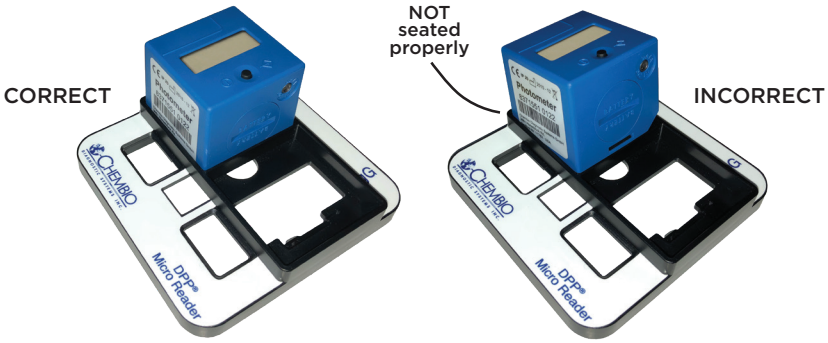
DPP Micro Reader

DPP Test Device Holder

DPP Micro Reader with Holder

a. Connect the DPP Micro Reader to the supplied holder. Insert the base of the reader so that the "slanted" edge meets the corresponding "slanted corner" in the holder cavity. The reader should lay flat in the holder and the button and battery compartment should face the sample well and the user.

"Slanted" Edge



b. At the time indicated for reading the test results, place the reader and holder on the TOP IgM Test Window of the device and push the button. ***"ON"*** will appear in the display window.

c. Press the button again; the display will read ***"RFID"***. Place the DPP ZCD IgM/IgG RFID card on top of the reader and an audible beep will sound. Remove the card and ***"TEST"*** will appear in the display window.

d. Press the button and ***"RUN"*** will appear in the display window. After approximately 3 seconds, numerical values for the IgM results for each of the test lines are displayed; **record the IgM results (refer to INTERPRETATION OF TEST RESULTS)**.

Move the reader to the BOTTOM IgG Test Window.

e. Press the button again; the display will read ***"RFID"***. Place the DPP ZCD IgM/IgG RFID card on top of the reader and an audible beep will sound. Remove the card and ***"TEST"*** will appear in the display window.

Press the button and ***"RUN"*** will appear in the display window. After approximately 3 seconds, numerical values for the IgG results for each of the test lines are displayed; **record the IgG results (refer to INTERPRETATION OF TEST RESULTS)**.

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.

Discard the used Test Device into a biohazard waste container.

QUALITY CONTROL

Built-in Control Feature

The control line serves as a built-in internal control and gives confirmation of sample addition and proper test performance. The reader verifies the presence of the control line and measures color intensity at each of the test line positions; it interprets the results using an algorithm including assay-specific cut-off values, and reports for each test line a numerical value indicating the intensity of the line, followed by the interpretation of that test line as Reactive ***("R")***, Non-reactive ***("NR")***, Indeterminate ***("IND")*** or Invalid ***("INV")***. Please see: **Interpretation of Test Results**.

INTERPRETATION OF TEST RESULTS

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

Test Line 1: DENGUE

NON-REACTIVE

A non-reactive result suggests the absence of antibodies to Dengue virus in the sample and does not exclude the possibility of Dengue virus infection. In this case, the following messages will scroll through the display

where ## is ≤18

Note: Even if a subtle line is visible, the result displayed by the reader as ***"NR"*** should be considered non-reactive.

REACTIVE

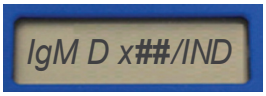
A reactive test means that antibodies to Dengue virus were detected. An IgM reactive result indicates a possible primary immune response to infection. A reactive IgG result indicates a possible current or past infection. An IgM and IgG reactive result indicates a possible late primary immune response. In this case, the following messages will scroll through the display.

where ## is ≥22

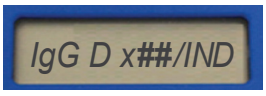
ATTENTION: A REACTIVE RESULT SHOULD BE CONFIRMED ACCORDING TO LOCAL GUIDELINES.

