June 3, 2020

Chembio Diagnostic Systems
Louise Muscat Sigismondi
R&D Director of Regulatory Affairs
3661 Horseblock Road
Medford, New York 11763

Re: K200506
Trade/Device Name: DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader
Regulation Number: 21 CFR 866.3935
Regulation Name: Zika Virus Serological Reagents
Regulatory Class: Class II
Product Code: QFO, QCH, JJQ
Dated: February 27, 2020
Received: March 2, 2020

Dear Louise Sigismondi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven Gitterman, M.D., Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200506

Device Name
DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader

Indications for Use *(Describe)*

DPP Zika IgM System

The DPP Zika IgM System is intended for the presumptive qualitative detection of Zika virus IgM antibodies in human serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood, or fingerstick whole blood 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 symptom onset or after potential exposure as a sample collected earlier may return a negative result. If testing is needed after day 4 but before day 8 and results are negative, testing must be repeated one week later. Positive results must be confirmed by following the latest CDC guidelines for the diagnosis of Zika virus infection.

Results of this test are intended to be used in conjunction with clinical observations, patient history, epidemiological information, and other laboratory results. Zika IgM levels over the course of illness are not well characterized. Zika IgM levels are variable during the course of infection and may be detectable near day 4 post-onset of symptoms and persist up to approximately 12 weeks following initial infection.

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

The Chembio DPP Zika IgM System is not indicated for testing blood or plasma donors.

The test cannot be visually interpreted by the operator and must be read on the DPP Micro Reader.

DPP Zika IgM System Control Pack

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

DPP Micro Reader

The DPP Micro Reader is a reflectance reader used to obtain test results from DPP Zika IgM System. The DPP Micro Reader is necessary to minimize errors from direct visual interpretation; therefore, the results of DPP Zika IgM System cartridges must be read exclusively with the DPP Micro Reader.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Assigned 510(k) Number: K200506

I.	**Date Prepared:**	June 1, 2020
II.	**Applicant Information:**	Louise Sigismondi, Ph.D. Research & Development Director of Regulatory Affairs Chembio Diagnostic Systems Inc. 3661 Horseblock Rd. Medford, NY 11763 Phone: 631-924-1135 Fax: 631-924-2065 Email: lsigismondi@chembio.com
III.	**Regulatory Information:**	
	Trade Name:	DPP® Zika IgM System DPP® Zika IgM System Control Pack DPP® Micro Reader
	Common Name:	Zika virus assay
	Classification Names:	Zika Virus Serological Reagents: Class II, 21 CFR 866.3935; Microbiology (83) Assayed quality control material for clinical microbiology assays: Class II, 21CFR 866.3920; Microbiology (83) Colorimeter, Photometer, Spectrophotometer for Clinical Use: Class I, 21 CFR §862.2300; Clinical Chemistry (75)
	Product Code:	QFO - Zika Virus Serological Reagents QCH - Assayed quality control material for clinical microbiology assays JJQ - Colorimeter, Photometer, Spectrophotometer for Clinical Use
IV.	**Predicate Device:**	InBios ZIKV Detect™ 2.0 IgM Capture ELISA (DEN180069)

V. Intended use/Indication for use:

DPP Zika IgM System

The DPP Zika IgM System is intended for the presumptive qualitative detection of Zika virus IgM antibodies in human serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood, or fingerstick whole blood 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 symptom onset or after potential exposure as a sample collected earlier may return a negative result. If testing is needed after day 4 but before day 8 and results are negative, testing must be repeated one week later. Positive results must be confirmed by following the latest CDC guidelines for the diagnosis of Zika virus infection.

Results of this test are intended to be used in conjunction with clinical observations, patient history, epidemiological information, and other laboratory results. Zika IgM levels over the course of illness are not well characterized. Zika IgM levels are variable during the course of infection and may be detectable near day 4 post-onset of symptoms and persist up to approximately 12 weeks following initial infection.

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

The Chembio DPP Zika IgM System is not indicated for testing blood or plasma donors.

The test cannot be visually interpreted by the operator and must be read on the DPP Micro Reader.

DPP Zika IgM System Control Pack

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

VI. Device Description:

Chembio' s DPP Zika IgM System is a qualitative immunochromatographic assay for the presumptive detection of IgM antibodies to Zika virus. The DPP Zika IgM System is composed of:

1. A single-use immunochromatographic test for the presumptive detection of ZIKV IgM antibodies in human serum (plain or separation gel), potassium-EDTA

plasma, potassium-EDTA venous whole blood, or fingerstick whole blood specimens.

