Dengue IgG/IgM Rapid Test Kit

Cat No.: S001-03

In vitro Diagnostics

INTENDED USE

Sensit Dengue IgG/IgM Rapid Test Kit is a qualitative immunochromatographic assay for the detection of IgG/IgM antibodies produced in human Serum/Plasma. Sensit Dengue IgG/IgM Rapid Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA.

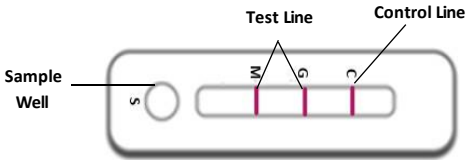
SUMMARY & TEST DESCRIPTION

Dengue viruses, transmitted by the Aedes aegypti and Aedes albopictus mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. There are four known distinct serotypes (dengue virus 1, 2, 3 and 4). In children, infection is often subclinical or causes a self-limited febrile disease. However, if the patient is infected a second time with a different serotype, a more severe disease, dengue haemorrhagic fever or dengue shock syndrome, is more likely to occur. Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality it causes. Traditionally, the serological diagnosis of an acute dengue virus infection has relied on showing a 4-fold or greater rise in anti-dengue virus antibody between paired acute and convalescent phase sera from a patient. Usually, IgM does not become detectable until 5 to 10 days after the onset of illness in the primary infections, IgG appear 14th day and persist for life. Secondary infections show that IgGs rise within 1-2 days after the onset of symptoms and induce IgM response after20 days of infection.

Sensit Dengue IgG/IgM Rapid Test device utilizes Anti-human IgG and Anti-human IgM antibodies as the capture molecules. Dengue Recombinant Antigens-colloidal gold conjugates are used as detection antigens.

TEST DESCRIPTION & PRINCIPLE

Sensit Dengue IgG/IgM Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad, which contains Detection molecule, colloidal gold conjugated; b) a nitrocellulose membrane strip containing three lines; M: Anti-Human IgM antibody, G: Anti-Human IgG antibody and C: Goat Anti-Mouse antibody.



Test sample that is added to the sample well, with adequate amount of buffer migrates from the sample pad along the conjugate pad where Dengue specific IgG/IgM antibodies present in the sample will bind to the colloidal gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone where the complex will bind to the immobilized Anti-Human IgG/IgM Antibodies (on test line) producing a visible line on the membrane. If the antibody is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each test pouch contains:
   a. One test card and dropper
   b. Desiccant
2. Assay Diluent- In dropper bottle
3. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTION & WARNING

1) Use within 10 minutes after opening pouch.
2) Do not touch result window.
3) Use only the buffer supplied along with the kit.
4) Do not mix components from different kits.
5) Do not use with specimen containing precipitates

SAMPLE COLLECTION AND PREPARATION

Serum:

- Collect the whole blood in to a syringe (Not containing anti-coagulants). Leave the syringe preferably at an angle, to settle for 30 minutes. Once blood coagulates, collect the clotted blood in to centrifuge tube and centrifuge to get serum specimen as supernatant.

Plasma:

- Collect the whole blood using a syringe or vacutainer (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Centrifuge the blood to get plasma specimen as supernatant.

Note:

- *If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20^{0}C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10 µl of the specimen to the Sample well "S". (To take 10 µl, aspirate only up to the bubble point in the dropper provided Refer Diagram .1.)

Diagram 1. 10µl sample

Aspirate to the bubble to obtain a 10µl sample

3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample well.
4. Wait for 10 minutes and interpret the result. The result is considered invalid after 15 minutes.

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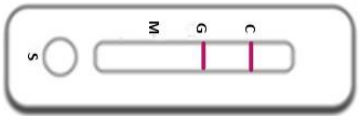
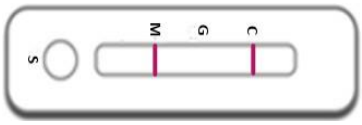
INTERPRETATION OF TEST RESULT

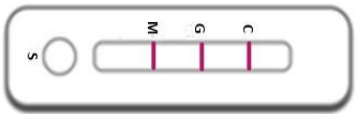
Dengue IgG Positive: A clear pink control band ("C") and a detectable test band ("IgG") appear, indicating the presence of Dengue specific IgG antibody in the sample, probably a secondary Dengue infection.



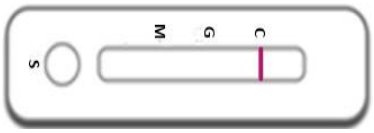
Dengue IgM Positive: A clear pink control band ("C") and a detectable test band ("IgM") appear, indicating the presence of Dengue specific IgM antibody in the sample, probably a primary Dengue infection.



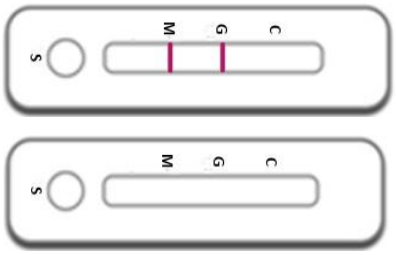
Dengue IgG & IgM Positive: A clear pink control band ("C") and detectable test bands ("IgG and IgM") appear, indicating the presence of Dengue IgG or IgM antibodies in the sample, probably a secondary Dengue infection.



Negative: A pink colored band appears only at control region ("C") indicating the absence of Dengue antibodies in the sample.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.



DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Dengue IgG/IgM Rapid Test for single-step detection of Dengue IgG/IgM antibodies are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by,

ubio Biotechnology Systems Pvt Ltd
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