Dengue IgG/IgM Combo Test Device
(Serum/Plasma/Whole Blood)
Instructions for Use
Catalog Number: B804C

A rapid and sensitive test for the qualitative detection of IgG and IgM antibodies to the dengue virus in human serum, plasma, or whole blood.

For professional in vitro diagnostic use only.

Intended Use

The *TELL ME FAST* Dengue IgG/IgM Combo Test Device (Serum/Plasma/Whole blood) is a qualitative test for the detection of IgG and IgM antibodies to dengue virus in human serum plasma or whole blood. The test provides a differential detection of anti-dengue IgG and anti-dengue-IgM antibodies and can be used for the presumptive distinction between a primary and secondary dengue infection. This test is for In-Vitro Diagnostic use only.

Summary

Dengue virus, a virus belonging to the Flavavirus group of viruses, is one of the most significant mosquito-born diseases in the world in terms of morbidity and mortality.

Transmitted principally by the mosquito types *Aedes aegypti* and *Aedes albopictus*, the virus is found commonly throughout the tropic and subtropic regions of the world. There are four known serotypes of dengue. Symptoms of dengue fever include high fever, headache, muscle pain and skin rash. The complications often associated with this infection are dengue hemorrhagic fever or dengue shock syndrome. The immune response to this virus includes the production of IgM antibodies by the 5th day of symptoms, which remain in the circulatory system for 30-60 days. IgG antibodies appear by the 14th day of infection and persist for life. A secondary infection often results in high fever and, in many cases, initiates hemorrhagic events and circulatory failure. A secondary infection also induces an IgM antibody response after 20 days of infection and IgG antibodies rise within 1-2 days after the onset of symptoms. Therefore, patients with secondary infections will have a positive IgG result, usually with a positive IgM result as well. Thus, the use of a reliable and sensitive rapid serological test that can simultaneously detect the presence of anti-dengue IgG and IgM antibodies is of great clinical utility. Biocan TELL ME FAST Dengue IgG/IgM rapid test provides an excellent methodology for specifically detecting anti-dengue IgG and IgM antibodies. The presence of high titers of IgG antibodies does not interfere with the detection of IgM antibodies in the sample. By using a mixture of highly purified dengue proteins, the test is able to detect all 4 Dengue serotypes.

Principle

The *TELL ME FAST* Dengue IgG/IgM Combo Test Device (Serum/Plasma/Whole blood) is a qualitative test for the detection of IgG and IgM antibodies to dengue virus in human serum plasma, or whole blood. The test provides a differential detection of anti-dengue IgG and anti-dengue-IgM antibodies and can be used for the presumptive distinction between a primary and secondary dengue infection. Serum, plasma, or Whole blood samples may be used with this test. First a specimen is dispensed with sample buffer, the Gold antigen conjugate will bind to anti-Dengue IgG and IgM antibodies in the specimen sample which in turn will bind with Anti-Human IgG and Anti-Human IgM coated on the membrane as two separate lines in the test region as the reagent move across the membrane. The anti-Human antibodies on the membrane will bind the IgG or IgM antigen complex at the relevant IgG and or IgM test lines causing pale or dark pink lines to form at the IgG or IgM region of the test membrane. The intensity of the lines will vary depending upon the amount of antibody present in the sample. The appearance of pink line in a specific test region (IgG or IgM) should be considered as positive for that particular antibody type (IgG or IgM).

Reagents

The test strip contains Dengue antigens coated particles and anti-Human IgG and anti-Human IgM coated on the membrane.

Precautions

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as infectious agents.
- The test should be discarded in a proper biohazard container after testing.
- Optimal assay performance requires strict adherence to the assay procedure described in this Instruction sheet and any deviations from the procedure may lead to aberrant results.

Storage & Stability

Store as packaged in the sealed pouch at 4 - 30°C and not in direct sunlight. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials Provided:

- Test Cassette Device
- Instructions for Use
- Test Buffer

Materials Required but not Provided:

- Specimen collection container
- Timer
- Pipette capable of delivering 5-10 µL sample volume

Specimen Collection & Preparation

- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.

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Specimens should not be frozen and thawed repeatedly.

- If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.

Directions for Use:

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Pipette 5 µL of serum, plasma or whole blood into the sample well.
3. Add 4 drops (160 µL) of test buffer to sample well.
4. Wait for the red line(s) to appear. The test result should be read between 15 and 20 minutes. Result may be read up to 30 minutes.

   Note: Do not interpret the result after 60 minutes.

Interpretation of Results:

(Please refer to the illustration)

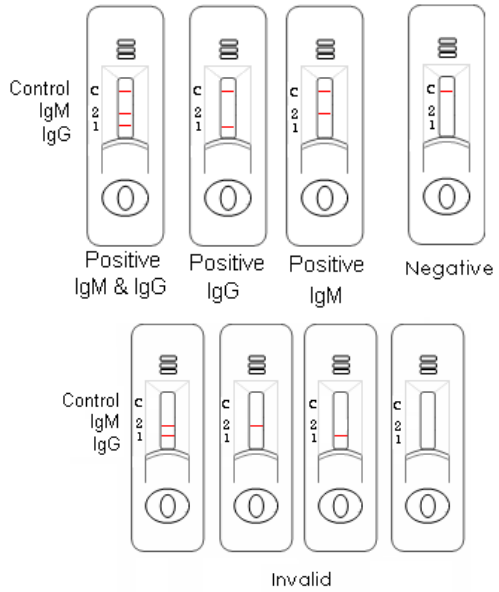
IgM POSITIVE: Two distinct red lines appear. The control line (C) and IgM (M) line are visible on the test cassette. The test is positive for IgM antibodies. This is indicative of a primary dengue infection.

IgG POSITIVE: Two distinct red lines appear. The control line (C) and IgG (G) line are visible on the test cassette. The test is positive for IgG antibodies. This is indicative of a past dengue infection.

IgM and IgG POSITIVE: Three distinct red lines appear. The control line (C), IgM (M) and IgG (G) lines are visible on the test cassette. The test is positive for IgM and IgG antibodies. This is indicative of a secondary dengue infection.

NEGATIVE: One distinct red line appears. The control line (C) is the only line visible on the test cassette. No IgG or IgM antibodies were detected. The result does not exclude dengue infection. A new sample should be drawn from the patient in 3-5 days and then should be retested.

INVALID: Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of lines in the IgG (G) or IgM (M) region of the cassette. Repeat the test using a new cassette.



NOTE: The intensity of the red color in the test line regions (G) and (M) will vary depending on the concentration of IgG and IgM present in the specimen. However, neither the quantitative value nor the rate of increase in IgG or IgM can be determined by this qualitative test.

Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

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

Bibliography

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