CE IVD

FRENOVO

Zika IgG/IgM Rapid Test Kit

Instructions For Use

PRODUCT NAME

Zika IgG/IgM Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

Zika IgG/IgM Rapid Test is an in vitro qualitative immunochromatographic assay for the rapid detection of IgG and IgM antibodies to Zika Virus in human blood, serum and plasma specimens simultaneously. The test results are intended to aid in the diagnosis of Zika infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Zika fever, also known as Zika virus disease or simply Zika, is an infectious disease caused by the Zika virus. Most cases have no symptoms, but when present they are usually mild and can resemble Zika fever. Symptoms may include fever, red eyes, joint pain, headache, and a maculopapular rash.Symptoms generally last less than seven days. It has not caused any reported deaths during the initial infection.Mother-to-child transmission during pregnancy can cause microcephaly and other brain malformations in some babies.Infections in adults have been linked to Guillain–Barré syndrome (GBS). Serology for the detection of specific IgM and IgG antibodies to Zika virus can be used. IgM antibodies can be detectable within 3 days of the onset of illness. Serological cross-reactions with closely related flaviviruses such as Zika and West Nile virus as well as vaccines to flaviviruses are possible.

Zika IgG/IgM Rapid Test utilizes the principle of Immunochromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. During testing, the specimen reacts with Zika antigen-coated particles in the test cassette. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates a positive test results. Absence of this colored band in the test window indicates a negative test result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

Each kit contains:

1. test cassettes: 20 pieces test cassettes individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 10 ul.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micro-pipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kits for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. Zika IgG/IgM Rapid Test Kit is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test cassettes from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples: Whole Blood/Serum/Plasma.
2. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected as soon as possible. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
8. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

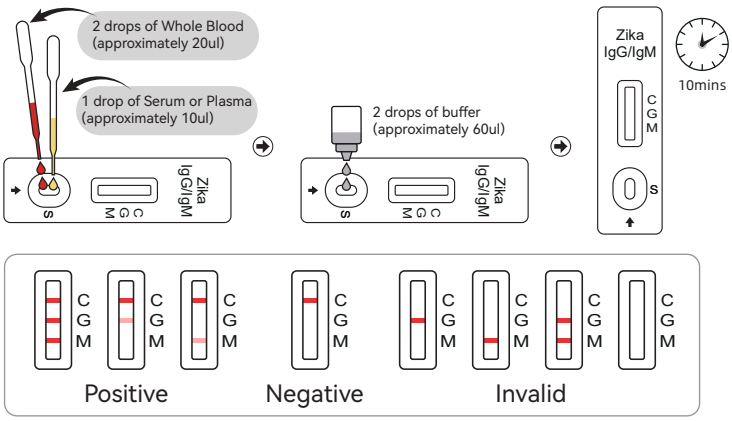
TEST PROCEDURE

Allow the test cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. For Serum or Plasma Specimens
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately

10ul), then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer.
For Whole Blood Specimens
To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 20ul), then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
To use a micro-pipette: Pipette and dispense 20ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add two drops wash buffer solution inside (approximately 60ul) to the sample well and start the timer.

3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

IgG and IgM POSITIVE: Three lines appear. One colored line should be in the control line region(C), and two colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.

IgG POSITIVE: Two lines appear. One colored line should be in the control line region(C), and a colored line appears in IgG test line region.

IgM POSITIVE: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of Zika antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s)should be considered positive.

NEGATIVE: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The Zika IgG/IgM Rapid Test is for in vitro diagnostic use only. This test should be used for detection of IgG and IgM antibody to Zika virus in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of IgG or IgM antibodies to Zika can be determined by this qualitative test.
2. The Zika IgG/IgM Rapid Test will only indicate the presence of IgG and IgM antibodies to Zika in the specimen and should not be used as the sole criteria for the diagnosis of Zika infections.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Zika infection.
5. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The Zika IgG/IgM Rapid Test was compared with a leading commercial EIA Zika IgG tests and Zika IgM tests; the results show that Zika IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

Zika IgM Study		EIA		
Zika IgG/IgM Rapid test	Results	IgM Positive	IgM Negative	Total Results
	IgM Positive	17	0	17
	IgM Negative	1	90	91
Total Results		18	90	108

Zika IgM Study Summary Results:
Clinical sensitivity =94.44% (72.71% ~ 99.86%)
Clinical specificity = 100.00% (95.98% ~ 100.00%)
Accuracy=99.07% (94.95% ~ 99.98%)

Zika IgG Study		EIA		
Zika IgG/IgM Rapid test	Results	IgG Positive	IgG Negative	Total Results
	IgG Positive	22	1	23
	IgG Negative	0	89	89
Total Results		22	90	112

Zika IgG Study Summary Results:
Clinical sensitivity =100.00% (84.56% ~ 100.00%)
Clinical specificity = 98.89% (93.96% ~ 99.97%)
Accuracy=99.11% (95.13% ~ 99.98%)

Interference Substances
The following compounds have been tested using the Zika IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) and no interference was observed.

Substance	Tested Concentration
Acetaminophen	20 mg/dL
Albumin	2 g/dL
Bilirubin	1g/dL
Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Gentisic Acid	20 mg/dL
Ascorbic Acid	2g/dL
Creatin	200mg/dL
Hemoglobin	1000mg/dL
Oxalic Acid	60mg/dL

Cross Reaction
The Zika IgG/IgM Rapid Test has been tested for anti-HAV IgM, HBsAg, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-H. Pylori IgG, anti-Rubella IgG, anti-Rubella IgM, anti-ToxoIgG, anti-ToxoIgM, anti-HSV 1 IgG, anti-HSV 1 IgM, anti- HSV 2 IgG, anti-HSV 2 IgM, anti-Dengue IgG+IgM and anti-Chikungunyalg-G+IgM positive specimens. The results showed no cross-reactivity.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks	CE	CE mark

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INSTRUCTION APPROVAL AND REVISION DATE

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