Dengue IgG/IgM Rapid Test Kit

INTENDED USE

The Dengue IgG/IgM Rapid Test Kit is a lateral flow immunoassay designed for the qualitative detection of IgG and IgM antibodies to Dengue virus in human whole blood, serum, or plasma. It serves as an aid in the diagnosis of Dengue virus infection.

INTRODUCTION

The Dengue IgG/IgM Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Dengue virus in whole blood, serum or plasma to aid in the diagnosis of Dengue viral infection. Dengue viruses, transmitted by the Aedes aegypti and Aedes albopictus mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. Classic symptoms include sudden fever, severe headache, muscle and joint pain, and rash. The test detects anti-Dengue IgG and IgM antibodies and offers a non-invasive, easy-to-use, and rapid diagnostic tool.

PRINCIPLE

The Dengue IgG/IgM Rapid Test Kit is a qualitative membrane strip-based immunoassay for the detection of IgG and IgM antibodies to Dengue virus in human whole blood, serum or plasma. The test kit consists of: 1) a burgundy coloured conjugate pad containing dengue recombinant envelope antigens conjugated with colloid gold (dengue conjugates); 2) a membrane strip containing two test lines (IgG and IgM lines) and a control line (C line). The IgM line is pre-coated with the Mouse anti-Human IgM antibody; IgG line is coated with Mouse anti-Human IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the test kit, the specimen migrates by capillary action across the kit. IgM anti-dengue, if present in the specimen, will bind to the dengue conjugates. The immunocomplex is then captured by the reagent coated on the IgM line, forming a burgundy-coloured IgM line, indicating a dengue IgM positive test result and suggesting a fresh infection. IgG anti dengue, if present in the specimen, will bind to the dengue conjugates, The immunocomplex is then captured by the reagent pre-coated on the IgG band, forming a burgundy-coloured IgG line, indicating a dengue IgG positive test result and suggesting a recent or repeat infection. Absence of both T lines (IgG and IgM) suggests a negative result; to serve as a procedural control, a coloured line will always appear at the control line region, indicating that a proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS AND METHODS

1. Individual sealed pouches, each pouch containing:
   a. 1 × Test Kit
   b. 1 × Desiccant Pouch
   c. 1 × Dropper
2. Buffer tube

STORAGE AND STABILITY

- Keep the test kit between 2 - 30°C in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for use.

SPECIMEN COLLECTION

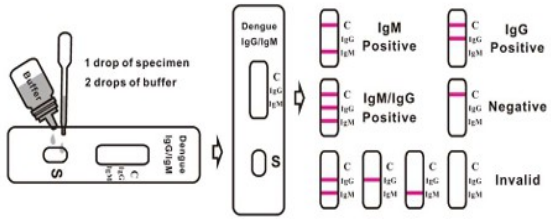
1. The Test can be performed using Whole Blood, Serum or Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-hemolyzed specimens.
3. Specimens may be stored at 2-8°C if not testing immediately. Store specimens at 2-8°C for up to 7 days. For long-term storage, specimens should be kept below -20°C. Do not freeze whole blood specimens.
4. Bring specimens to room temperature prior to testing.

5. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
6. Do not use samples showing gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

TEST PROCEDURE

Allow the test kit, specimen and buffer to equilibrate to room temperature (15-30 °C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test kit from the sealed pouch and use it within one hour.
2. Place the kit on a clean and level surface.
3. Hold the dropper vertically and transfer 1 drop of specimen (approx. 10 µL) to the specimen area, and then add 2 drops of buffer (approximately 70 µL), and start the timer.
4. Wait for the colored line(s) to appear. Read the results in 15 minutes. Do not interpret the result after 20 minutes.



RESULT:

Result	Interpretation
Positive	Control line + IgM line → Recent infection Control line + IgG line → Past/secondary infection Control line + both lines → Possible secondary infection
Negative	Only control line visible → No detectable antibodies
Invalid	No control line → Repeat test with a new device

PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the Dengue IgG/IgM Rapid Test Kit and commercially available Dengue rapid tests. A statistical comparison was made between the results yielding the following data.

Dengue IgG	Sensitivity: 99.12% Specificity:99.70% Accuracy: 99.50%
Dengue IgM	Sensitivity: 98.55% Specificity:99.54% Accuracy: 99.20%

LIMITATIONS

1. To ensure an appropriate diagnosis, the test results should be analysed in conjunction with the patient's clinical history and results from additional diagnostic procedures.
2. Negative results may occur if antibody levels are below detection limit or if the infection is very recent.
3. For reliable results, specimens must be handled and stored properly. Hemolysis, contamination, or sample deterioration may impact the test's performance.
4. It is a Qualitative test, and it does not indicate antibody concentration.

REFERENCES

1. Halstead SB, Pathogenesis of dengue: challenges to molecular biology. Science 1988; 239:476-481.
2. Halstead SB. Selective primary health care: XI. Dengue. Rev Infect Dis. 1984;6:251–264.

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