INDETERMINATE RESULT

An Indeterminate Result indicates that it was not possible to define whether the sample is reactive or not. In this case, the following messages will scroll through the reader display.



where ## is >18 and <22



IgM

If there is an indeterminate result in the IgM window, it is recommended that the test be repeated with a new collection. If the result persists, a new sample collection should be performed after 2 or 3 days and the test should be repeated.

IgG

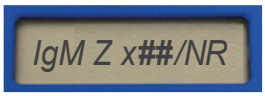
If there is an indeterminate result in the IgG window, this result suggests a suspected infection by other arboviruses.

INTERPRETATION OF TEST RESULTS, cont.

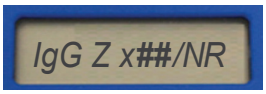
Test Line 2: ZIKA

NON-REACTIVE

A non-reactive result suggests the absence of antibodies to Zika virus in the sample and does not exclude the possibility of Zika virus infection. In this case, the following messages will scroll through the display.



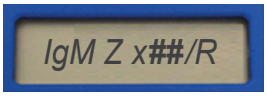
where ## is ≤18



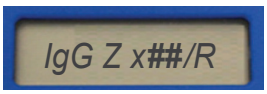
Note: Even if a subtle line is visible, the result displayed by the reader as ***"NR"*** should be considered non-reactive.

REACTIVE

A reactive test means that antibodies to Zika virus were detected. An IgM reactive result indicates a possible primary immune response to infection. A reactive IgG result indicates a possible current or past infection. An IgM and IgG reactive result indicates a possible late primary immune response. In this case, the following messages will scroll through the display.



where ## is ≥22

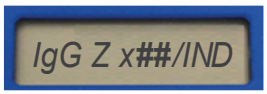


ATTENTION: A REACTIVE RESULT SHOULD BE CONFIRMED ACCORDING TO LOCAL GUIDELINES.

INDETERMINATE RESULT

An Indeterminate Result indicates that it was not possible to define whether the sample is reactive or not. In this case, the following messages will scroll through the reader display.

where ## is >18 and <22



IgM

If there is an indeterminate result in the IgM window, it is recommended that the test be repeated with a new collection. If the result persists, a new collection should be performed after 2 or 3 days and the test should be repeated.

IgG

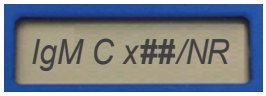
If there is an indeterminate result in the IgG window, this result suggests a suspected infection by other arboviruses.

INTERPRETATION OF TEST RESULTS, cont.

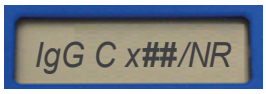
Test Line 3: CHIKUNGUNYA

NON-REACTIVE

A non-reactive result suggests the absence of antibodies to Chikungunya virus in the sample and does not exclude the possibility of Chikungunya virus infection. In this case, the following messages will scroll through the display.



where ## is ≤18



Note: Even if a subtle line is visible, the result displayed by the reader as ***"NR"*** should be considered non-reactive.

REACTIVE

A reactive test means that antibodies to Chikungunya virus were detected. An IgM reactive result indicates a possible primary immune response to infection. A reactive IgG result indicates a possible current or past infection. An IgM and IgG reactive result indicates a possible late primary immune response. In this case, the following messages will scroll through the display.

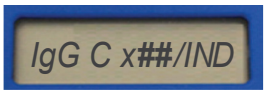
where ## is ≥22

ATTENTION: A REACTIVE RESULT SHOULD BE CONFIRMED ACCORDING TO LOCAL GUIDELINES.

