Ana-Chek® DENGUE IgG/IgM

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC19

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

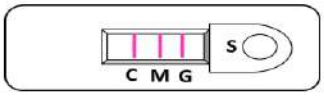
INTENDED USE: Test for detection of IgG and IgM antibody against Dengue virus in human serum and plasma samples.

CLINICAL SIGNIFICANCE

Dengue virus, a virus belonging to the Flavivirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. 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 haemorrhagic 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 haemorrhagic 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. The Ana-Chek® Dengue IgG and IgM Combo Rapid Test is a qualitative test for the detection of IgG and IgM antibodies to dengue virus in human serum plasma. 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, samples may be used with this test. This test is able to detect all 4 Dengue serotypes.

PRINCIPLE

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).

KIT COMPONENTS

Test Device, Assay Buffer, Sample Dropper and Instructions for use.

PRECAUTIONS

1. Wear protective gloves while handling specimens wash thoroughly afterwards.
2. The device is sensitive to humidity as well as heat. Therefore, take out the device from sealed pouch just before test.
3. Do not mix reagents from different lot.
4. Dispose all the samples and kits properly as per the instruction after test in accordance to GLP.
5. Follow the testing procedure exactly as mentioned in the insert.

STORAGE & STABILITY

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

Fresh Serum or Plasma: If testing is not performed within 3 days of collection of specimen, the specimen should be refrigerated immediately at 2-8 °C.

TEST PROCEDURE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing

1. Place the test device on a clean and level surface. Pipette 5 µL of serum, plasma into the sample well.
2. Add 2 drops (60 µl) of assay buffer to sample well.
3. Wait for the red line(s) to appear. The test result should be read between 15 and 20 minutes.

INTERPRETATION OF THE RESULTS

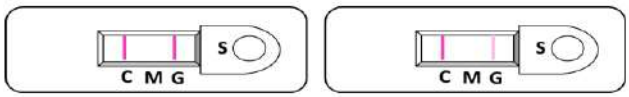
NEGATIVE RESULT:

One band appears in the control region (C). No apparent bands appear in the test regions (1 or 2).

POSITIVE RESULT:

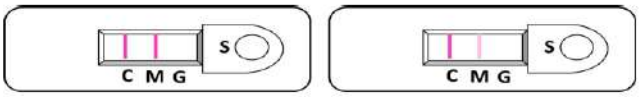
IgG Positive:

The presence of a band at (C) and (G) within the Result Window, indicates a positive result for IgG antibodies.



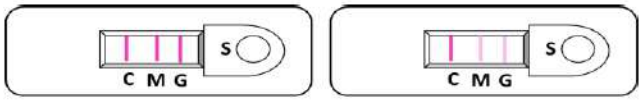
IgM Positive:

The presence of a band at (C) and (M) within the Result Window, indicates a positive result for IgM antibodies.



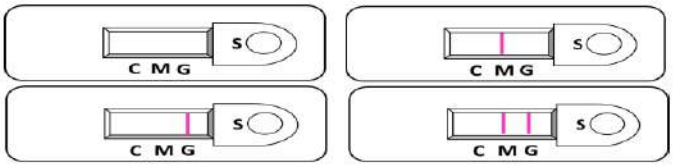
IgG and IgM Positive:

The presence of a band at (C) and bands at (G) and (M) within the Result Window, no matter which band appear first, indicates a positive result for IgG and IgM antibodies respectively.



INVALID TEST:

No visible band at the control (C) region. Repeat with a new test device.



QUALITY CONTROL

A procedural control is included in the test. A coloured 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.

LIMITATION OF PROCEDURE

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The intensity of the red colour in the test line regions (T) will vary depending on the concentration of IgG/IgM present in the specimen. However, neither the quantitative value nor the rate of increase in IgG/IgM can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- Dengue antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. This test is for single use only. Do not reuse the test.

BIBLIOGRAPHY

1. Sabin, AB and Schlesinger RW. Production of immunity to Dengue with virus modified by propagation in mice: Science (1945), 101:640.
2. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.
3. Innis, BL, Nisalak, A., et.al. An enzyme-linked immunosorbent assay to characterize dengue infections where dengue and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene (1989), 40:418-427.
4. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
5. Siti-Strong. Diagnosis, prevention, and treatment of tropical disease, 7th ed., Philadelphia, the Ablakiston Company

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE