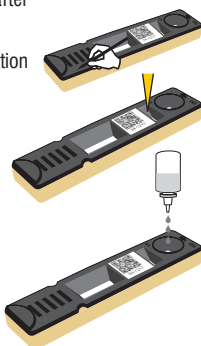


TEST PROCEDURE

1. Bring the complete kit and specimen to be tested to room temperature prior to testing.
2. Remove the test cartridge from the foil pouch prior to use and place it on a flat and dry surface. The test should be performed immediately after removing the test card from the foil pouch.

RT
20-30°C

3. Label the test cartridge with patient's name or identification number. **Do not write on QR code.**
4. Add 10µl Serum/ Plasma sample using micropipette onto the sample pad in the sample well 'S'. **Care should be taken to avoid any spillage on the QR Code.**



NOTE: Make sure that the sample from the micropipette has been completely transferred to the sample pad.

5. Add 3 drops of the Assay Buffer in the buffer well 'B'. Screw cap the vial after use.
6. Allow the reaction to occur for 40 minutes.
7. Insert the test cartridge into the i-Quant Analyzer with arrow (←) marked side on the top of cartridge facing towards the analyzer and press RUN icon. Note down the value displayed on the screen of i-Quant Analyzer & interpret the result as mentioned below.
8. Discard the Dengue IgM Quanti Card immediately after reading results at 40 minutes considering it to be potentially infectious.

Important Note: Do not read results after 40 minutes.

INTERPRETATION OF RESULTS

The iQuant Analyzer will display results as Reactive, Equivocal or Non-Reactive as follows:

IgM Reactive: > 1.1 U and above: interpret the result as Dengue IgM Antibody reactive.

Equivocal: > 0.9 to ≤ 1.1 U: Interpret the result as equivocal. Repeat the test after centrifuging the sample at 5000 rpm for 20 minutes. Even after repeating the test, if result comes equivocal, further test the sample with alternative method or collect another sample.

Non-Reactive: Below ≤ 0.9 U: Interpret the result as Dengue IgM Antibody non-reactive.

LIMITATIONS AND INTERFERENCES

1. The test is for in vitro diagnostic use only.
2. This test detects the presence of Dengue IgM antibodies to dengue virus in the specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
3. In early infections and some secondary infections, detectable levels of IgM antibodies may be low. Some patients may not produce detectable levels of antibody within the first seven to ten days after infection. Where symptoms persist, patients should be re-tested 3-5 days after the first testing date.
4. Serological cross-reactivity across the Flavivirus group (St. Louis encephalitis, Japanese encephalitis, West Nile and yellow fever virus) is common.
5. As with all diagnostic tests, all results must be correlated with other clinical findings. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of an early infection of Dengue virus.
6. This is only a screening test. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and serological test like haemagglutination inhibition test, more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus infection.

PERFORMANCE CHARACTERISTICS OF DENGUE IgM & IgG QUANTI CARD

The kit has been evaluated in-house with the known panel of fresh as well as frozen Dengue IgM antibody positive and Negative samples. The performance of the test kit was evaluated and compared with the a license commercially available ELISA test kit. The samples included cross-reacting samples; Epstein-Barr virus, Malaria, Rheumatoid factor, Leptospirosis, Japanese encephalitis, yellow fever and West Nile viruses. Following is the in-house evaluation.

Sample Type	No. of Samples tested	Result of Dengue IgM ELISA test		Dengue IgM Quanti Card	
		Positive	Negative	Positive	Negative
Negative	855	0	855	11	844
Dengue IgM Positive	120	120	0	118	2
Dengue IgG Positive	75	0	75	0	75

Sensitivity: **96.72%**

Specificity: **97.45%**

Precision:

Intra assay precision

Within run (Intra assay) precision have been determined by testing 10 replicates of two negative and five dengue IgM antibody positive samples (3 weak, 1 medium & 1 strong). The C.V. (%) of all the samples were within 10% of the unit.

Inter assay precision (Reproducibility)

Between run (Inter assay) precision have been determined by testing 10 replicates of two negative and five Dengue IgM antibody positive samples (3 weak, 1 medium & 1 strong) in 10 sequential days. The C.V. (%) of all the samples were within 10% of the unit.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an in vitro diagnostic assay within the limitations and specifications as described in the product instruction-manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

TROUBLE SHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
1. False negative	a) Low sample volume along with less volume of Assay Buffer used.	Repeat the test with proper volume of samples and/or Assay Buffer.
2. False positive	a) Less volume of Assay Buffer added/used.	Repeat the test with proper volume of Assay Buffer

BIBLIOGRAPHY OF SUGGESTED READING

4. Dengue: guidelines for diagnosis, treatment, prevention and control –New Edition WHO/HTM/NTD/DEN/2009.1
2. Rapid Dengue Diagnosis: A prospective study using a Commercial RapidTest* (S.K. Lam+ and L.C.S. Lum++)
3. Dengue disease diagnosis: A puzzle to be solved Jaime Eduardo Castellanos 1.2. Carolina Coronel-Ruiz1 Rev. Fac. Med. 2014 Vol. 62 No. 4:617-629

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