2. The DPP Micro Reader to minimize errors from direct visual interpretation.

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 strip with immobilized 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 Product Insert for the DPP Zika IgM System

1 Quick Reference Guide for the DPP Zika IgM System

Materials required but not provided (system related)

- Chembio DPP Micro Reader.
  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

Additional required materials (assay related)

- Chembio DPP Zika IgM System Control Pack (Catalog #62-1001-1)
  - 1 DPP Zika Reactive Control (300 µl): undiluted, naturally occurring Zika IgM positive plasma samples.
  - 1 DPP Zika Non-Reactive Control (300 µl): undiluted, naturally occurring Zika IgM negative plasma samples.
  - 1 DPP Zika Diluent (300 µl): undiluted, naturally occurring Zika IgM negative plasma samples.
  - 1 Product Insert

  All reagents are supplied ready to use.
- 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 serum, potassium-EDTA plasma, and potassium-EDTA venous whole blood specimens or with the Chembio DPP Zika IgM System Control Pack)

- Microcentrifuge Tubes
- Disposable gloves
- Antiseptic wipes
- Biohazard disposal container
- For fingerstick whole blood specimens:
  - Sterile gauze
  - Sterile Safety Lancets for fingerstick whole blood specimens
- For venous whole blood or serum/plasma specimens:
  - Collection devices

For a fingerstick whole blood sample, sample collection uses a 10 µl Microsafe Tube. For human serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood specimens, 10 µl of sample is collected using a calibrated laboratory pipet. Once the sample and buffer combination are added to the DPP Zika IgM Test Device, results are read by using the Chembio DPP Micro Reader, a portable, maintenance-free, battery-powered instrument that is operated by a single, multi-function button. The results of the DPP Zika IgM Test Device are presented through a 14-segment liquid crystal display (LCD) on the top of the DPP Micro Reader. The DPP Micro Reader is necessary to minimize errors from direct visual interpretation, therefore the results **must not** be visually interpreted by the operator. Controls are kit lot specific and must not be interchanged between different DPP Zika IgM System lots.

VII. Purpose for Submission:

The purpose of this premarket notification is to submit a new device (DPP Zika IgM System) to FDA for consideration for clearance as a 510(k).

VIII. Comparison with predicate:

A comparison of the similarities and differences between the DPP Zika IgM System and the predicate is provided in the table below:

Item	DPP Zika IgM System (K200506)	ZIKV *Detect*™ 2.0 IgM Capture ELISA (DEN 180069)
Similarities		
Analyte	Human IgM antibodies	Human IgM antibodies
Intended Use	The DPP Zika IgM System is intended for the presumptive qualitative detection of Zika virus IgM antibodies in human serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood, or fingerstick whole blood 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	The ZIKV *Detect* 2.0 IgM Capture ELISA is intended for the qualitative detection of Zika virus IgM antibodies in human sera for the presumptive clinical laboratory diagnosis of Zika virus infection. The assay is intended for use only in patients with clinical signs and symptoms consistent 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

	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 symptom onset or after potential exposure as a sample collected earlier may return a negative result. If testing is needed after day 4 but before day 8 and results are negative, testing must be repeated one week later. Positive results must be confirmed by following the latest CDC guidelines for the diagnosis of Zika virus infection. Results of this test are intended to be used in conjunction with clinical observations, patient history, epidemiological information, and other laboratory results. Zika IgM levels over the course of illness are not well characterized. Zika IgM levels are variable during the course of infection and may be detectable near day 4 post-onset of symptoms and persist up to approximately 12 weeks following initial infection. Negative results may be seen in specimens collected before day four post-onset of symptoms or after the window of detectable IgM closes and therefore do not preclude the possibility of Zika virus infection, past or present. The Chembio DPP Zika IgM System is not indicated for testing blood or plasma donors. The test cannot be visually interpreted by the operator and must be read on the DPP Micro Reader.	travel, or other epidemiological criteria for which Zika virus testing may be indicated). Assay results are for the presumptive detection of IgM antibodies to Zika virus (ZIKV). Positive results must be confirmed by following the latest CDC guidelines for the diagnosis of Zika virus infection. Results of this test are intended to be used in conjunction with clinical observations, patient history, epidemiological information, and other laboratory evidence to make patient management decisions. Zika IgM levels are variable over the course of the infection, and may be detectable near day four post onset of symptoms and persist up to approximately 12 weeks following initial infection. Negative results may be seen in specimens collected before day four post onset of symptoms or after the window of detectable IgM closes, and therefore do not preclude the possibility of Zika virus infection, past or present. This assay is not indicated for testing blood or plasma donors.
Differences		
Sample Type	Human serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood, or fingerstick whole blood specimens	Human serum
Sample Size	Minimum of 10 µL before dilution	Minimum of 4 µL before dilution
Antibody Target	NS-1 protein	Zika envelope glycoproteins
Type of Test	Lateral cross-flow dual path platform (DPP) immunochromatographic assay	IgM Capture enzyme-linked immunosorbent assay (ELISA)
External Quality Control	Provided Separately	Included
Interpretation of Results	Qualitative analysis by instrument: reactive or non-reactive for Zika IgM antibodies; invalid	Qualitative analysis by instrument Presumptive Zika Positive, Presumptive Other Flavivirus Positive (non-Zika); negative

	Interpretation of Results is performed by the DPP Microreader. No calculations are required by the user.	Interpretation requires calculations performed by the user prior to reporting the result
Time to Result	Time to result is 15 minutes after addition of Buffer into Well#2.	Time to result is approximately 3.5 hrs.
Reagent Storage	2-8°C Refrigerator or up to 23°C	2-8°C Refrigerator only

IX. Performance Standard:

Standard	Title
CLSI EP05-A3	Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline
CLSI EP07-3rd Ed.	Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition
CLSI EP12-A2	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline, Second Edition
CLSI EP15-A3	User of Performance for Precision and Trueness, Approved Guideline—Third Edition
CLSI EP17-A2	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition
CLSI EP25-A	Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline.
CLSI EP37	Supplemental Tables For Interference Testing In Clinical Chemistry
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
21CFR 820	Quality System Regulation
21CFR 809.10	Labeling for in vitro diagnostic products
21 CFR §866.3935	Special controls, Zika virus serological reagents
21 CFR §862.2300	Colorimeter, photometer, or spectrophotometer for clinical use

X. Performance Characteristics:

a. Clinical Studies

Positive Predictive Agreement

Positive Percent Agreement (PPA) was estimated for serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood, or fingerstick whole blood specimens by comparison with either the EUA or the FDA-cleared comparator assay.

Serum

Positive percent agreement for serum samples was evaluated using the following samples collected from patients residing in flavivirus areas:

- 99 serum samples collected from symptomatic individuals living in Peru, collected within 5-7 days after the onset of symptoms. All samples tested positive by a RT-PCR assay for Zika virus. Only 98 were tested in the EUA comparator assay due to a volume shortage in one sample.

- 11 serum samples sera from individuals living in the Dominican Republic, 6 being Zika-positive by a RT-PCR assay.
- 32 serum samples collected from 26 individuals during a time of arbovirus outbreaks in a flavivirus endemic region of Brazil. All 26 individuals tested positive by a RT-PCR assay for Zika virus. The samples collected from individuals living in Brazil consisted of an initial serum specimen collected from 26 individuals on 1 to 17 days following the onset of fever symptoms, and a second serum specimen collected from 6 of these individuals after 6 to 9 days following the initial blood collection, for a total of 32 specimens.

For samples 'expected' to be positive, forty-one (41) samples were positive by the comparator assay. Overall PPA for serum samples with the EUA comparator assay was 95.1% (39/41; 95% CI=83.9-98.7%). A high percentage of false positive results was observed against the comparator, largely contributed to by the source of the samples.

Overall Serum Agreement

Collection Site	**Total (n)**	**Comparator[1] Zika IgM Reactive**			**Comparator[1] Zika IgM Non-Reactive**		
		DPP Zika IgM System Reactive (R) [2]	DPP Zika IgM System Non-Reactive (NR) [2]	**Positive Percent Agreement (95% CI)**	DPP Zika IgM System Reactive (R) [2]	DPP Zika IgM System Non-Reactive (NR) [2]	Negative Percent Agreement
Dominican Republic	11	8	2[3]	**80% (8/10)**	1[4]	0	0% (0/1)
Peru	98	23	0	**100% (23/23)[5]**	68	7	9.3% (7/75[5, 6])
Brazil	32	8[7]	0	**100% (8/8)**	4	20	83.3% (20/24)
Total	141	39	2	**95.1% (39/41)[8] (83.9-98.7%)**	73	27	27% (27/100)

[1] EUA comparator assay reactive samples include Possible and Presumptive Zika Positive Specimens. EUA comparator assay non-reactive samples include Negative and Presumptive Other Flavivirus Positive specimens.
[2]This study was performed with an older version of the DPP Zika IgM System that was determined equivalent to the one under clearance.
[3]Negative for Zika IgM antibody by both the DPP Zika IgM System and a second authorized Zika IgM assay, while positive by an EUA Zika virus rtPCR assay and the EUA test used as a comparator.
[4]Negative for Zika IgM antibody by both the EUA test used as a comparator and a second authorized Zika IgM assay, while positive by an EUA Zika virus rtPCR assay.
[5]All samples tested positive by a rtPCR assay for Zika virus.
[6]All samples were ≤7 days post onset of symptoms. Even when positive by PCR, depending on the sensitivity of the assay, the level of antibodies may be low for detection.
[7]There were 8 positive samples in total in the 32. Two out of eight (2/8) samples were a single sample picked in both the first and second blood draw; 1/8 was only picked on the first blood draw; 5/8 were picked only on the second blood draw.
[8]Two of the eight (2/8) Brazilian positive samples were a single sample picked in both the first and second blood draw and counted twice for final performance calculations. Without double counting the specimen, the total PPA would be 95.0% (83.5-98.6%).

Potassium-EDTA Plasma

Positive percent agreement for potassium-EDTA plasma was evaluated using archived samples consisting of eight serial samples collected from 50 symptomatic subjects confirmed positive for Zika virus by nucleic acid testing from the Dominican Republic. Of these, 299 IgM antibody samples from 48 individuals tested positive by the comparator. Samples included 12 pregnant women. Testing was performed at the manufacturer's laboratory. The results from this study demonstrate 100% positive agreement between the DPP Zika IgM Assay and the comparator for Zika IgM-positive potassium-EDTA plasma samples. Results are presented in the following table:

Potassium-EDTA Plasma Panel, Stratified by Days Post-Onset of Symptoms (Manufacturer Study)

Days Post onset of Symptoms	Comparator[1] Zika IgM Reactive[2]	Comparator[1] Zika IgM Non-Reactive[3]
	Positive Percent Agreement	**Negative Percent Agreement**
0-7*	54.5% (6/11)	72.5% (29/40)
8-14	100.0% (39/39)	NT
15-28	100.0% (82/82)	0% (0/4)
29-42	100.0% (79/79)	0% (0/7)
43-56	100.0% (61/61)	0% (0/21)
57-70	100.0% (19/19)	10% (1/10)
71-84	100.0% (8/8)	0% (0/3)
Total	**100.0% (288/288) (95% CI 98.7-100.0%)**	2.2% (1/45)

* Data from Days 0 – 7 is not included in the calculation of total PPA because obtaining samples prior to 8 days after symptom onset or exposure is not recommended and false negative results are anticipated.
[1] EUA comparator assay
[2] Comparator reactive samples include Possible and Presumptive Zika Positive Specimens.
[3] Comparator non-reactive samples include Negative and Presumptive Other Flavivirus Positive specimens.
NT: Not tested.

Positive percent agreement was also evaluated at external sites using 171 comparator positive IgM antibody potassium-EDTA plasma specimens from 39 individuals living in the Dominican Republic. Forty-nine (49) potassium-EDTA plasma samples prospectively collected from asymptomatic pregnant woman living in the continental United States that were found to be negative in the cleared comparator assay were interspersed for blinding. The 220 samples were divided and sent to two external clinical sites. The combined data are summarized in the following table.

Potassium-EDTA Plasma Panel, Stratified by Days Post-Onset of Symptoms (External Sites)

Days Post-Onset of Symptoms	Comparator Assay Zika IgM Reactive[1]		Positive Percent Agreement (95% CI)
	DPP Zika IgM System Reactive	DPP Zika IgM System Non-Reactive	
8-14	29	0	100.0% (29/29) (88.3-100.0%)
15-28	48	0	100.0% (48/48) (92.6-100.0%)
29-42	46	0	100.0% (46/46) (92.3-100.0%)

43-56	29	0	100.0% (29/29) (88.3-100.0%)
57-70	12	0	100.0% (12/12) (75.8-100.0%)
71-84	7	0	100.0% (7/7) (64.6-100.0%)
Total	171	0	**100.0% (171/171) (97.8-100.0%)**

Nonendemic Normal / Pregnant	**Comparator Assay Zika IgM Non-Reactive[2]**		**Negative Percent Agreement (95% CI)**
	DPP Zika IgM System Reactive	DPP Zika IgM System Non-Reactive	
Asymptomatic	1	48	98.0% (48[3]/49) (89.3-99.6%)

[1] EUA comparator assay reactive samples include Possible and Presumptive Zika Positive Specimens.
[2] Cleared comparator assay non-reactive samples include Negative and Presumptive Other Flavivirus Positive (non-Zika) specimens.
[3] For one sample, the microreader value indicated a negative result, but the end-user recorded an interpretation of "R" for Reactive.

Potassium-EDTA Venous Whole Blood

The PPA of the DPP Zika IgM System for potassium-EDTA venous whole blood was evaluated by two studies. For the first study, samples were tested at either an internal site or at external sites:

- Samples tested at the internal site:
  - 41 plasma samples prepared from a plasma replacement study[1] with serial bleeds over days from symptom onset from 6 individuals residing in the Dominican Republic. All donors were confirmed positive for Zika virus antibodies by the comparator assay.
  - Frozen natural potassium-EDTA venous whole blood samples from ten (10) antibody positive individuals from the Dominican Republic by the comparator assay.

- Samples tested at external sites:
  - 171 antibody positive plasma specimens from a plasma replacement study using the same subset described above for potassium-EDTA plasma plus the 49 antibody negative potassium-EDTA plasma specimens from asymptomatic pregnant women from the US as described above. Results were confirmed by the comparator assay.

Results are summarized in the following table:

[1] Plasma replacement is used here to describe a procedure by which venous whole blood was centrifuged, the plasma portion was removed and the pellet carefully suspended in an equal volume of plasma from another source positive for Zika antibodies.

Potassium-EDTA Venous Whole Blood Agreement
Across Internal and Clinical Sites

Days Post onset of Symptoms	Comparator[1]		Comparator
	Zika IgM Reactive		Zika IgM Non-Reactive
	Positive Percent Agreement	95% Confidence Interval	Negative Percent Agreement
Negative[2]	0% (0/1)	N/A	98% (48[3]/49)
0-7*	83.3% (10/12)	55.2-95.3%	NT
8-14	97.1% (33[4]/34)	85.1-99.5%	NT
15-28	94.7% (54/57)	85.6-98.2%	NT
29-42	96.4% (53/55)	87.7-99.0%	NT
43-56	84.2% (32/38)	69.6-92.6%	NT
57-70	80.0% 12/15	54.8-93.0%	0% (0/1)[1, 5]
71-84	90.9% (10/11)	62.3-93.4%	NT
Total			96.0% (48/50)
Total 8-84	**92.4% (194/210)**	**88-95.3%**	

[1] EUA comparator assay reactive samples include Possible and Presumptive Zika Positive Specimens.
[2] Cleared comparator assay non-reactive samples include Negative and Presumptive Other Flavivirus Positive (non-Zika) specimens.
[3] For one sample, the microreader value indicated a negative result, but the end-user recorded an interpretation of "R" for Reactive.
[4] For one sample, the microreader value indicated a reactive result, but the end-user recorded an interpretation of "NR" for Non-Reactive.
[5] One sample was negative by 2nd authorized Zika IgM serology test.
* Data from Days 0 – 7 is not included in the calculation of total PPA because obtaining samples prior to 8 days after symptom onset or exposure is not recommended and false negative results are anticipated.
NT: Not Tested, and not included in the calculations.

