One Step Dengue IgG & IgM Test
(Serum / Whole Blood)
For In vitro Diagnostic Use Only

INTENDED USE:
The Dengue IgM and IgG Combo Rapid Test is a qualitative test for the detection of IgM and IgG antibodies to dengue virus in human serum, plasma or whole blood. This test is for *in-vitro* diagnostic use only.

INTRODUCTION:
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. By using a mixture of highly purified dengue proteins, the test is able to detect all 4 Dengue serotypes.

TEST PRINCIPLE:
Serum, plasma or whole blood samples may be used with this test. When a specimen is added to the test, IgG and IgM antibodies in the specimen sample react with gold particles coated with dengue envelope proteins. As this specimen/particle mixture migrates along the length of the test, the anti-dengue IgG or IgM antibody particle complex is captured by test band located in the test device window causing a pale to dark red band to form at the Test region of the test device window. The intensity of the bands will vary depending upon the amount of antibody present in the sample. The appearance of any color in test region should be considered as positive for IgG or IgM antibody. A red procedural control line should always develop in the test device window to indicate that the test has been performed properly.

PRECAUTIONS:
1. All Specimens should be handled as being potentially infectious.
2. Biological decontamination procedures should be followed for all equipment, containers, surfaces, etc. that come in contact with potentially infectious specimens. All disposables that come in contact with these samples should be disposed of as infectious waste.
3. For best results, strict adherence to these instructions is required. Be careful not to touch the tip of the buffer bottle to the sample tube when adding buffer to the tube. This will greatly minimize the likelihood of contaminating the buffer reagent.
4. The buffer contains a low concentration of sodium azide as a preservative **(less than 0.1 %).** Sodium azide is toxic. Do not drink this buffer. High concentrations of sodium azide may also react with lead and copper in plumbing to form explosive compounds. If you dispose of this buffer down a drain, flush the drain with excess amounts of water to minimize the accumulation of potentially explosive metal-azide compounds.
5. Do not use the test devices or wash buffer beyond the stated expiration date marked on the package label.
6. Store the test kits and reagents according to the temperature range stated on the package label.
7. All test devices, buffer and specimens must be at room temperature **(2-30 ℃)** before running the assay.
8. Do not re-use the test devices or buffer.

STORAGE AND SHELF LIFE OF REAGENTS:
Store the kit between **2 ℃ and 30 ℃**. Do not store the kit in direct sunlight. Be sure to open only the number of devices to be used. Once the device pouch has been opened, the test device should be used immediately. The test kit may be used until its expiration date, which can be found on the package label.

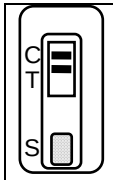
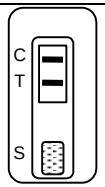
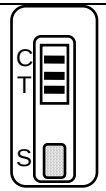
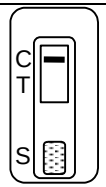
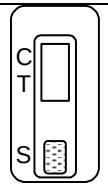
SPECIMEN COLLECTION:
1. Wash your hands with soap and warm water. Choose a puncture site on the fingertip. Clean the fingertip with alcohol. Squeeze the end of the fingertip and pierce it with the lancet. Wipe away the first drip of blood with cotton. Using pipette provided, collect blood from the puncture site.
2. Whole blood samples should be used immediately, if possible.
3. For serum test, centrifuge whole blood to get plasma or serum specimen.
4. If Serum or plasma specimens cannot be tested immediately, they should be refrigerated at 2 to 8 ℃. For storage periods greater than three (3) days, freeze the specimen at -20 ℃ or below.

MATERAILS SUPPLIED
1 Dengue test device
2 Assay diluent
3 Instruction for use
4 Disposable pipette
5 Sterile lancet
A complete set may also contain:
6 Bandage
7 Alcohol pre pad

TEST PROCEDURE:
• Remove the appropriate number of Dengue Combo Test Device pouches from the kit box.
• Tear open the foil pouch and remove the device. Lay the test device on a clean, flat work surface.
• Add 1 drop (approximately 30ul) of whole blood or 2-3 drops serum /plasma into sample well with a pipet.
• Then add 1-2 drops (approximately 50-90ul) of wash buffer provided in the dropper bottle holding the bottle vertically from the sample well.

