

OneStep

Dengue IgG/IgM Whole Blood/Serum/Plasma

RapiCard™ InstaTest**Cat # 173106L-25**

A qualitative Immunochromatographic test for the simultaneous detection of IgG and IgM Antibodies to Dengue Virus in human Whole Blood, Serum or plasma

INTENDED USE

OneStep Dengue RapiCard™ InstaTest is a immunochromatographic assay for the simultaneous detection of IgG and IgM antibodies to Dengue virus in human whole blood, serum or plasma. The assay is used as a screening test for Dengue viral infection and as an aid for differential diagnosis of primary and secondary infections in conjunction with other criteria.

INTRODUCTION

Dengue fever is one of the most important mosquito-borne diseases in the world in the terms of morbidity, mortality. Dengue fever virus (serotypes 1 – 4) belongs to the group flavivirus, and is transmitted in nature by day-biting Aedes mosquitoes. The most important mosquito vector is highly domesticated and urban species, *Aedes aegypti*. Primary Dengue infection, also known as Dengue Fever, is the most common type of dengue illness. It is associated with mild to high fever, headache, muscle pain and skin rash. Secondary infection is known as Dengue Hemorrhagic Fever (DHF) or Dengue Shock Syndrome, and often results in high fever and in many cases, with hemorrhagic events and circulatory failure. The fatality rate in patients with Dengue Shock Syndrome can be as high as 44%. Dengue presents typically as a fever of sudden onset with headache, retrobulbar pain, pain in the back and limbs (break-bone fever), lymphadenopathy and maculopapular rash. Patients diagnosed with dengue in endemic areas generally have secondary infection,

whereas patients in non-endemic areas are usually diagnosed with primary infection. Specific antibody responses to Dengue virus enable serodiagnosis and differentiation between primary and secondary dengue infections.

OneStep Dengue RapiCard™ InstaTest is a new generation Immunochromatographic test using recombinant dengue viral antigens of all four serotypes to detect specific antibody response.

TEST PRINCIPLE

OneStep Dengue RapiCard™ InstaTest utilizes the principle of Immunochromatography. Mouse anti-human IgM and human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgG line in the test window is closer to the sample well and followed by IgM line. As the test sample flows through the membrane assembly within the test device, the colored–Dengue specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM or IgG) of Dengue virus, if present in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-human IgM and/or human IgG binding proteins coated on the membrane leading to formation of a colored band, which confirms a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test has performed properly, regardless of the presence or absence of anti-Dengue virus antibodies in the specimen.

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:

1. OneStep Dengue RapiCard™ InstaTest in foil pouch
2. Sample buffer
3. Product insert

MATERIALS NOT PROVIDED

1. Specimen collection container
2. 1-20µL Pipetter
3. Timer

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30°C for the duration of the shelf life as indicated on the pouch.

PRECAUTIONS

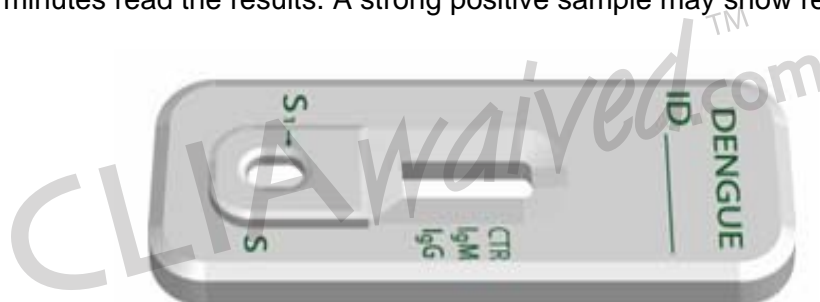
1. This kit is for **IN VITRO** diagnostic use only.
2. This kit is for **PROFESSIONAL** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is complete, dispose specimens after autoclaving them at 121° C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and no smoking or eating while performing assays.
9. Wear gloves during the whole procedure.

SPECIMEN COLLECTION AND PREPARATION

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. Fresh serum / plasma is preferable. Serum / plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods.
3. The test works best on fresh whole blood samples. If testing cannot be done immediately, Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate should be stored at 2-8°C up to 3 days. Blood samples should not be frozen.
4. Repeated freezing and thawing of the specimen should be avoided.
5. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
7. Do not heat inactivate the sample.
8. Shipment of samples should comply with local regulations for transport of etiologic agents.

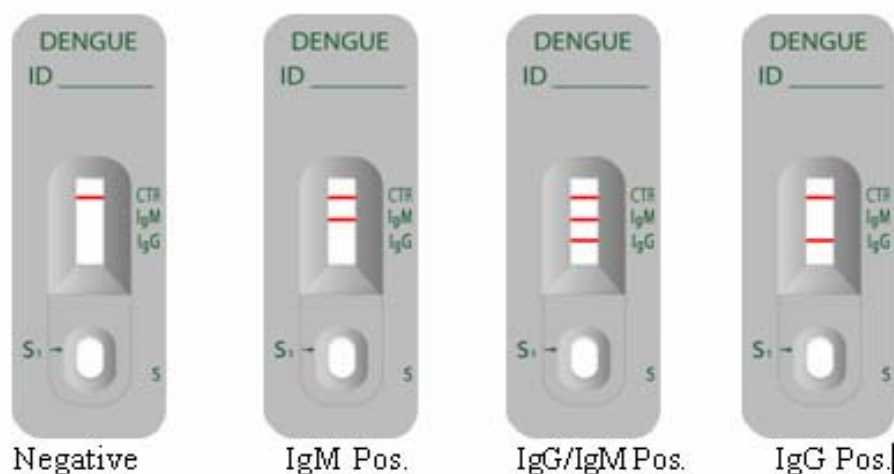
PROCEDURE

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the Card. Once opened, the test card must be used immediately.
3. Label the test card with patients identity.
4. Apply 5 µL of serum, plasma or whole blood to the “S1” area indicated by the **arrow mark**.
5. Add 2 drops of sample buffer to well marked as “S”.
6. At the end of 20 minutes read the results. A strong positive sample may show result earlier.



INTERPRETATION OF RESULTS

1. Negative
Only control line appears.
2. IgM Positive
Both control line and the second test line (the higher test line) appear. It indicates the possibility of primary infection.
3. IgM and IgG Positive
Control line and both test lines appear. It indicate the possibility of acute secondary infection.
4. IgG Positive
Both control line and the second test line (the lower test line which is closer to the sample well) appear. It indicates the possibility the secondary infection or past infection.
5. Invalid Result
If after 20 minutes no control line appears, the result is invalid. The test should be repeated with a new device.



QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

LIMITATIONS

1. The test is for qualitative detection of anti-Dengue antibody in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.
2. The test is for *in vitro* diagnostic use only.
3. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Accuracy

A panel of 60 positive and 40 negative patient sera was tested with a reference OneStep Dengue RapiCard™ InstaTest, Dengue Duo Cassette (Panbio, Australia). The results are summarized in the following table. The agreement is 100%.

	Dengue Duo Cassette		
		Positive	Negative
Dengue Test	IgM Positive	35	0
	IgG Positive	12	0
	IgM/IgG Pos.	13	0
	Negative	0	40

2. Cross Reactivity

No cross reactivity with bilirubin (10 mg/dL), hemoglobin (18mg/dL) or triglycerides (up to 600 mg/dL).

REFERENCES

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Date Adopted	Reference No.
2007-10-19	DA-Dengue IgG/IgM Combo-2009

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