The second study was conducted at 3 clinics in the US using prospectively-collected potassium-EDTA venous whole blood from subjects enrolled in an "all comers" fashion. One of the 300 subjects was excluded because their naïve whole blood tested reactive in the DPP Zika IgM System without being spiked, leaving 299 subjects for analysis. In order to assess positive agreement, samples were contrived by potassium-EDTA plasma replacement into venous whole blood samples to yield negative, low positive, and moderate positive specimens. The contrived samples were tested in a blinded fashion across three

sites. Results were compared against the expected results based on the spiking level for each sample.

Venous Whole Blood Results

Sample	Agreement	Score 95% CI	Combined Agreement
Negative	100% (120/120)	96.9-100.0%	NPA 100% (120/120) (95%CI 96.9-100%)
Low Reactive (2.5x - <3x Cut-Off)	99.1% (115/116)	95.3-99.9%	PPA 99.4% (178/179) (95%CI 96.9-100%)
Moderate Reactive (≥3x - 5x Cut-Off)	100% (63/63)	94.3-100.0%	

Fingerstick Whole Blood

The performance of the DPP Zika IgM System for fingerstick whole blood was evaluated at 4 near-patient sites in the US. A total of 375 adult subjects across the four sites were enrolled on an "all comers" basis. Fresh seronegative fingerstick whole blood samples (non-anticoagulated) were collected using sample vials that were pre-spiked with Zika IgM antibody positive plasma or potassium-EDTA plasma to create negative, low positive and moderate positive Zika samples. Presence or absence of Zika IgM antibodies in the spiking material was corroborated by comparator testing. Of the 375 subjects, two (2) were eliminated due to protocol deviations in data transcription and one (1) subject was excluded because their naïve whole blood tested reactive in the DPP Zika IgM System without being spiked, leaving 372 subjects for analysis. The vials were coded so that study staff and the two trained operators at the clinical laboratory were not aware of the predetermined reactivity of the spiked sample vials. The results are summarized below.

Fingerstick Whole Blood Results

Sample	Agreement	Score 95% CI	Combined Agreement
Negative	97.8% (132/135)	93.7-99.2%	NPA 97.8% (132/135) (95%CI 93.7-99.2%)
Low Reactive (2.5x - <3x Cut-Off)	98.0% (146/149)	92.3-99.3%	PPA 98.7% (234/237) (95%CI 96.4-99.6%)
Moderate Reactive (≥3x - 5x Cut-Off)	100.0% (88/88)	95.8-100.0%	

Negative Predicative Agreement

Negative Percent Agreement of the DPP Zika IgM System was established using prospectively collected potassium-EDTA venous and fingerstick whole blood samples from 250 subjects living in a Zika endemic area and 250 subjects living in a Zika non-endemic area. Potassium-EDTA venous samples and fingerstick whole blood were tested

at seven (7) point-of-care sites including four (4) sites in areas endemic for mosquito-borne flaviviruses and three (3) sites in non-endemic areas.

Paired serum and potassium-EDTA plasma were forwarded to a reference laboratory where they were tested for Zika virus antibodies with the DPP Zika IgM System and the comparator method. Samples were expected to be negative for Zika IgM antibodies due to the low prevalence of Zika virus during the study. For those samples found positive, results were expressed as a percentage of positive results in the total population under study. Samples were tested using the DPP Zika IgM System, the cleared comparator assay, and an additional serology EUA test. Results are summarized in the following tables.

Endemic Area

	NPA[#] of ***DPP Zika IgM System*** by Comparison with Samples Negative By				Percent of Positive Results in Population	
	FDA Cleared Comparator[1]	Additional EUA Test[2]	Both FDA Cleared and EUA tests	***DPP Zika IgM System***[3]	FDA Cleared Comparator[1]	Additional EUA Test[2]
Serum	94.3% (213/226) 95%CI 90.4-98.6	94.8% (218/230) 95%CI 91.1-97.0	95.7% (202/211) 95%CI 92.1-97.7	8.0% (20[a]/250)	9.6% (24/250)	7.6% (19/250)
Potassium-EDTA Plasma	93.4% (211/226) 95%CI 89.3-95.9	93.0% (214/230) 95%CI 89.0-95.7	93.8% (198/211) 95%CI 89.8-96.4	8.8% (22[b]/250)	9.6% (24/250)	7.6% (19/250)
Potassium-EDTA Venous Whole Blood	93.8% (212/226) 95%CI 89.9-96.3	94.4% (217/230) 95%CI 90.6-96.7	94.8% (200/211) 95%CI 90.9-97.1	7.6% (19[c]/250)	9.6% (24/250)	7.6% (19/250)
Capillary Whole Blood	96.0% (217/226) 95%CI 92.6-97.9	96.5% (222/230) 95%CI 93.3-98.2	97.2% (205/211) 95%CI 93.9-98.7	5.6% (14[d]/250)	9.6% (24/250)	7.6% (19/250)

[#]Calculated using the score method.
[1] Detects IgM antibodies against envelope
[2] Detects IgM and IgG antibodies anti NS-1
[3] Detects IgM antibodies anti NS-1
[a] 15 agree in 3 or all matrices, the remaining in 2 or less
[b] 14 agree in 3 or all matrices, the remaining in 2 or less
[c] 14 agree in 3 or all matrices, the remaining in 2 or less
[d] 11 agree in 3 or all matrices, the remaining in 2 or less

