ImmunoScience INDIA

ImmunoQuick

Dengue IgG/IgM Ab

Rapid Dengue IgG/IgM Test – Device

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

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1. OVERVIEW

Dengue is caused by any of the four distinct but antigenically related serotype of flavivirus (DEN-V1, DEN-V2, DEN-V3 and DEN-V4) found largely in tropic and subtropics areas. The viruses are transmitted to human by mosquito Aedes aegypti and Aedes albopictus causing dengue fever with sever flu like symptoms. WHO estimates that 55-60 million cases of dengue fever occur worldwide each year, including a more severe form called the dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS). During Primary infection the classical symptoms are sudden onset of fever, intense headache, myalgia, arthralgia and rash. Secondary infections most common in many parts of South east Asia and South America. In primary infections there is a rise in IgM antibodies which are detectable 5 days after the onset of illness, and then gradually decrease after a few months. IgG can only be detected after a few weeks from infection. With secondary infection there are low levels of IgM and very high levels of IgG antibodies detectable after 2 days from onset.

2. INTENDED USE

Rapid Dengue IgG/IgM test is an immunochromatographic assay for the qualitative Detection of Dengue specific IgG/IgM antibodies in human serum/plasma.

3. PRINCIPLE

After addition of the serum or plasma and the assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant Dengue specific antigens and streptavidin. If the sample contains detectable levels of the Dengue specific IgM and IgG antibodies, it reacts with the gold conjugated recombinant Dengue specific antigens to form a complex. This complex moves further and Dengue specific IgM antibodies conjugate complex reacts with anti-human IgM test line and the Dengue specific IgG antibodies react with the anti-human IgG antibodies test line on the nitrocellulose membrane area to form colored band/s. The unbound complex and the Streptavidin conjugated colloidal gold particles move further to the Biotin coated control area to form a colored band (Control line). The appearance of test line/s and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

4. CONTENTS OF KIT

1. Test Device
2. Package Insert
3. Plastic Dropper
4. Assay Buffer

5. OPTIONAL MATERIAL REQUIRED

1. Timer
2. Sample container
3. Micro pipette
4. Disposable Gloves

6. PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

7. WARNINGS

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose off hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.

8. SPECIMEN COLLECTION

Testing should be performed as early as possible after collection. Do not leave serum/Plasma at room temperature for prolonged periods.

9. TEST PROCEDURE

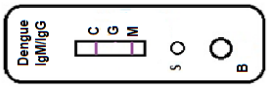
1. Allow the test device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the test device, desiccant and plastic dropper from the pouch and use it as early as possible.
3. Add one drop (10 µl) of serum or plasma sample in well 'S' and add two drops (Approx. 60µl) of assay buffer in well 'B'.
4. Start the timer.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

10. INTERPRETATION OF RESULTS

Negative: Only one colored line appears at the control region 'C' only

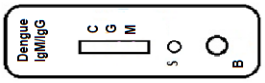
Positive: A) A distinct colored line appears at the control region 'C' and at the test region 'IgG' and 'IgM'.

B) A distinct colored line appears at the control region 'C' and at the test region 'IgM'



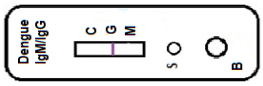
C) A distinct colored line appears at the control region 'C' and at the test region 'IgG'

Invalid: The test should be considered invalid if,
A) no line appears at 'C' region, 'IgG' and 'IgM' region

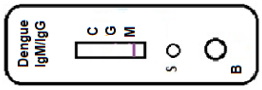


B) No line appears at 'C' region and line appear at 'IgM' and 'IgG' region

C) No line appears at 'C' and at 'IgM' region and line appear at 'IgG' region



D) No line appears at 'C' and at 'IgG' region and line appear at 'IgM' region



NOTE: The intensity of the color of test lines will vary depending upon the antibodies present in specimen.

11. PERFORMANCE CHARACTERISTICS

Internal Evaluation:

In an in-house study, total 270 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 70/70) and the relative specificity was 100 % (i. e. 200/200).

The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Dengue IgG/IgM Antibody Test - Device		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Dengue IgG/IgM Positive Serum samples	50	50	0	100	-
Dengue IgG/IgM Positive Plasma samples	20	20	0	100	-
Dengue IgG/IgM Negative Serum samples	100	-	100	-	100
Dengue IgG/IgM Negative Plasma samples	100	-	100	-	100

External Evaluation:

In an external study, total 160 samples (60 Positive and 100 Negative) were evaluated for sensitivity and specificity. Relative sensitivity was 100 % (i. e. 60/60) and the relative specificity was 100 % (i. e. 100/100). Positive Predictive Value (PPV) and Negative Predictive Value (NPV) for the test was 100%.

The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Dengue IgG/IgM Antibody Test - Device		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
		Positive	Negative				
Dengue IgG Positive Samples	30	30	0	100	-	100	-
Dengue IgM Positive Samples	30	30	0	100	-	100	-
Dengue Negative Samples	100	-	100	-	100	-	100

12. LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.

13. REFERENCES

1. Clinical Evaluation of a rapid immunochromatographic test for the diagnosis of Dengue Virus Infection, Chew Theng Sang, Lim Siew Hoon, Andrea Cuzzubbo, Peter Devine. Clinical and Diagnostic Laboratory Immunology, May 1998, Vol. 5, No. 3 p. 407-409.
2. Innis BL, and Nisalak A, et al: An enzyme-linked immunosorbent assay to characterize dengue infections where denude and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene. 1989: 40: 418-427.Songee L. ranch and Paul N. Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue virus. Clin. Diagn. Lab. Immunol. Vol. 6(4) p 555-557, 1999

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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