TruQuick™ Zika 10T

A rapid test for the qualitative detection of NS1 antigen of Zika virus in whole blood, serum or plasma.

REF **TQ2010** IVD **Rx Only**

INTENDED USE
TruQuick Zika is a rapid chromatographic immunoassay for the qualitative detection of NS1 antigen of Zika virus in whole blood, serum, or plasma as an aid in the diagnosis of Zika infections. Any positive result should be confirmed with alternative test methods and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Zika virus (ZIKV) is a member of the virus family Flaviviridae.[1] It is spread by daytime-active Aedes mosquitoes, such as *A. 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]

TruQuick Zika is a rapid test that utilizes Zika NS1 antibody-coated colored particles for the detection of Zika NS1 antigen in whole blood, serum, or plasma.

BIOLOGICAL PRINCIPLES
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 pale or dark 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/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The Test Cassette contains anti-Zika NS1 antibody-conjugated gold particles and anti-Zika NS1 antibody-coated on the membrane. Each cassette is packaged in a foil pouch.
- Buffer: A buffered solution containing Proclin as a preservative. The Buffer is supplied in a dropper vial ready for use.
- Droppers
- Package insert

MATERIALS NOT PROVIDED
- Specimen collection containers
- Centrifuge (for plasma only)
- Micropipette
- Timer
- Lancets (for fingerstick whole blood only)

PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. 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.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.

HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
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
1. TruQuick Zika can be performed using whole blood, serum, or plasma. Collect and prepare whole blood, serum or plasma according to standard laboratory methods.
2. 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.

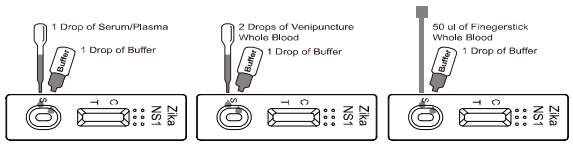
   Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
   - Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
   - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the Test Cassette.

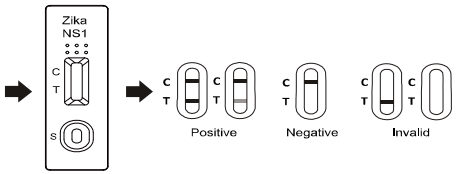
   Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
   - Position the patient's finger so that the drop of blood is just above the specimen area of the Test Cassette.
   - Allow two hanging drops of fingerstick whole blood to fall into the center of the specimen area on the Test Cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
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 three 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 two 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 federal regulations for transportation of etiologic agents.

TEST PROCEDURE
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 25 µL) to the specimen area, then add 1 drop (approx. 40 µL) of Buffer and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µL) 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 50 µL 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.
   - To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50 µL) to fall into 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 colored line should be in the control region (C) and another colored 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 colored 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 Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
Clinical testing was performed on 60 samples suspected of containing Zika NS1. The performance of TruQuick Zika was compared to PCR and correlated with PCR results 91.7% of the time.

LIMITATIONS OF THE PROCEDURE
1. The TEST PROCEDURE and the INTERPRETATION OF RESULTS sections must be followed closely when testing for the presence of Zika Ag in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
2. TruQuick Zika is limited to the qualitative detection of Zika Ag in whole blood, serum or plasma. The intensity of the test band does not linear correlate 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 TruQuick Zika is negative or nonreactive, it is recommended to resample the patient a 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.

SPECIFIC PERFORMANCE CHARACTERISTICS
TruQuick Zika was evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The results were compared to a reference PCR method. A specimen was considered positive if the PCR result was positive. A specimen was considered negative if the PCR result was negative.

Method		PCR		Total Result
TruQuick Zika NS1	Results	Positive	Negative	
	Positive	8	3	11
	Negative	2	47	49
Total Result		10	50	60

Sensitivity: 80.0% (95% CI*: 44.4% - 97.5%)
Specificity: 94.0% (95% CI*: 83.5% - 98.7%)
Correlation: 91.7% (95% CI*: 81.6% - 97.2%)
*Confidence Intervals

ANALYTICAL SENSITIVITY
TruQuick Zika was tested against dilutions of Zika NS1 recombinant antigen in plasma. The Limit of Detection was determined to be 17 ng/mL of the antigen.

REPRODUCIBILITY
Intra-Assay Precision
Repeatability was determined using 10 replicates for serum and plasma for each of three samples (negative, low positive, high positive). The specimens produced the correct results > 99.9% of the time.
Inter-Assay Precision
Between lot precision was demonstrated in 10 replicates of serum and plasma for each of three samples (negative, low positive, high positive) and three product lots. The results were consistent between lots. Sample were correctly identified > 99.9% of the time.

CROSSREACTIVITY
TruQuick Zika was tested with samples from patients diagnosed with the following as confirmed by ELISA: HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HIV, Syphilis, HAMA, RF, Mononucleosis, Rubella, Toxoplasmosis, CMV. The samples showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES
The following potentially interfering substances were added to Zika positive and negative specimens:

Acetylsalicylic acid 20 mg/dL	Acetaminophen 20 mg/dL
Ascorbic acid 2 g/dL	Creatine 200 mg/dL
Hemoglobin 1 g/dL	Albumin 2 g/dL
Gentisic acid 20 mg/dL	Caffeine 20 mg/dL
Bilirubin 1 g/dL	Oxalic acid 60 mg/dL

REFERENCES

1. Malone RW, Homan J, Callahan MV, et al. Zika Virus: Medical countermeasure development challenges. PLoS Negl Trop Dis. 2016;10(3):e0004530.doi:10.1371/journal.pntd.0004530..
2. Sikka V, Chattu VK, Popli RK, et al. The emergence of zika virus as a global health security threat: A review and a consensus statement of the INDUSEM Joint Working Group (JWG). J Global Infect Dis. 8(1):3–15. 11 February 2016.
3. Symptoms, diagnosis, and treatment. Zika virus. Atlanta: Centers for Disease Control and Prevention. 3 March 2016.
4. Rasmussen SA, Jamieson DJ, Honein MA, Petersen LR. Zika virus and birth defects — reviewing the evidence for causality. N Engl J Med. 374:1981–1987. 13 April 2016.
5. CDC concludes Zika causes microcephaly and other birth defects. CDC. 13 April 2016.
6. Zika virus microcephaly and Guillain–Barré syndrome situation report. WHO. 7 April 2016.

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SYMBOL USAGE

You may see one or more of these symbols on the labeling/packaging of this product:

Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.