INDETERMINATE RESULT

An Indeterminate Result indicates that it was not possible to define whether the sample is reactive or not. In this case, the following messages will scroll through the reader display.

where ## is >18 and <22



IgM

If there is an indeterminate result in the IgM window, it is recommended that the test be repeated with a new collection. If the result persists, a new collection should be performed after 2 or 3 days and the test should be repeated.

IgG

If there is an indeterminate result in the IgG window, this result suggests a suspected infection by other arboviruses.

INVALID RESULT

A purple / pink line must be identified by the reader in the CONTROL area (C) of both test windows, regardless of the presence or not of the line in the TEST (T) area. If a purple / pink line is not identified by the reader in the CONTROL area (C) of one or both test windows, the test is considered INVALID. In this case, the following message will appear on the display:

An invalid result cannot be interpreted. Repeat the test procedure with a new test device.

Summary interpretation of results for all 3 test lines

REFERENCE TABLE						
RESULT	**Dengue**		**Zika**		**Chikungunya**	
	IgM	IgG	IgM	IgG	IgM	IgG
NON-REACTIVE	≤18	≤18	≤18	≤18	≤18	≤18
INDETERMINATE	>18 and <22	>18 and <22	>18 and <22	>18 and <22	>18 and <22	>18 and <22
REACTIVE	≥22	≥22	≥22	≥22	≥22	≥22

LIMITATIONS OF THE PROCEDURE

1. The DPP ZCD IgM/IgG System must ONLY be used with capillary (fingerstick) blood, venous whole blood, serum or plasma. Using other types of samples or testing of venipuncture whole blood samples/plasma collected using a tube containing an anticoagulant other than EDTA may not yield accurate results. For serum samples, collect blood without anticoagulant.
2. The DPP ZCD IgM/IgG System must be used in accordance with the instructions in this product insert to obtain accurate results.
3. Reading test results earlier than 15 minutes or later than 20 minutes after the addition of Sample/ Buffer mix to Well 1 may yield erroneous results.
4. Reading test results visually may yield erroneous results.
5. Do not open the sealed foil pouch until just prior to use.
6. Do not use kit contents beyond labeled expiration date.
7. Ensure finger is completely dry before performing fingerstick.
8. Perform test procedure and read results in a well-lit area.
9. A REACTIVE result using the DPP ZCD IgM/IgG System suggests the presence of Zika, Chikungunya, and/or Dengue antibodies in the sample and the REACTIVE test result is interpreted as Preliminary Positive for the virus. The DPP ZCD IgM/IgG System is intended as an aid in the diagnosis of infection with Zika, Chikungunya and/or Dengue virus. REACTIVE test results have to be confirmed by additional testing with a different test method.
10. A NON-REACTIVE result does not preclude the possibility of exposure to Zika, Chikungunya and/ or Dengue or infection with the Zika, Chikungunya, and/or Dengue virus.
11. This assay has not been evaluated for testing cord blood, for testing neonates, for testing blood or plasma donors, for prenatal screening, or for general population screening.

SENSITIVITY STUDIES

DENV SENSITIVITY

The sensitivity of the DPP ZCD IgM/IgG System for DENV IgM antibodies was evaluated using 74 plasma samples reactive with a CE Marked DENV IgM EIA and for DENV IgG, using 130 plasma samples reactive with a CE Marked DENV IgG EIA. Relative sensitivities of the DPP ZCD IgM/IgG compared to the EIA tests are presented in Table 1.

Table 1: Relative Sensitivities of DPP ZCD IgM/IgG System for IgM and IgG

Specimen ID	DPP ZCD IgM/IgG System Dengue IgM+, Comparator EIA IgM+	DPP ZCD IgM/IgG System Dengue IgG+, Comparator EIA IgG+
Plasma Services Group Puerto Rican Plasma	14/15 = 93.3%	41/44 = 93.2%[2]
Discovery Life Sciences Vietnamese Plasma	53/54 = 98.1%[1]	79/83 = 95.2%[3]
Total	67/69 = 97.1%	120/127 = 94.5%

[1] Five DPP IgM IND not included in calculation
[2] One DPP IgG IND not included in calculation
[3] Two DPP IgG IND not included in calculation

The DPP ZCD IgM/IgG System detected the presence of antibodies to Dengue specimens similarly to the Dengue EIAs. Relative sensitivities for both IgM and IgG antibodies were 93% or greater.