Non-Endemic Area

	NPA[#] of ***DPP Zika IgM System*** by Comparison with Samples Negative By				Percent of Positive Results in Population		
	FDA Cleared Comparator[1]	Additional EUA Test[2]	Both FDA Cleared and EUA tests		***DPP Zika IgM System***[3]	FDA Cleared Comparator[1]	Additional EUA Test[2]
Serum	98.0% (239/244) 95%CI 95.3-99.1	98.3% (225/229) 95%CI 95.6-99.3	98.2% (220/224) 95%CI 95.5-99.3		2.0% (5[a]/250)	2.4% (6/250)	8.4% (21/250)
Potassium-EDTA Plasma	96.7% (236/244) 95%CI 93.7-98.3	97.8% (224/229) 95%CI 95.0-99.1	97.8% (219/224) 95%CI 94.9-99.0		3.2% (8[b]/250)	2.4% (6/250)	8.4% (21/250)
Potassium-EDTA Venous Whole Blood	97.1% (237/244) 95%CI 94.2-98.6	97.4% (223/229) 95%CI 94.4-98.8	97.3% (218/224) 95%CI 94.3-98.8		2.8% (7[c]/250)	2.4% (6/250)	8.4% (21/250)
Capillary Whole Blood	98.4% (239/243)[4] 95%CI 95.9-99.4%	98.7% (226/229) 95%CI 96.2-99.6	98.7% (221/224) 95%CI 96.1-99.5		1.6% (4[d]/250)	2.4% (6/250)	8.4% (21/250)

[#] Calculated using the score method.
[1] Detects IgM antibodies against envelope
[2] Detects IgM and IgG antibodies anti NS-1
[3] Detects IgM antibodies anti NS-1
[4] FS result from one subject excluded due to protocol deviation (Test read < 15-minutes)
[a] 4 agree in 3 or all matrices, the remaining in 2 or less
[b] 4 agree in 3 or all matrices, the remaining in 2 or less
[c] 4 agree in 3 or all matrices, the remaining in 2 or less
[d] 3 agree in 3 or all matrices, the remaining in 2 or less

Performance Against the FDA Plasma Zika Panel

Performance of the DPP Zika IgM System was evaluated by testing a panel of samples provided to the sponsor by FDA. The panel consists of plasma samples from individuals infected with Zika, West Nile, or Dengue viruses. Samples were collected at different time points from Zika infection documented by PCR; samples taken early or late after infection may be anticipated to be antibody negative. Samples were randomized and blinded for testing. Results were as follows:

		DPP Zika IgM System	
		Presumptive Zika Positive	**Negative**
Zika IgM Consensus	**Positive (n=24)**	23	1
	Negative (n=12)	1	11

PPA= 23/24 = 95.8%
NPA= 11/12 = 91.7%

		DPP Zika IgM System	
		Presumptive Zika Positive (False Positives)	Negative
Cross-reactivity Evaluation	West Nile* (n=10)	1	9
	Dengue* (n=10)	0	10

* Samples were antibody positive for West Nile or Dengue viruses, and negative for Zika virus.

This evaluation was performed using samples provided by Blood Systems Research Institute (BSRI, now Vitalant Research Institute) from a study supported by Contract No. HHSN268201100001I from the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health. The panel composition and consensus results are the responsibility of the FDA and do not necessarily represent the official views of BSRI, the NHLBI, or the National Institutes of Health.

b. Analytical performance:

i. Precision/Reproducibility of the DPP Zika IgM System:

DPP Zika IgM System reproducibility was evaluated at 3 different US sites with two runs per day, each run performed by one operator with one unique instrument (6 operators and 6 instruments in total) on 5 separate days. All samples were run as three replicates using three (3) lots of the DPP Zika IgM System. A blinded panel consisting of four plasma samples, including a 'negative', 'high negative', 'low positive,' and 'moderate positive,' were tested in this study.

Precision estimates were derived for reproducibility.

Reproducibility of the DPP Zika IgM System

Sites, Days, Operators			Within-Run		Between-Operator/Instrument		Between-Day		Between-Lot		Between-Sites		Total*	
Sample ID	**Mean Value**	**N**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Moderate Positive	110.0	270	13.4	12.2	2.8	2.5	0.0	0.0	6.3	5.8	0.0	0.0	15.1	13.7
Low Positive	36.5	270	5.5	15.0	2.4	6.7	0.0	0.0	3.6	1.0	0.0	0.0	7.0	19.0
High Negative	15.1	270	3.3	21.5	1.5	9.8	0.0	0.0	1.0	6.6	0.0	0.0	3.7	24.5
Negative	1.7	270	1.3	n/a	0.0	n/a	0.0	n/a	0.0	n/a	1.3	n/a	1.8	n/a
%CV coefficient of variation expressed as a percentage; SD standard deviation.														

