QUICK PROFILE™ *Dengue IgG/IgM Combo Test*

Movies available at YouTube www.youtube.com/QuickProfileDengueGM

REF 71019

A Rapid Qualitative Immunochromatographic Test for the Simultaneous Detection of IgG and IgM Antibodies to Dengue Virus in Human Whole Blood, Serum or Plasma

INTENDED USE

QuickProfile™ Dengue Test is a rapid 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 Aceder mosquitos. 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.

QuickProfile™ Dengue Test is a new generation rapid Immuno-chromatographic test using recombinant dengue viral antigens of all four serotypes to detect specific antibody response.

TEST PRINCIPLE

QuickProfile™ Dengue Test utilizes the principle of Immuno-chromatography. 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 within the test device, the colored–Dengue specific recombinant antigen-colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) of Dengue virus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the anti-human IgM and/or human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates 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. QuickProfile™ Dengue Test Card in foil pouch
2. Sample Buffer
3. Five (5) µL Capillary Pipet
4. Instructions for Use

MATERIALS NOT PROVIDED

1. Sepcimen collection container
2. Timer

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4-30ºC for the duration of the shelf life as indicated on the pouch.

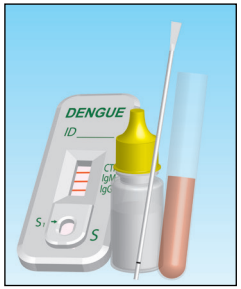
PRECAUTIONS

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 completed, dispose specimens after autoclaving them at 121º 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. The test works best on fresh whole blood / serum / plasma samples. If testing cannot be performed immediately, serum / plasma may be stored at 2-8ºC up to 3 days in case of delay in testing. For long-term storage, serum / plasma specimens can be frozen at -20ºC for 3 months or -70ºC for longer period. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate may be stored at 2-8ºC up to 3 days. Blood samples should not be frozen.
3. Repeated freezing and thawing of the specimen should be avoided.
4. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6. Do not inactivate the sample by heating.
7. Shipment of specimens should comply with local regulations for transportation of etiologic agents.

PROCEDURE



1

Bring the kit components to room temperature before testing.

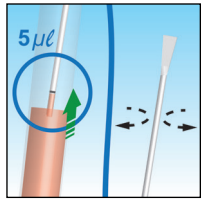
2

Open the pouch and remove the Card .
Once opened, the test card must be used immediately.

3

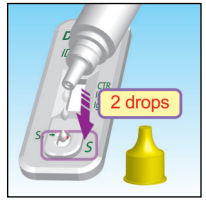
Label the test card with patients identity.

4



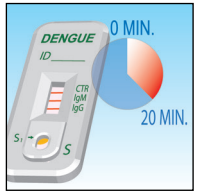
Apply 5µL of serum, plasma or whole blood to the "**S1**" area indicated by the **arrow mark**.

5



Add 2 drops of sample buffer to well marked as "**S**".

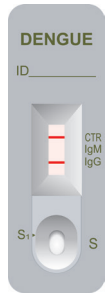
6



At the end of 20 minutes read the results. A strong positive sample may show result earlier.
Note: Result after 20 minutes may not be accurate.

INTERPRETATION OF RESULTS

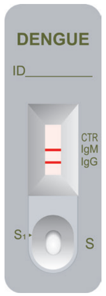
POSITIVE

		
Both IgG/IgM Positive	**IgM Positive** **IgG Negative**	**IgM Negative** **IgG Positive**
Control line and both test lines appear. It indicate the possibility of acute secondary infection.	Both control line and the second test line (the higher test line) appear. It indicates the possibility of primary infection.	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.

NEGATIVE

Only control line appears.

INVALID



The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test 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**

QuickProfile™ Dengue IgG/IgM Combo Test wase evaluated on one thousand and forty one (1041) samples. The test results were compared with an approved predicate kit.

Table 1. Accuracy results of Dengue IgM

		Predicate Test		Total
QuickProfile™ Dengue IgG/IgM Combo Test		IgM Positive	IgM Negative	
	IgM Positive	249	9	258
	IgM Negative	12	771	783
	Negative	261	780	1041

Out of two hundred and sixty one (261) samples that were tested positive by the predicate kit, two hundred and forty nine (249) were positive on QuickProfile™ Dengue IgG/IgM Combo Test. Out of seven hundred and eighty (780) samples that were tested negative by the predicate kit, seven hundred and seventy one (771) were negative on QuickProfile™ Dengue IgG/IgM Combo Test. Twenty one (21) samples that have disagreed results were verified by IFA. Six (6) samples have the results agreed with QuickProfile™ Dengue IgG/IgM Combo Test while fifteen (15) samples agreed with the predicate kit. The agreement with the predicate kit is summarized as below.

Agreement of positive = 249/261 = 95.40%
Agreement of Negative = 771/780 = 98.85%
Total Agreement = 1020/1041 = 97.98%

Table 2. Accuracy results of Dengue IgG

		Predicate Test		Total
QuickProfile™ Dengue IgG/IgM Combo Test		IgG Positive	IgG Negative	
	IgG Positive	128	12	140
	IgG Negative	12	889	901
	Negative	140	901	1041

Out of one hundred and forty (140) samples that were tested positive by the predicate kit, one hundred and twenty eight (128) were positive on QuickProfile™ Dengue IgG/IgM Combo Test. Out of nine hundred and one (901) samples that were tested negative by the predicate kit, eight hundred and eighty nine (889) were negative on QuickProfile™ Dengue IgG/IgM Combo Test. Twenty four (24) samples that have disagreed results were verified by IFA. Seven (7) samples have the results agreed with QuickProfile™ Dengue IgG/IgM Combo Test while seventeen (17) samples agreed with the predicate kit. The agreement with the predicate kit is summarized as below.

Agreement of positive = 128/140 = 91.43%
Agreement of Negative = 889/901 = 98.67%
Total Agreement = 1017/1041 = 97.69%

Assay Specificity

1. Other infectious diseases

QuickProfile™ Dengue IgG/IgM Combo Test has tested sixty (60) samples that were infected by of the following diseases:HAV, HBV, HCV, HEV, Lupus and CMV. All the samples showed no affect on the specificity of the assay.

2. Blood compounds

QuickProfile™ Dengue IgG/IgM Combo Test has tested samples with high Rheumatoid Factor (RF), Bilirubin,
Triglycerol and Hemoglobin. The results showed that these compounds had no effect on the specificity of the assay up to the listed concentration.

Rheumatoid factor	167 IU/ml
Bilirubin	218 IU/ml
Triglycerol	24.68 mL/L
Hemoglobin	9 mg/ml

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4°C 30°C

IVD

EC REP

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