Additionally, relative sensitivity for the DPP ZCD IgM/IgG System was evaluated using three commercially available panels:

1. SeraCare Dengue Mixed Titer Panel 0845-0074 (21 panel members)
2. Zeptometrix SeroDetect Dengue Fever Verification Panel K-ZMC028 (10 panel members)
3. Plasma Services Group Arbovirus Panel ID #17262 (5 panel members)
   These panels are composed of undiluted naturally occurring plasma samples demonstrating reactivity ranging from non-reactive to strongly reactive for antibodies to dengue.

The calculated relative sensitivities for IgM and IgG antibodies to Dengue of the DPP ZCD IgM/IgG System as compared to the same CE Marked assays are presented in Table 2.

Table 2: Reactivity with Dengue Mixed Titer Performance Panel

Panel ID	DPP ZCD IgM/IgG System Dengue IgM+, Comparator EIA IgM+	DPP ZCD IgM/IgG System Dengue IgG+, Comparator EIA IgG+
SeraCare Dengue Panel # 0845-0074	6/6 = 100%	16/18 = 89%
Zeptometrix Dengue Panel K-ZMC028	5/5 = 100%[4]	8/8 = 100%
Plasma Services Group Arbovirus Panel	3/4 = 75%	5/5 = 100%

[4] One DPP IgM IND not included in calculation

ZIKV SENSITIVITY

The sensitivity of the DPP ZCD IgM/IgG System for antibodies to Zika virus was evaluated using Zika seroconversion panels obtained from Boca Biolistics for 15 individuals. Eight visits were made for each individual resulting in a total of 120 specimens tested. The negative and positive percent agreements of the DPP ZCD IgM/IgG System with two IgM EIAs and one IgG EIA at specific intervals post onset of symptoms are shown in Tables 3 and 4.

Table 3: Seroconversion Comparisons for DPP ZCD IgM/IgG System with Two EIAs for IgM Antibody Detection

Days Post Onset of Symptoms	Comparator IgM EIA-1 Zika IgM Non-Reactive	Comparator IgM EIA-1 Zika IgM Reactive	Comparator IgM EIA-2 Zika IgM Non-Reactive	Comparator IgM EIA-2 Zika IgM Reactive
	Negative Percent Agreement	Negative Percent Agreement	Negative Percent Agreement	Negative Percent Agreement
0-7	11/12 = 91.7%	3/5 = 60.0%	11/15 = 73.3%	0/0
8-14	0/0	12/12 = 100%	0/3 = 0%	9/9 = 100%
15-28	0/1 = 0%	25/25 = 100%	0/20 = 0%	1/1 = 100%
29-42	0/0	26/26 = 100%[1]	0/26 = 0%	0/0
43-56	0/3 = 0%	18/19 = 94.7%[2]	1/22 = 4.5%[2]	0/0
57-70	1/6 = 16.7%	3/4 = 75.0%[1]	0/10 = 0%[1]	0/0
71-84	0/1 = 0%	2/2 = 100%	0/3 = 0%	0/0

[1] One DPP IND not included in calculations
[2] Two DPP IND not included in calculations

Comparator ZIKV IgM EIA-1 FDA Cleared
Comparator ZIKV IgM EIA-2 CE Marked
Comparator ZIKV IgG EIA-3 CE Marked

Table 4: Seroconversion Comparisons for DPP ZCD IgM/IgG System with an EIA for IgG Antibody Detection