Negative results must be confirmed after 20 minutes. Do not read results after 30 minutes.

INTERPRETATION OF THE RESULTS:

				
IgG Positive	**IgM Positive**	**IgG & IgM Positiv**	**Negative**	**Invalid**

IgG Positive.
The control line and IgG line are visible on the test stripe. The test is positive for IgG antibodies. This is indicative of a past dengue infection.

IgM Positive
The control line and IgM line are visible on the test strip. The test is positive for IgM antibodies. This is indicative of a primary dengue infection.

IgM and IgG Positive.
The control line, IgM and IgG lines are visible on the test strip. The test is positive for IgM and IgG antibodies. This is indicative of a secondary dengue infection.

Negative Test Result
The control line is the only line visible in the test device window. No IgG or IgM antibodies were detected. The result does not exclude dengue infection. If symptoms persist, a new sample should be drawn from the patient in 3-5 days and then should be retested (see the limitations section).

Invalid Test Result
If the control line does not appear in the test device window, the test results are INVALID regardless of the presence or absence of line in the test region of the device window. Repeat the test using a new device.

EXPECTED VALUES:
Primary dengue is characterized by the presence of detectable IgM antibodies 5 days after the onset of infection.
Secondary dengue is characterized by the elevation of specific IgM antibodies and the elevation of specific IgG antibodies. Usually IgG antibodies will rise within 1-2 days after the onset of symptoms and IgM antibodies will be detectable after 20 days of infection. Therefore, depending on the sampling day, some secondary dengue infections may not have a detectable IgM titer. A final diagnosis should be based on these test results in conjunction with other clinical and laboratory findings.

QUALITY CONTROL:
1. For the assay to be considered valid, the control line must appear. If it does not appear, the test results are not valid and the test must be repeated.
2. In addition to your laboratory's standard quality control procedures, a positive and negative external control be tested at least once within each 25-test kit and by each operator performing testing within a kit. This will verify that the reagents and test devices are working properly and the operator is able to correctly perform the test procedure.

SENSITIVITY AND SPECIFICITY:
A clinical study using a total 87 serum samples was conducted at various sites in 4 countries. The results of the Dengue IgG/IgM combo test were compared with a commercially available ELISA test. The sensitivity and specificity of the IgG and IgM test results are given below:

	ELISA(+)	ELISA(-)
One Step Dengue Test (+)	36	2
One Step Dengue Test (-)	1	48

Sensitivity: 97% Specificity: 96%

ACCURACY: of 98% based on internal Quality Control Standards.

STABILITY:
The Dengue IgG/IgM combo test has been found to be stable for up to 24 months from the date of manufacture when stored between 4 to 30C.The expiration date of each test can be found on the kit box label. No component or reagent of the test should be used beyond its printed expiration date.

LIMITATIONS OF THE TEST:
1. This test detects the presence of antibodies to dengue in the specimen and should not be used as the sole criterion for the diagnosis of a dengue viral infection. Serological cross reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile, yellow fever, etc.), therefore it is possible that patients with these viruses may show some level of reactivity with this test.
2. As with all diagnostic tests, the result must be correlated with clinical findings. If the test result is negative and a dengue infection suspicion still exists, additional follow-up testing using other clinical methods is recommended.
3. A negative serological result at any time does not preclude the possibility of an early infection of Dengue virus.
4. The use of icteric or lipemic samples should be avoided.
5. Strict adherence to the test procedure is required. Do not re-use negative devices. Do not adulterate the wash solution reagent.
6. This test cannot be used to monitor therapy or to estimate the relative antibody titer.
7. This test should not be used on specimens from immunosuppressed individuals.
8. A final diagnosis should be based on these test results in conjunction with other clinical and laboratory findings.