* Total = Within-Run + Between-Operator/Instrument + Between-Day + Between-Lot + Between-Site

ii. Precision/Reproducibility of the DPP Zika IgM Control Kit

Internal precision for the DPP Zika IgM Control Kit was tested at a single site over the course of 5 days by two different technicians using two instruments per operator. All samples were run in duplicate per run with 2 runs per day, morning and afternoon. One lot of the DPP Zika IgM System and one lot of the DPP Zika IgM Control Kit consisting of a DPP Zika Reactive Control, a DPP Zika Non-Reactive Control and a DPP Zika Diluent was used. The DPP Zika Reactive Control and DPP Zika Diluent was used in a ratio of 1:3 to make the low-reactive control as per the instructions for use fresh, each day of testing.

5-day Precision Results for DPP Zika IgM System Control Pack

			Within-Run		Between-Run		Between-Instrument		Between-Operator		Between-Day		Total*	
Sample ID	Mean Reader Value	N	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Moderate Positive Control	54.1	80	8.5	15.7	0.0	0.0	4.7	8.6	0.0	0.0	0.0	0.0	9.7	17.9
Low Positive Control	31.9	80	5.6	17.5	0.9	3.0	1.8	5.6	4.2	13.0	0.0	0.0	7.2	22.7
Negative Control	3.4	80	1.3	n/a	0.3	n/a	0.6	n/a	0.0	n/a	0.3	n/a	1.5	n/a

* Total = Within-Run + Between-Run + Between-Instrument + Between-Operator + Between-Day

iii. Linearity/assay reportable range:

N/A

iv. Analytical specificity:

a. Cross-Reactivity:

Cross-reactivity of the DPP Zika IgM System was evaluated by testing a total of 329 specimens from patients with IgM antibodies to closely related viruses as well as pathogens where infection produces symptoms similar to those observed during Zika virus infection, and autoantibodies which could potentially cause false positive results. A total of eighteen (18) different organisms/conditions per the supplier's Certificate of Analysis for various disease states, using FDA cleared/ approved devices when possible, were assessed. Of those, two (2) were found to be cross-reactive on the DPP Zika IgM System. The % Cross Reactivity for Cytomegalovirus and Dengue Virus on the DPP Zika IgM System is 5.3% and 2%, respectively. Babesia cross-reactivity was not evaluated.

Summary of DPP Zika IgM System Cross Reactivity

			DPP® Zika IgM System		
	Organism/Condition	**# of Specimens**	**# Zika Negative**	**# Zika Positive**	**% Cross-reactivity**
Flavivirus	Anti-Chikungunya virus IgM	26	26	0	0%
	Anti-Dengue Virus IgM	48	47	1*	2.0%
	Anti-West Nile Vile IgM	28	28	0	0%
	Yellow fever virus post-immunization[1]	32	32	0	0%
Other Viruses/ diseases	Anti- Malaria/anti-*plasmodium falciparum*[2]	20	20	0	0%
	Anti-*Borrelia sp*. (Lyme Disease) IgM	10	10	0	0%
	Anti-Cytomegalovirus (CMV) IgM	38	36	2**	5.3%
	Anti-Epstein Barr Virus (EBV) IgM	10	10	0	0%
	Anti-Hepatitis (B) virus (Total)	13	13	0	0%
	Anti-Hepatitis (C) virus (Total)	10	10	0	0%
	Anti-Herpes simplex virus 1 and 2 (HSV-1, HSV-2) IgM	23	23	0	0%
	Anti-Leptospira (Lepotospirosis) IgM[3]	16	16	0	0%
	Anti-nuclear Antibodies (ANA)	11	11	0	0%
	Anti-Parvovirus B19 IgM	7	7	0	0%
	Anti-Rubella virus IgM	12	12	0	0%
	Rheumatoid Factor	12	12	0	0%
	Anti-Varicella zoster virus IgM	3	3	0	0%
	Human Anti-mouse Antibody (HAMA)	10	10	0	0%
	Total	329	326	3	

* Negative by an FDA cleared Zika Assay. West Nile equivocal.
** Negative by an FDA cleared Zika Assay.
[1] IgM levels could not be established.
[2] Specimens were confirmed positive for Malaria infection by Giemsa and Microscopy but serological status is not known.
[3] Pretreated with rheumatoid factor-absorbent prior to IgM detection.

b. Interference:

Potentially interfering endogenous substances were evaluated with the DPP Zika IgM System. Interfering substances were spiked into low reactive (n=3) and normal human plasma samples (n=3) to evaluate their impact on assay performance. Only one operator was involved in interpreting results in these studies. No interference was observed.

Interfering Substances for the DPP Zika IgM System

Interfering Substance	**Concentration**	**DPP Zika IgM system (#reactive/#tested)**	
		Negative Diluent (Non-Reactive)	**Zika IgM Spike (2x LoD)**
Hemoglobin	10 mg/mL	0/3	3/3
Bilirubin, Conjugated	0.4 mg/mL	0/3	3/3

Bilirubin, Un-Conjugated	0.4 mg/mL	0/3	3/3
Serum Proteins	60 mg/mL	0/3	3/3
HAMA	732 ng/mL	0/3	3/3
Cholesterol	4 mg/mL	0/3	3/3
Rheumatoid Factor	2000 IU/mL	0/3	3/3
Triglycerides	15 mg/mL	0/3	3/3

v. Traceability, Stability, Expected values (controls, calibrators, or methods):

a. *Traceability/Analytical Sensitivity*:

The analytical sensitivity at the cut-off values for the DPP Zika IgM System was established using WHO 1st International standard for anti-Asian lineage Zika virus antibody (human) (NIBSC 16/352). This preparation contains antibodies reactive to Dengue virus. The standard was used to prepare a dilution series. The concentration of the reference reagent that corresponds to average reader values just above the cut-off of 20 (average values of <30 when analyzed by the DPP Micro Reader) and where at least 95% of all replicates tested reactive was 650 IU/mL in serum, 700 IU/mL in potassium-EDTA plasma, and 725 IU/mL in potassium-EDTA venous whole blood.

b. *Stability*:

Evaluations to determine the stability of the Chembio DPP Zika IgM System, Chembio DPP Zika IgM controls and the storage stability of human plasma and serum specimens are summarized below.