Days Post Onset of Symptoms	Comparator IgG EIA-3 Zika IgG Non-Reactive	Comparator IgG EIA-3 Zika IgG Reactive
	Negative Percent Agreement	Negative Percent Agreement
0-7	3/4 = 75%	11/11 = 100%[3]
8-14	0/0	12/12 = 100%
15-28	0/0	26/26 = 100%
29-42	0/0	27/27 = 100%
43-56	0/0	24/24 = 100%
57-70	0/0	11/11 = 100%
71-84	0/0	3/3 = 100%

[3] Two DPP IND not included in calculations

The DPP ZCD IgM/IgG System sensitivity agrees well with all three EIAs. However, as illustrated by the fact that no EIA-2 positive IgM results were detected from day 29 to 84 the EIA-2 sensitivity to IgM antibodies is very low. The comparison with IgM EIA-1 produces a better indication of performance.

The performance of the DPP ZCD IgM/IgG System was also evaluated using three different commercially available panels:

1. SeraCare Accuset Zika Performance Panel # 0845-0142 (10 panel members)
2. Zeptometrix Zika Seroconversion Panel # KZMC047 (7 panel members)
3. Plasma Services Group Arbovirus Evaluation Panel (6 panel members)

The results as compared to those for the same EIA-1 IgM (where available), EIA-2 IgM and EIA-3 IgG assays are tabulated below in Table 5.

Table 5: Relative Reactivity of DPP ZCD IgM/IgG System with Three Zika Panels Compared to EIAs

Panel ID	DPP ZCD IgM/IgG System Zika IgM+ Comparator EIA-1 IgM+	DPP ZCD IgM/IgG System Zika IgM+ Comparator EIA-2 IgM+	DPP ZCD IgM/IgG System Zika IgG+ Comparator EIA-3 IgG+
SeraCare Zika Panel # 0845-0142	7/8 = 88%	1/1 = 100%	10/10 = 100%
Zeptometrix Zika Panel KZMC047	Not Available	4/4 = 100%	4/4 = 100%
Plasma Services Group Arbovirus Panel	3/3 = 100%[4]	3/3 = 100%[4]	3/3 = 100%

[4] One DPP ZCD IgM/IgG System IND for Zika IgM not included in calculations

The DPP ZCD IgM/IgG System sensitivity for Zika IgM and IgG antibodies compared well with the EIA results for these panels.

Table 6 below illustrates the relative sensitivity of the DPP ZCD IgM/IgG System as compared to the same EIA assays using six well-characterized El Salvador Zika samples obtained from Advance Biosource and PCR Zika reactive specimens from Peru.

Table 6: Relative Reactivity with El Salvador and Peru Zika Samples Compared to EIAs

Sample ID	# of Panel Members Tested	DPP ZCD IgM/IgG System Zika IgM+ Comparator EIA-1 IgM+	DPP ZCD IgM/IgG System Zika IgM+ Comparator EIA-2 IgM+	DPP ZCD IgM/IgG System Zika IgG+ Comparator EIA-3 IgG+
Advance Biosource *El Salvador*	6	5/5 = 100%	1/1 = 100%	6/6 = 100%
PCR Zika Reactive *Peru*	98 with EIA-1 49 with EIA-2 49 with EIA-3	17/21 = 81.0%[5]	0/0	49/49 = 100%

[5] Thirteen DPP ZCD IgM/IgG System IND for Zika IgM not included in calculations

The DPP ZCD IgM/IgG System again detected the presence of IgM and IgG antibodies to Zika specimens similarly to the Zika EIA assays.

CHIKV SENSITIVITY

The sensitivity of the DPP ZCD IgM/IgG System for IgM and IgG antibodies to chikungunya virus was evaluated by testing 37 chikungunya samples obtained from Plasma Services Group along with 5 positive chikungunya samples which are part of a Plasma Services group arbovirus panel. Results obtained on the DPP ZCD IgM/IgG System were compared to results obtained with a CE Marked CHIKV IgM EIA and a CE Marked CHIK IgG EIA. Results are summarized in Table 7.

