Zika NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood) Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF ZIKA NS1 ANTIGEN IN HUMAN SERUM/PLASMA/WHOLE BLOOD.
For Professional In Vitro Diagnostic Use Only.

INTENDED USE

The Zika NS1 Antigen Rapid Test Cassette is a lateral flow chromatographic immunoassay forqualitative detection of NS1 antigen in human serum、plasma or whole blood.This kit is intended to be used as a screening test and as an aid in the diagnosis of infection with NS1.
Any reactive specimen with the NS1 Antigen Rapid Test Cassette must be confirmed with altemative testing method(s) and clinical findings.

SUMMARY

Zika virus (ZIKV) is a single-stranded RNA virus belonging to the Flaviviridae family, genus Flavivirus. It is antigenically and structurally related to the viruses that cause dengue, yellow fever, Japanese encephalitis, and West Nile virus infections.
Zika virus was first identified in 1947 in a rhesus macaque monkey in the Zika Forest of Uganda, with subsequent evidence of human infection documented in other African countries during the 1950s. From the 1960s through the 1980s, sporadic human infections were detected across Africa and Asia. The virus was not considered a significant human pathogen until the first large-scale outbreaks occurred in the South Pacific islands in 2007. In May 2015, local transmission was first reported in Brazil, followed by spread throughout Central America and the Caribbean. From February to November 2016, the World Health Organization declared a Public Health Emergency of International Concern (PHEIC) regarding microcephaly, other neurological disorders, and Zika virus.
Although cases of Zika virus disease have declined globally since 2017, transmission persists at low levels in several countries in the Americas, Asia, and Africa, where sporadic outbreaks continue to be documented. As of May 2025, there are no geographic areas with an active major Zika virus outbreak. To date, a total of 92 countries and territories have reported evidence of mosquito-transmitted Zika virus infection.

PRINCIPLE

The NS1 Antigen Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The test Cassette consists of: 1) a red colored conjugate containing NS1 antibody conjugated with latex (NS1 antibody conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated NS1 antibody, 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 Cassette, the specimen migrates by capillary action across the Cassette. The antigen to NS1 if present in the specimen will bind to the NS1 conjugates. The immune complex is then captured on the membrane by the pre-coated NS1 antibody, forming a burgundy colored T band, indicating a NS1 antigen positive test result.
Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immune complex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antigens to NS1. Otherwise, the test result is invalid and the specimen must be retested with another Cassette.

REAGENTS

The test contains NS1 antibody pre-coated on the surface of the membrane. And NS1 antibody conjugated latex.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established 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 being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **Do not freeze**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

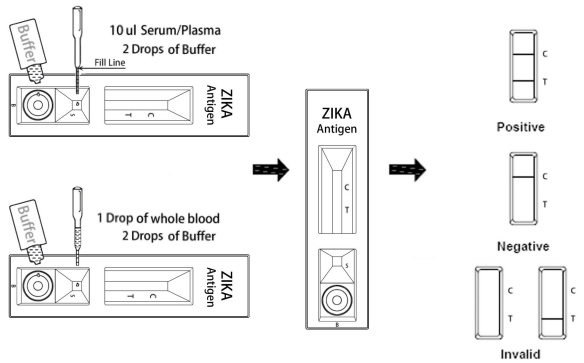
1. The NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2. To collect **Finger stick Whole Blood specimens:**
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- 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.
- Touch the end of the dropper to the blood until filled to approximately 20μl.Avoid air bubbles.
- Place the bulb onto the top end of the dropper,then squeeze the bulb to dispense the whole blood to the specimen area of the test Cassette.
3. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4. 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.
5. 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.
6. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided			
• Test Cassette	• Dropper	• Buffer	• Package Insert
Materials required but not provided			
• Specimen collection containers		• Timer	
• Lancets (for fingerstick whole blood only)		• Centrifuge	

DIRECTIONS FOR USE

Allow the test cassette, 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 as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the test cassette on a clean and level surface.
   For **Serum or Plasma** specimens: Hold the dropper vertically and draw the serum or plasma up to the fill line as shown in illustration below (approximately 10μL). Transfer the specimen to the specimen well (S), then add 2 drops of buffer (approximately 80μL) to the specimen well (B), and start the timer. See illustration below.
   For **Venipuncture Whole Blood** specimens: Using the provided 10μL dropper and transfer 1 drop (about 20μL) of whole blood to the specimen area, then add 2 drops of buffer (approximately 80μL) to the buffer hole and start the timer. See illustration below.
   For **Finger stick Whole Blood** specimens: To use a dropper: Hold the dropper vertically and transfer 20μL of Finger stick Whole Blood to the specimen well (S) of the test cassette,then add 2 drop of buffer (approximately 80μL) to the specimen well (B), and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 15 minutes.** Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE:* Two lines appear.One colored line should always appear in the control line region(C) and another one apparent colored line should be in the test line region(T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of NS1 antigen present in the specimen. Therefore, any shade of color in the test line regions should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored lines appear in any of the test line region(T). This indicates that the concentration of NS1 antigen are below the minimum detection levels.

INVALID: Control line (C) 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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 Test Result Interpretation must be followed closely when testing the presence of antigen to NS1 in serum/plasma/whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2. The Zika NS1 Antigen Rapid Test Cassette is limited to the qualitative detection of the antigen to Zika in human serum/plasma/whole blood. The intensity of the test band does not linear correlation with the antigen titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable Zika. However, a negative test result does not preclude the possibility of exposure to or infection with Zika.
4. A negative result can occur if the quantity of the Zika antigen present in the specimen is below the detection limits of the assay, or the antigen 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 antigens or rheumatoid factor may affect expected results.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity

The Zika NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood) has been evaluated with a leading commercial Zika NS1 Antigen EIA test using clinical specimens. The results show that relative to leading EIA tests, the Zika NS1 Antigen Rapid Test Cassette (Serum/Plasma/Whole Blood) exhibits 95% sensitivity and 98.8% specificity .

Zika NS1 Antigen Test vs. EIA

Method		**EIA**		**Total Results**
Zika NS1 Antigen Test	**Results**	**Positive**	**Negative**	
	Positive	138	2	140
	Negative	0	98	98
Total Results		138	100	238

Relative Sensitivity: 100% (95%CI*: 96.74%~100%)*
Relative Specificity: 98.0% (95%CI*: 92.56%~99.89%)*
Accuracy: 99.16% (95%CI*: 96.79%~99.97%)*
*Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of three specimens:a negative, a low positive,and a high positive.The negative,low,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 three specimens,a negative,a low positive,and a high positive.Three different lots of the Zika NS1 Antigen Rapid Test Cassette(Serum/Plasma/Whole blood) have been tested over a 3-day period using negative,low positive,and high positive specimens.The specimens were correctly identified >99% of the time.

Cross-reactivity

The Zika NS1 Antigen Rapid Test Cassette(Serum/Plasma/Whole blood) has been tested with specimens positive for: HAV, HBV, HCV, HEV, HIV and TP. No cross-reactivity was observed, indicating that the performance of the Zika NS1 Antigen Rapid Test (Whole Blood/Serum/Plasma) is stable in presence of these factors.

Interfering Substances

The Zika NS1 Antigen Rapid Test Cassette(Serum/Plasma/Whole blood) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. Results indicate that no interference was observed in specimens containing up to 1000 mg/dL hemoglobin; up to 1000mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

BIBLIOGRAPHY

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SYMBOLS

Symbol	**Meaning**	**Symbol**	**Meaning**
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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