TruQuick™ Dengue IgG/IgM 10T

A rapid test for the qualitative detection of antibodies (IgG and IgM) to Dengue virus in whole blood, serum, or plasma.

REF **TQ3110** IVD **Rx Only**

INTENDED USE
TruQuick Dengue IgG/IgM is a rapid immunoassay for the qualitative detection of IgG and IgM antibodies to Dengue virus in whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary Dengue infections. Any positive reactions with TruQuick Dengue IgG/IgM should be confirmed with alternative testing and clinical findings.

SUMMARY AND EXPLANATION OF THE TEST
Dengue is a flavivirus, transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes. It is widely distributed throughout the tropical and subtropical areas of the world,[1] and causes up to 100 million infections annually.[2] Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash. Primary Dengue infection causes IgM antibodies to increase to a detectable level in 3 to 5 days after the onset of fever. IgM antibodies generally persist for 30 to 90 days.[3] Most Dengue patients in endemic regions have secondary infections,[4] resulting in high levels of specific IgG antibodies prior to or simultaneous with IgM response.[5] Therefore, the detection of specific anti-Dengue IgM and IgG antibodies can also help to distinguish between primary and secondary infections.

The TruQuick Dengue IgG/IgM is a rapid test that utilizes a combination of Dengue antigen-coated colored particles for the detection of IgG and IgM Dengue antibodies in whole blood, serum, or plasma.

BIOLOGICAL PRINCIPLES
This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with Dengue antigen-coated particles in the Test Cassette. The mixture then migrates upward on the membrane by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to Dengue, a colored line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. Dengue IgM antibodies, if present in the specimen, reacts with the anti-human IgM and the Dengue antigen-coated particles in the Test Cassette, and this complex is captured by the anti-human IgM, forming a colored line in IgM test line region. Therefore, if the specimen contains Dengue IgG antibodies, a colored line will appear in IgG test line region. If the specimen contains Dengue IgM antibodies, a colored line will appear in IgM test line region. If the specimen does not contain Dengue antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

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 Dengue antigen conjugated to gold colloidal particles, anti-human IgM and anti-human IgG coated on the membrane. Each cassette is packaged in a foil pouch.
- Buffer: A buffered solution containing Proclin 300 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.

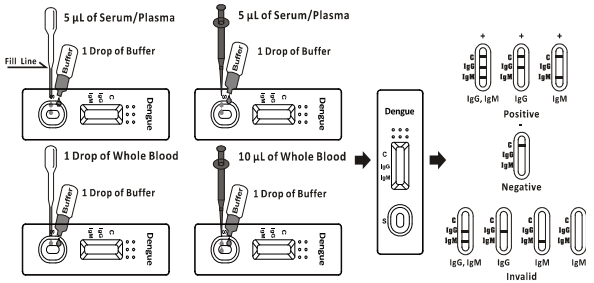
HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

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 Dengue IgG/IgM can be performed using whole blood, serum, or plasma. Collect and prepare whole blood, serum and 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 Cassette by using a dropper or micropipette measuring 10 µL. The dropper provided with the test dispenses approximately 10 µL in one drop even if more blood is aspirated in the dropper.
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. Remove the Test Cassette from the sealed pouch and use it within one hour.
2. Place the Test Cassette on a clean and level surface.
   For Serum or Plasma Specimens:
   - To use a dropper: Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 5 µL), and transfer the specimen to the specimen well of the Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer. Avoid trapping air bubbles in the specimen well.
   - To use a micropipette: Pipette and dispense 5 µL of specimen to the specimen well of the Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer.

   For Whole Blood (Venipuncture/Fingerstick) Specimens:
   - To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the Fill Line, and transfer 1 drop of whole blood (approximately 10 µL) to the specimen well of the Test Cassette, then add 1 drop of Buffer (approximately 40 uL) and start the timer.
   - To use a micropipette: Pipette and dispense 10 µL of whole blood to the specimen well of the Test Cassette, then add 1 drop of Buffer (approximately 40 µL) and start the timer.
3. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
IgG and IgM POSITIVE:* **Three lines appear**. One colored line should be in the control line region (C), and colored lines should appear at the IgG test line region and the IgM test line region. The color intensities of the lines do not have to match. The result is positive for IgG and IgM antibodies and suggests the end stage of primary Dengue infection and early stage of secondary Dengue infection.
IgG POSITIVE:* **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for Dengue virus specific-IgG and is probably indicative of secondary Dengue infection.
IgM POSITIVE:* **Two lines appear**. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for Dengue virus specific-IgM antibodies and is indicative of primary Dengue infection.
*NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of Dengue antibodies in the specimen. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.
NEGATIVE: **One colored line should be in the control line region (C)**. No line appears in IgG and IgM test line region(s).
INVALID: **Control line fails to appear**. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure 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.
An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, confirming sufficient buffer volume and adequate membrane wicking.