Table 7: DPP ZCD IgM/IgG Comparison to IgM and IgG Anti-Chikungunya Virus EIAs

Specimens	DPP ZCD IgM/IgG System Chikungunya IgM+ Comparator EIA IgM+	DPP ZCD IgM/IgG System Chikungunya IgG+ Comparator EIA IgG+
Plasma Services Group *37 Chikungunya Specimens*	35/35 = 100%	35/35 = 100%[1]
Plasma Services Group *Arbovirus Panel Chikungunya Specimens*	5/5 = 100%	5/5 = 100%

[1] One DPP IND and one EIA equivocal not included in calculations

The DPP ZCD IgM/IgG System results are equivalent to those of both the EIA assays.

SPECIFICITY STUDIES

ENDEMIC SAMPLES

The specificity of the DPP ZCD IgM/IgG System was evaluated using 300 serum samples procured from an endemic region in Rio, Brazil. Samples were presumed negative at the time of collection during routine hospital visits.

Table 8: Specificity with Specimens from Asymptomatic Individuals from an Endemic Region

	DPP ZCD IgM/IgG System											
	Lot 1						Lot 2					
	DENV	ZIKV	CHIKV	DENV	ZIKV	CHIKV	DENV	ZIKV	CHIKV	DENV	ZIKV	CHIKV
	IgM			IgG			IgM			IgG		
Non-Reactive	293	299	292	44	151	269	292	299	285	50	161	269
Reactive	4	1	5	252	141	31	6	1	9	249	133	31
Indeterminate	3	0	3	4	8	0	2	0	6	1	6	0
Total	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**	**300**
% Non-Reactive	97.7	99.7	97.3	14.7	50.3	89.7	97.3	99.7	95.0	16.7	53.7	89.7
% Reactive	1.3	0.3	1.7	84	47	10.3	2.0	0.3	3.0	83	44.3	10.3
% Indeterminate	1.0	0	1.0	1.3	2.7	0	0.7	0	2.0	0	2.0	0

IgM specificity of 95% or greater for the DPP ZCD IgM/IgG System was demonstrated for the specimens from an endemic region.

DENV SPECIFICITY

A total of 440 specimens consisting of 280 bloods, 100 plasma and 60 sera sourced from asymptomatic individuals living in the United States, presumed negative for Dengue virus, were evaluated with the DPP ZCD IgM/IgG System. Results are tabulated in Table 9 below.

Table 9: Specificity with Specimens from Asymptomatic Individuals in the United States

Specimens from United States Matrix	DPP ZCD IgM/IgG System Specificity for Dengue IgM	DPP ZCD IgM/IgG System Specificity for Dengue IgG
Whole Blood	277/278 = 99.6%[1]	265/278 = 95.3%
Plasma	98/100 = 98.0%	97/98 = 99.0%[2]
Sera	59/59 = 100%[3]	60/60 = 100%
Total	434/437 = 99.3%	422/436 = 96.8%

[1] Two DPP IgM IND not included in calculation
[2] Two DPP IgG IND not included in calculation
[3] One DPP IgM IND not included in calculation

Specificities with the DPP ZCD IgM/IgG System for the non-endemic specimens was 98% or greater for IgM detection and greater than 95% for IgG detection. These results with specimens from areas non-endemic for dengue virus illustrate good specificity for both IgM and IgG detection.

Additionally, 37 specimens from an endemic region of Colombia, negative for Dengue IgM with a CE Marked DENV IgM EIA were tested with the DPP ZCD IgM/IgG System. Table 10 summarizes the Dengue IgM results for this testing.

Table 10: Relative Specificity for Specimens from Endemic Areas compared to a CE Marked IgM EIA

Specimen ID	DPP ZCD IgM/IgG System Relative Specificity for Dengue IgM
Plasma Services Group Colombia Specimens	34/35 = 97.1%[4]

[4] Two DPP IgM IND not included in calculation

IgM specificity for the DPP ZCD IgM/IgG System relative to the CE Marked IgM EIA of 95% or greater was demonstrated for the specimens from an endemic region.

