SCREEN® Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

REF IZIG-402	English

A rapid test for a qualitative test for the detection of NS1 antigen of Zika virus in human whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of NS1 antigen of Zika virus in human whole blood, serum, or plasma as an aid in the diagnosis of Zika infections.

【SUMMARY】

Zika virus (ZIKV) is a member of the virus family Flaviviridae.[1] It is spread by daytime-active Aedes mosquitoes, such asA. aegypti and A. albopictus.[1] Its name comes from the Zika Forest of Uganda, where the virus was first isolated in 1947.[2]Zika virus is related to the dengue, yellow fever, Japanese encephalitis, and West Nile viruses.[4] Since the 1950s, it has been known to occur within a narrow equatorial belt from Africa to Asia. From 2007 to 2016, the virus spread eastward, across the Pacific Ocean to the Americas, leading to the 2015–16 Zika virus epidemic.

The infection, known as Zika fever or Zika virus disease, often causes no or only mild symptoms, similar to a very mild form of dengue fever.[1] While there is no specific treatment, paracetamol (acetaminophen) and rest may help with the symptoms.[3]As of 2016, the illness cannot be prevented by medications or vaccines.[3] Zika can also spread from a pregnant woman to her fetus. This can result in microcephaly, severe brain malformations, and other birth defects.[4][5] Zika infections in adults may result rarely in Guillain–Barré syndrome.[6]

The Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of Zika NS1 antibodies coated colored particles for the detection of Zika NS1 antigen in human whole blood, serum, or plasma.

【PRINCIPLE】

The Zika NS1 Rapid Test Cassette(Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Zika NS1 antigen in whole blood, serum, or plasma. During testing, the specimen reacts with Zika NS1 antibody-conjugate in the test cassette. The Gold antibody conjugate will bind to Zika NS1 antigen in the specimen sample which in turn will bind with Anti-Zika NS1 coated on the membrane. As the reagent moves across the membrane, the Zika NS1 antibody on the membrane will bind the antibody-antigen complex causing a dark red or pink line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink line in the test region should be considered as positive result.

【REAGENTS】

The test cassette contains anti-Zika NS1 antibody conjugated gold particles and anti-Zika NS1 antibody coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observeestablished precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The ZikaNS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

【MATERIALS】

Materials provided

- Test cassettes
- Buffer
- Droppers
- Package insert

Materials required but not provided

- Specimen collection containers
- Micropipette
- Lancets (for fingerstick whole blood only)
- Centrifuge (for plasma only)
- Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma specimen**:

- Hold the dropper vertically and transfer **1 drop of serum or plasma** (approximately 25µL) to the specimen area, then add **1 drop of buffer** (approx. 40µL) and start the timer. See illustration below.

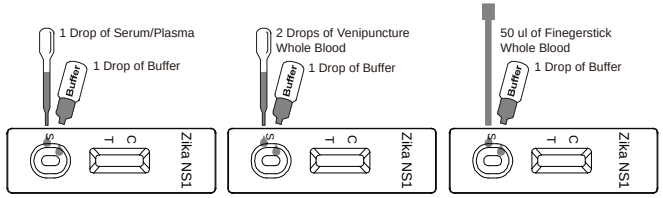
For **Venipuncture Whole Blood** specimen:

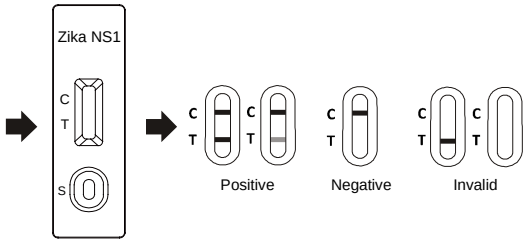
- Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 50µL) to the specimen area, then add **1 drop of buffer** (approximately 40 µL), and start the timer. See illustration below.

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and transfer approximately **50µL of fingerstick whole blood** specimen to the specimen area of test cassette, then add **1 drop of buffer** (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. Read results at **15 minutes**. Do not interpret the result after 20 minutes.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE: * **Two distinct colored lines appear.** One color line should be in the control region (C) and another color line should be in the test region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Zika NS1 antigen present in the specimen. Therefore, any shade of red in the test region should be considered positive.

NEGATIVE: One color line appears in the control region (C). No apparent red or pink line appears in the test region (T).

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

【QUALITY CONTROL】

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

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.

【LIMITATIONS】

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of Zika NS1 Antigen in whole blood, serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Zika NS1 Rapid Test is limited to the qualitative detection of Zika NS1 Ag in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with Zika Ag titer of the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with Zika viruses.
4. A negative result can occur if the quantity of Zika Ag present in the specimen is below the detection limits of the assay, or the Zika Ag that are detected are not present during the stage of disease in which a sample is collected.
5. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6. If the symptom persists, while the result from Zika NS1 Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device such as PCR, ELISA.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with PCR tests; the results indicate following sensitivity and specificity of Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma).

Method		PCR		Total Result
Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	8	3	11
	Negative	2	47	49
Total Result		10	50	60

Relative sensitivity: 80.0% (95%CI:*44.4%-97.5%)
Relative specificity: 94.0% (95%CI:*83.5%-98.7%)
Accuracy:91.7% (95%CI:*81.6%-97.2%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a middle positive and a high positive. The negative, low positive, middle positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a middle positive and a high positive. Three different lots of the Zika NS1 Rapid Test cassette (Whole Blood/Serum/Plasma) have been tested over a 10-days period using negative, low positive, and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

The Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-Syphilis, anti-*H. Pylori*, anti-CMV, anti-TOXO, anti-HSV 1/2, anti-MONO and anti-HIV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Zika NS1 Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Acetaminophen: 20mg/dl	Caffeine: 20mg/dl	Hemoglobin: 1000mg/dl
Acetylsalicylic Acid: 20mg/dl	Gentisic Acid: 20mg/dl	Albumin: 2000mg/dl
Ascorbic Acid: 2g/dl	Oxalic Acid: 60mg/dl	Creatin: 200mg/dl
Bilirubin: 1000mg/dL		

【BIBLIOGRAPHY】

1. Malone, Robert W.; Homan, Jane; Callahan, Michael V.; et al. (2 March 2016). *"Zika Virus: Medical Countermeasure Development Challenges"*.
2. Sikka, Veronica; Chattu, Vijay Kumar; Popli, Raaj K.; et al. (11 February 2016). *"The emergence of zika virus as a global health security threat: A review and a consensus statement of the INDUSEM Joint working Group (JWG)"*. Journal of Global Infectious Diseases.
3. *"Symptoms, Diagnosis, & Treatment"*. Zika virus. Atlanta: Centers for Disease Control and Prevention. 3 March 2016.
4. Rasmussen, Sonja A.; Jamieson, Denise J.; Honein, Margaret A.; Petersen, Lyle R. (13 April 2016). *"Zika Virus and Birth Defects — Reviewing the Evidence for Causality"*. New England Journal of Medicine.**374**: 1981–1987
5. *"CDC Concludes Zika Causes Microcephaly and Other Birth Defects"*.CDC. 13 April 2016.
6. *"Zika Virus Microcephaly And Guillain–Barré Syndrome Situation Report"* (PDF). World Health Organization. 7 April 2016.

Index of Symbols

⚠	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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CE

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