Summary of Stability Claims for the DPP Zika IgM Assay System Reagents and Controls	
Stability Type	**Claim**
DPP Zika IgM Assay System Device Shelf-Life Stability (up to 23 °C)	6 months
DPP Zika IgM Assay System Device Shelf-Life Stability (2-8 °C)	12 months
DPP Zika IgM System Reagent In Use (up to 23 °C)	1 month when used within the expiration date
DPP Zika IgM Assay System Control Shelf-Life Stability (-20 °C)	6 months
DPP Zika IgM System Control In Use Stability (-20 °C)	N/A*
DPP Zika IgM System Control Freeze-Thaw Cycles	3

* It is recommended that the end user divide the controls into smaller aliquots that are then frozen back. The end user dilutes the controls only before use, and immediately discards any remaining material after use. Frozen aliquots are acceptable if they are both within the freeze-thaw cycles and the shelf life claimed above.

The user must not open the pouch until ready to perform a test.

The Chembio DPP Zika IgM System must be performed on human serum (plain or separation gel), potassium-EDTA plasma, potassium-EDTA venous whole blood, or fingerstick whole blood specimens. Studies were performed to determine the stability of plasma and serum samples at storage temperatures of 2 to 8°C (36 to 46°F). A multiple freeze/thaw (F/T) study was also performed. Testing was performed with reactivities across the dynamic range of the assay including negative and low positive samples. Stability of samples was determined to be as follows:

Storage	Serum	Plasma
Refrigerated at 2- 8 °C	3 days	3 days
Freeze-thaw cycles	2 cycles	5 cycles

Potassium-EDTA venous whole blood and fingerstick whole blood should be tested at the time of specimen collection.

vi. Detection limit:

See Section v.a. *Traceability/Analytical Sensitivity*

vii. Assay cut-off:

Assay cut-off was evaluated following CLSI EP17-A2 describing the calculation of the Limit of Blank (LoB), using a non-parametric method based on the % cumulative frequency of the results. Samples tested included:

- 569 natural serum samples sourced from the United States and Mexico, both non-endemic populations;
- 184 natural plasma samples sourced from a non-endemic population from the United States (n=95) and an endemic population from Peru (n= 89);
- 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.

Assay cut-off was set at 20 when analyzed by the DPP Micro Reader.

viii. Prozone/ 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. Formal Hook Effect testing was not performed.

ix. Matrix Comparison:

Matrix equivalency was established in comparison to natural matched potassium-EDTA plasma samples or expected reactivity after positive potassium-EDTA plasma spiking. Matrices tested were:

- 11 positive and negative natural matched frozen potassium-EDTA whole

blood, potassium-EDTA plasma and serum samples

- 49 whole blood samples prepared by plasma-replacement using positive potassium-EDTA plasma specimens
- 30 samples for each serum and potassium-EDTA plasma prepared from 5 individual negative sera and plasma sources and spiked with up to a 10% volume of positive potassium-EDTA plasma specimens to obtain high negative, low positive, and 4 values across the dynamic range of the DPP assay run in duplicate
- 50 matched negative sample sets for serum and potassium-EDTA plasma samples sources and spiked with up to a 10% volume of positive potassium-EDTA plasma specimens to obtain high negative, low positive, mid positive, and high positive specimens run in duplicate. Un-spiked negative samples were also included.

Of the multiple combinations of antibody levels and negative individual matrix; disagreement between plasma and serum was observed only for high negative specimens prepared by spiking. Above the cut-off of the assay, there was 100% agreement between matrices.

Summary Table for Matrix Equivalency of the DPP Zika IgM System with Known Positive and Negative Zika Specimens

Matrix	Potassium EDTA Whole Blood	Serum^
Potassium EDTA Plasma	100% (60/60) (% CI 94.0 – 100%)	97.3% (88.5/91) (%CI 91.5-99.2%)

^ Average of mean agreement values for each experiment were used. Some studies have 1 while others 2 replicates per sample. When one replicate agreed and one disagreed, it was counted as 0.5 sample agreement.

x. Class Specificity

To determine if cross reactivity with IgG is a potential assay interferent, a study was performed where the reducing agent Dithiothreitol (DTT) was added to three (3) clinical specimens containing various levels of Zika virus IgM antibodies and high levels of Zika virus IgG antibodies.

All IgM positive samples resulted in non-reactive DPP Zika IgM System results after treatment with DTT. The study results support IgM class specificity.

xi. Carry-Over:

Not applicable as a single sample is run per device.

XI. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision. The labelling is sufficient and it satisfies the requirements of 21CFR 809.10