ZIKA SPECIFICITY

A total of 440 specimens consisting of 280 bloods, 100 plasma and 60 sera sourced from asymptomatic individuals living in the United States, presumed negative for Zika virus, were evaluated with the DPP ZCD IgM/IgG System. Results are tabulated in Table 11 below.

Table 11: Specificity with Specimens from Asymptomatic Individuals in the United States

Specimens from United States Matrix	DPP ZCD IgM/IgG System Specificity for Zika IgM	DPP ZCD IgM/IgG System Specificity for Zika IgG
Whole Blood	279/280 = 99.6%	280/280 = 100%
Plasma	100/100 = 100%	100/100 = 100%
Sera	60/60 = 100%	60/60 = 100%
Total	439/440 = 99.8%	440/440 = 100%

Additionally, 23 HIV positive samples from an area in Brazil endemic for Zika but collected before the Zika outbreak, 71 samples from pregnant women and healthy persons in Peru, tested non-reactive for Zika using an IgM EIA, were examined for specificity with the results shown in Table 12 below.

Table 12: Specificity with Specimens from Brazil and Peru

Sample Source	DPP ZCD IgM/IgG System Specificity for Zika IgM	DPP ZCD IgM/IgG System Specificity for Zika IgG
Brazil HIV+	23/23 = 100%	23/23 = 100%
Peru Pregnant Women and Healthy Persons	71/71 = 100%	70/71 = 98.6%

The DPP ZCD IgM/IgG System exhibits excellent specificity for Zika IgM and IgG.

CHIKV SPECIFICITY

A total of 440 specimens consisting of 280 bloods, 100 plasma and 60 sera sourced from asymptomatic individuals living in the United States, presumed negative for Chikungunya virus, were evaluated with the DPP ZCD IgM/IgG System. Results are tabulated in Table 13 below.

Table 13: Specificity with Specimens from Asymptomatic Individuals in the United States

Specimens from United States Matrix	DPP ZCD IgM/IgG System Specificity for Chikungunya IgM	DPP ZCD IgM/IgG System Specificity for Chikungunya IgG
Whole Blood	276/280 = 98.6%	280/280 = 100%
Plasma	100/100 = 100%	100/100 = 100%
Sera	59/59 = 100%[5]	60/60 = 100%
Total	435/439 = 99.1%	440/440 = 100%

[5] One DPP IgM IND not included in calculation

Specificities for the DPP ZCD IgM/IgG System with the non-endemic specimens was greater than 98% for IgM detection and 100% for IgG detection. These results with these specimens from areas non-endemic for Chikungunya virus illustrate good specificity for both IgM and IgG detection.

Additionally, 50 samples from Peru and 40 samples from Vietnam that were found non-reactive using the CE Marked CHIKV IgM EIA were tested with the DPP ZCD IgM/IgG System and found to be non-reactive with relative specificity = 98.9%.

CROSS REACTIVITY

A total of 139 samples representing 12 unrelated medical conditions were evaluated to determine the level of cross reactivity (if any) to various medical conditions on the DPP ZCD IgM/IgG System. Results are summarized in Table 14 below.

