Asan Easy Test® Zika IgG/IgM

IVD

one step kit for the differential detection of IgG and IgM against zika virus from human serum, plasma or whole blood

Immunochromatography

ASAN

EXPLANATION OF THE TEST

Asan Easy Test® Zika IgG/IgM device is a chromatographic immunoassay kit for rapid and differential detection kit of immunoglobulin G (IgG) and immunoglobulin M(IgM) against all types of Zika viruses from human serum, plasma and whole blood.

Zika-specific antigen complexed with gold conjugate is placed in the conjugate pad, and anti-human IgG and anti-human IgM are immobilized on the membrane.

When Zika antibody-positive specimen is loaded into sample well, the antibodies are captured the immobilized anti-human antibodies. And then, the antibodies are reacted with Zika-specific antigen pad and Zika-Specific antibody-gold complex to make visible band in the test line.

MATERIALS PROVIDED

Asan Easy Test® Zika IgG/IgM contains following items to perform the assay.

1. Test device in aluminum pouch with a desiccant
2. 10 µl capillary pipette
3. Assay solution
4. Instruction manual for use

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1.Specimen Collection and Storage

[Whole blood] Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture.

If blood specimens are not immediately tested, they should be refrigerated at 2~8℃ and should be used within 3days or at -20℃ for longer period.

[Serum] Collect the whole blood into the collection tube(NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.

[Plasma] Collect the whole blood into the collection tube(containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

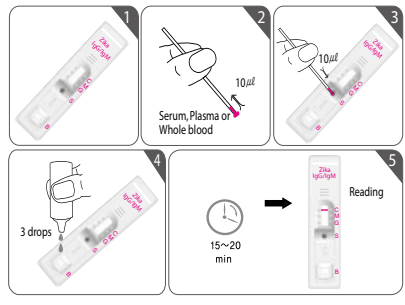
If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8℃ or -20℃ for longer period.

2.Precaution

1) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
2) Anticoagulants such as heparin, EDTA, and citrate do not affect the test result.
3) Use separately disposable capillay pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous result.

TEST PROCEDURE

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
3. Be sure to label the device with specimen's ID number.
4. Apply 103㎕ of serum, plasma or whole blood into the sample well. Then add 3drop (about 100-120 ㎕) of assay solution into the buffer well(B).
5. Set up timer.
6. Results can be read in 15~20 minutes. Don't read result after 20 minutes. To avoid confusion, discard the test device after interpreting the result.



INTERPRETATION OF THE TEST

1. Negative

The control line is only visible on the test device. No Zika-specific IgG and IgM antibodies were dectected. Retest in 3~5 days if zike infection is suspected.

2. IgM Positive

The control line (C) and IgM line (IgM) are visible on the test device. This is positive for IgM antibodies to zike vius. This is indicative of a primary zike infection.

3. IgG Positive

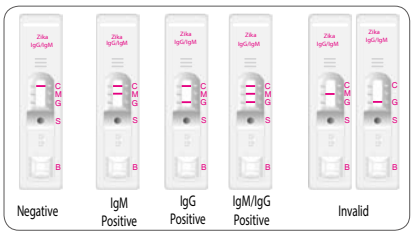
The control line (C) and IgG line (IgG) are visible on the test device. This is positive for IgG antibodies. This is indicative of a secondary of previous zike infection.

4.IgG and IgM Positive

The control line (C), IGM (IgM) and IgG (IgG) are visible on thet test device. This is positive for both IgM and IgG antibodies. This is indicative of a late primary or early secondary zika infection.

5. Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques may be the reasons for control line failure. Repeat the test using a new test device.



STORAGE & EXPIRATION

1. Asan Easy Test® Zika IgG/IgM should be stored between 1 ~ 30℃ (33.8~ 86 ℉).
2. Expiration date of this kit is 24months after its manufacture date.

PERFORMANCE CHARACTERISTICS

This clinical test was performed using a total of 365specimens. Each specimen was tested with Asan Easy Test Zika IgG/IgM and RT-PCR test. The results are summarized in the following tables.

N= 365			RT-PCR		Total
			Positive	Negative	
Asan Easy Test Zika IgG/M	IgG	Positive	78	4	82
		Negative	2	109	111
	IgM	Positive	66	4	70
		Negative	3	99	102
Total			149	216	365

※IgG: Relative Sensitivity (78/80)97.5% Relative Specificity (109/113)96.5%

IgM: Relative Sensitivity (66/69)95.7% Relative Specificity (99/103)96.1%

LIMITATION OF THE TEST

Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but be made by the physician after all clinical and laboratory findings have been evaluated.

ASAN

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