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
Primary Dengue infection is characterized by the presence of detectable IgM antibodies three to five days after the onset of infection. Secondary Dengue infection is characterized by the elevation of Dengue-specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.[5]

TruQuick Dengue IgG/IgM has been compared with a leading commercial Dengue ELISA test, demonstrating sensitivity of 83.3% for IgM in primary infection and 98.4% for IgG in secondary infection.

LIMITATIONS OF THE PROCEDURE
1. TruQuick Dengue IgG/IgM is for in vitro diagnostic use only. The test should be used for the detection of Dengue antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Dengue antibody concentration can be determined by this qualitative test.
2. TruQuick Dengue IgG/IgM will only indicate the presence of Dengue antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Dengue.
3. In the early onset of fever, anti-Dengue IgM concentrations may be below detectable levels. For primary infection, an IgM antibody-capture enzyme-linked immunosorbent assay (MAC-ELISA) showed that 80% of the Dengue patients tested exhibited detectable levels of IgM antibody by the fifth day after infection, and 99% of the patients tested IgM positive by day 10. It is recommended that patients be tested within this time. For the secondary infection, a low molar fraction of anti-Dengue IgM and a high molar fraction of IgG that is broadly reactive to flaviviruses characterize the antibodies.[5] The IgM signal may be faint and the cross reaction in the region of IgG line may appear.
4. Serological cross-reactivity across the flavivirus group (Dengue 1, 2, 3 & 4, St. Louis encephalitis, West Nile virus, Japanese encephalitis and yellow fever viruses) is common.[6-8] Positive results should be confirmed by other means.
5. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
6. Results from immunosuppressed patients should be interpreted with caution.
7. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
8. 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 Dengue infection.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick Dengue IgG/IgM has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial Dengue ELISA test. The results show that the overall sensitivity for the primary and secondary infection of TruQuick Dengue IgG/IgM is 94.3%, and the specificity is 99.1%, and the relative correlation is 98.3%.

Dengue Primary Infection for IgM/IgG test results

Method			ELISA		
TruQuick Dengue IgG/IgM	Results		Positive		Negative
			IgM	IgG	
	Positive	IgM	15	0	0
		IgG	3	0	0
	Negative		0	0	0
Sensitivity			83.3%	/	/

Dengue Secondary Infection for IgM/IgG test results

Method			ELISA		
TruQuick Dengue IgG/IgM	Results		Positive		Negative
			IgM	IgG	
	Positive	IgM	37	0	0
		IgG	15	52	0
	Negative		0	0	0
Sensitivity			71.2%	> 99.9%	/

Non-Dengue Infection for IgM/IgG test results

Method			ELISA		
TruQuick Dengue IgG/IgM	Results		Positive		Negative
			IgM	IgG	
	Positive	IgM	0	0	0
		IgG	0	0	0
	Negative		0	0	338
Specificity			/	/	/

Sensitivity: (15+52)/(18+52) = 95.7% (95% CI*: 88.0%~99.1%)
Specificity: 338/338 > 99.9% (95% CI*: 99.1%~100.0%)
Correlation: (15+52+338)/(18+52+338) = 99.3% (95% CI*: 97.9%~99.8%) *Confidence Intervals

REPRODUCIBILITY

Intra-Assay Precision

Within-run precision was determined by using 15 replicates of serum and plasma for four specimen types: a negative, an IgG positive, an IgM positive and a combined IgM/IgG positive. The specimens were correctly identified > 99% of the time.

Inter-Assay Precision

Between-run and between lot precision was determined by 15 independent assays on the same four specimen types: a negative, an IgG positive, an IgM positive and a combined IgM/IgG positive. Three different lots of the TruQuick Dengue IgG/IgM were tested using these specimens. The specimens were correctly identified > 99% of the time.

CROSSREACTIVITY

TruQuick Dengue IgG/IgM has been tested using samples from patients diagnosed with HIV, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, *H. pylori*, Syphilis, HAMA, RF, Mononucleosis, CMV, Rubella and Toxoplasmosis. The results showed no crossreactivity.

TESTS FOR INTERFERING SUBSTANCES

The following potentially interfering substances were added to Dengue negative and positive specimens.

Acetaminophen 20 mg/dL	Caffeine 20 mg/dL
Acetylsalicylic Acid 20 mg/dL	Gentisic Acid 20 mg/dL
Ascorbic Acid 2000 mg/dL	Albumin 2 g/dL
Creatin 200 mg/dL	Hemoglobin 1000 mg/dL
Bilirubin 1 g/dL	Oxalic Acid 60 mg/dL

None of the substances interfered in the assay at the concentration tested.

REFERENCES

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SNTQ3110 **REV. 05/17**

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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
	Do not use if package is damaged		

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.