Table 14: Specificity with Specimens Representing Unrelated Medical Conditions

Medical Condition	# Reactive / # Tested					
	IgM			IgG		
	DENV	ZIKV	CHIKV	DENV	ZIKV	CHIKV
Chikungunya Virus IgM/IgG	0/10	0/10	N/A	10/10[1]	1/10[2]	N/A
West Nile Virus IgM/IgG	0/3	0/3	0/3	1/3[3]	0/3	0/3
West Nile Virus IgM	0/8	0/8	0/8	1/8[4]	0/8	0/8
Dengue Virus IgM/IgG	N/A	0/16	0/16	N/A	1/16[5]	0/16
Yellow Fever Virus Post Vaccination	0/12	0/12	0/12	0/12	0/12	0/12
Zika Virus IgM/IgG	0/10	N/A	0/10	9/10[6]	N/A	3/10[7]
Hepatitis C Virus	0/10	0/10	0/10	0/10	0/10	0/10
Epstein Barr Virus IgM/IgG	0/7	0/7	0/7	0/7	0/7	0/7
Epstein Barr Virus IgM Only	0/2	0/2	0/2	0/2	0/2	0/2
Borrelia burgdorferi IgM/IgG	0/4	0/4	0/4	0/4	0/4	0/4
Borrelia burgdorferi IgM Only	0/8	0/8	0/8	0/8	0/8	0/8
Cytomegalovirus IgM/IgG	0/6	0/6	0/6	0/6	0/6	0/6
Cytomegalovirus IgM Only	0/5	0/5	0/5	0/5	0/5	0/5
Rheumatoid Factor	0/16	0/16	0/16	0/16	0/16	0/16
Anti-Nuclear Antibodies	0/11	0/11	0/11	0/11	0/11	0/11
Hepatitis B Virus	0/11	0/11	0/11	0/11	0/11	0/11

[1] DPP IgG reactive samples were also reactive by EuroImmun Anti-Dengue Virus IgG ELISA
[2] One DPP IgG reactive also reactive by EuroImmun Anti-Zika IgG ELISA
[3] One DPP IgG reactive also reactive by EuroImmun Anti-Dengue IgG ELISA
[4] One DPP IgG reactive also reactive by EuroImmun Anti-Dengue IgG ELISA
[5] One DPP IgG reactive also positive by EuroImmun Anti-Zika IgG ELISA
[6] Nine DPP IgG reactive also positive by EuroImmun Anti-Dengue IgG ELISA
[7] Three DPP IgG reactive also positive by EuroImmun Anti-Chikungunya IgG EIA

INTERFERENCE

Controlled studies of potentially interfering substances performed on samples near the clinical decision point showed no interference on the DPP ZCD IgM/IgG System at the highest concentration for each substance listed below in Table 15, with the exception of Rheumatoid Factor. Testing was performed as per CLSI guidelines EP7-A2. The results shown below in Table 15 is the consensus where 2 of the 3 results are in agreement. Only one operator was involved in interpreting results in these studies.

Table 15: Interfering Substances for the DPP ZCD IgM/IgG System

Potential Interfering Substance	Concentration
Hemoglobin	200 mg/mL
Bilirubin Conjugated	0.2 mg/mL
Bilirubin Unconjugated	0.2 mg/mL
Serum proteins (e.g. Human Serum Albumin)	110 mg/mL
Human Anti-mouse Antibody (HAMA)	400 ng/mL
Triglycerides	30 mg/mL
Cholesterol	5 mg/mL
Rheumatoid Factor	4000 IU/mL

PRECISION

Within Laboratory Precision / Repeatability

Within-run assay consistency or repeatability of the DPP ZCD IgM/IgG System was evaluated by using a five member blind-coded panel consisting of varying levels of Zika, Chikungunya and Dengue (ZCD) IgM/IgG antibodies to test one device lot of the DPP ZCD IgM/IgG System. The within-run assay consistency was 100% (300/300) for the IgM lines and 100% (300/300) for the IgG lines of the DPP ZCD IgM/IgG System.

Reproducibility

The reproducibility of the DPP ZCD IgM/IgG System was evaluated using a blinded five member panel containing Dengue, Zika and Chikungunya IgM/IgG antibody negative specimens and antibody positive specimens diluted to varying levels of reactivity. Each panel was conducted by three separate operators in triplicate using three DPP ZCD IgM/IgG System device lots. When tested by three different operators across three lots in triplicate, there was 100% reproducibility (405/405) for the IgM test lines and 100% reproducibility (405/405) for the IgG test lines of the DPP ZCD IgM/IgG System.

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