CE

IVD

Zika IgG/IgM Rapid Test Kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Human Zika IgM/IgG in human serum, plasma or whole blood. *For professional medical institutions use only,Not for self testing.*

PRODUCT NAME

Zika IgG/IgM Rapid Test Kit (Colloidal Gold)

SPECIFICATION

25 tests/kit;5 tests/kit;1 test/kit

INTENDED USE

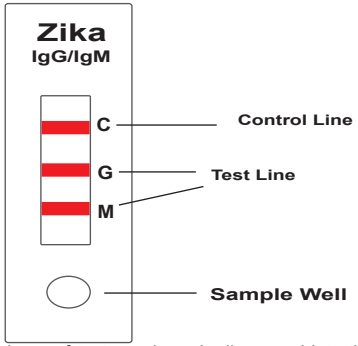
The Zika IgM/IgG Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgM/IgG anti-zika virus (ZIKA) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with ZIKA. Any reactive specimen with the Zika IgM/IgG Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION THE TEST

Zika virus (Zika): mainly transmitted through the bite of Aedes mosquito,mother and child, blood transfusion and sexual transmission.Because there is no vaccine at present,people is generally susceptible to infection. IgG/IgM antibody is produced one week after onset, so the detection of IgG/IgM is of great significance for the early diagnosis of Zika virus. Zika is diagnosed based on serological analysis and viral isolation in mice or tissue culture. An IgM immunoassay is the most practical lab test method. The zika IgM/IgG Rapid Test utilizes recombinant antigens derived from its structure protein, it detects IgM/IgG anti-zika in patient serum or plasma within 15 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Zika IgM/IgG Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant antigen conjugated with colloid gold (Zika conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of IgM anti-Zika, G band is pre-coated with reagents for the detection of IgG anti-Zika, and the C band is pre-coated with goat anti rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. Anti-Zika IgM if present in the specimen will bind to the Zika conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored M band, indicating a Zika IgM positive test result.

Anti-Zika IgG if present in the specimen will bind to the Zika conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored G band, indicating a Zika IgG positive test result.

Absence of any test bands (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

Components	25tests/kit	5tests/kit	1test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	25tubes (300ul/tube)	5tubes (300ul/tube)	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED

Clock or Timer

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2.Do not open the sealed pouch, unless ready to conduct the assay.
3.Do not use expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

Plasma

1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2.Separate the plasma by centrifugation.
3.Carefully withdraw the plasma into new pre-labeled tube.

Serum

1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2.Allow the blood to clot.
3.Separate the serum by centrifugation.
4.Carefully withdraw the serum into a new pre-labeled tube.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

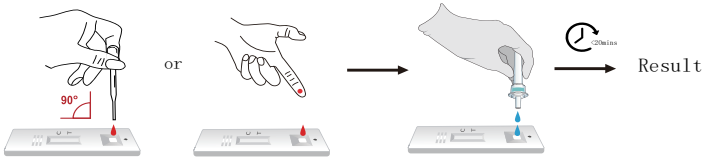
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.

Step 4: **For whole blood test**

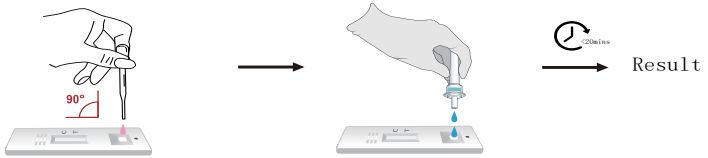
- Apply 1 drop of whole blood (about 20 μL) into the sample well.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test

- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30 μL-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 drops (about 60-70 μL) of Sample Diluent immediately.



1 drop of serum/plasma 2 drops of Buffer

Step 5:Set up timer.
Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.

Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.

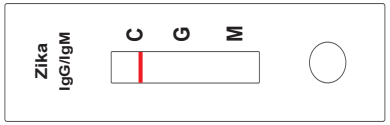
External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in particularly, under the following circumstances:

a. New operator uses the kit, prior to performing testing of specimens.
b.A new lot of test kit is used.
c.A new shipment of kits is used.
d.The temperature used during storage of the kit fall outside of 2°C -30°C .
e.The temperature of the test area falls outside of 15°C -30°C .

INTERPRETATION OF ASSAY RESULT

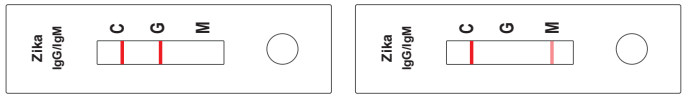
Negative Control

The colored line in the control line region (C) appears. No line appears in test line regions G or M.

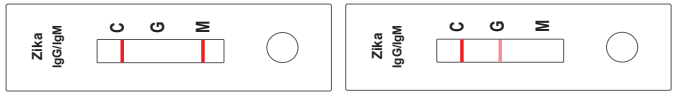


Positive Control

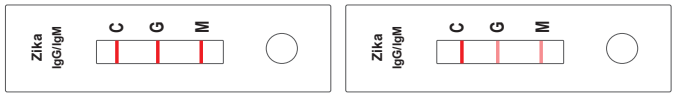
IgG Positive: The colored line in the control line region (C) appears and a colored line appears in test line region G. The result is positive for Zika specific-IgG and is probably indicative of Zika infection.



IgM Positive: The colored line in the control line region (C) appears and a colored line appears in test line region M. The result is positive for Zika specific-IgM antibodies and is indicative of Zika infection.



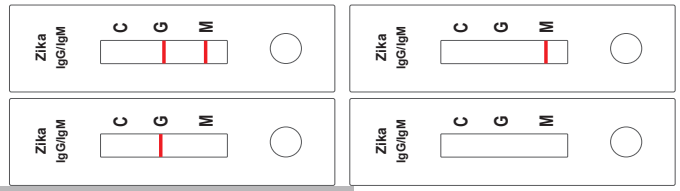
IgG/IgM Positive: The colored line in the control line region (C) appears and two colored lines should appear in test line regions C and T (G and M). The color intensities of the lines do not have to match. The result is positive for IgG & IgM antibodies and is indicative of Zika infection.



Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID:

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands(G and M) as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance For IgM Test

A total of 224 patient samples from susceptible subjects were tested by the Chagas IgG/IgM Combo Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

	Zika IgG/IgM Combo Rapid Test		
IgM EIA Test	Positive	Negative	Total
Positive	90	2	92
Negative	1	171	172
Total	91	173	264

Relative Sensitivity:97.83% , Relative Specificity:99.42%, Overall Agreement: 98.86%

2. Clinical Performance For IgG Test

A total of 326 patient samples from susceptible subjects were tested by the Chagas IgG/IgM Combo Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

	Zika IgG/IgM Combo Rapid Test		
IgM EIA Test	Positive	Negative	Total
Positive	98	2	100
Negative	1	225	226
Total	99	227	326

Relative Sensitivity: 98.0% , Relative Specificity: 99.56%, Overall Agreement: 99.08%

LMITATIONS OF TEST

1. The One Step Zika IgG/IgM Test is for in vitro diagnostic use only. The test should be used for the detection of Zika antibodies in Whole Blood/Serum/Plasma specimens only. Neither the quantitative value nor the rate of increase in Zika antibodies can be determined by this qualitative test.
2. The One Step Zika IgG/IgM Test will only indicate the presence of Typhoid antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Zika infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Zika infection.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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