

Dengue IgG/IgM Rapid Test (Serum/Plasma/Whole Blood)

One Step kits for the differential detection of IgG and IgM against Dengue virus Type I, II, III and IV using Human Serum/Plasma/Whole Blood.

INTENDED USE

First View Dengue Fever Rapid IgG/IgM is an immunochromatography assay designed for the qualitative detection and differentiation of specific IgM and IgG antibodies to dengue virus in human serum or plasma. It is intended to be used as in vitro diagnostic of dengue fever. The test provides a differential detection of anti-dengue IgM and anti-dengue-IgG antibodies and can be used for the presumptive distinction between a primary and secondary dengue infection. The results obtained should not be the sole determinant for clinical decision.

INTRODUCTION

Dengue is a flavivirus, transmitted by *Aedes aegypti* and *Aedes albopictus* mosquitoes.¹ It is widely distributed throughout the tropical and subtropical areas of the world,¹ and causes up to 100 million infections annually.² Classic Dengue infection is characterized by a sudden onset of fever, intense headache, myalgia, arthralgia and rash. Primary Dengue infection causes IgM antibodies to increase to a detectable level in 3 to 5 days after the onset of fever. IgM antibodies generally persist for 30 to 90 days.³ Most Dengue patients in endemic regions have secondary infections,⁴ resulting in high levels of specific IgG antibodies prior to or simultaneous with IgM response.⁵ Therefore, the detection of specific anti-Dengue IgM and IgG antibodies can also help to distinguish between primary and secondary infections.

The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid test that utilizes a combination of Dengue antigen coated colored particles for the detection of IgG and IgM Dengue antibodies in human whole blood, serum, or plasma.

PRINCIPLE OF TEST

The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue antibodies in whole blood, serum, or plasma. This test consists of two components, an IgM component and an IgG component. In the IgM component, anti-human IgM is coated in test line region 1 (IgM) of the test. During testing, if the Dengue IgM antibodies present in the specimen, reacts with the Dengue antigen-coated particles in the test strip, and this complex is captured by the anti-human IgM, forming a colored line in test line region 1 (IgM). In the IgG component, anti-human IgG is coated in test line region 2 (IgG) of the test. During testing, the specimen reacts with Dengue antigen-coated particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in test line region 2 (IgG). If the specimen contains IgG antibodies to Dengue, a colored line will appear in test line region 2 (IgG).

Therefore, if the specimen contains Dengue IgM antibodies, a colored line will appear in test line region 1 (IgM). If the specimen contains Dengue IgG antibodies, a colored line will appear in test line region 2 (IgG). If the specimen does not contain Dengue antibodies, no colored line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a colored line will always change from red to blue in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

ACTIVE REAGENTS AND MATERIALS PROVIDED

Dengue IgG/IgM Test cards contain the following:

- Test Device with activated silica gel
- Plastic Dropper.
- Assay Buffer Bottle
- Package Insert (Instruction for use)

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

- Digital Clock
- Specimen collection container Tube

WARNINGS AND PRECAUTIONS:

For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.
- Bring all reagent to room temperature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after performing the test.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to perform the test as bio-hazardous waste.

REAGENT PREPARATION AND STORAGE

INSTRUCTIONS: All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C, ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. Plasma

- **Step 1:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
- **Step 2:** Separate the plasma by centrifugation.
- **Step 3:** Carefully withdraw the plasma into a new pre-labeled tube.

2. Serum

- **Step 1:** Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer®) by venipuncture.
- **Step 2:** Allow the blood to clot.
- **Step 3:** Separate the serum by centrifugation.
- **Step 4:** Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. Store Specimens at 2-8°C if not tested immediately, for up to 5 days. The specimens should be frozen at -20°C for longer storage.

3. Whole Blood

- Drops of whole blood can be obtained by either finger tip puncture or venipuncture. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®). Do not use hemolyzed blood for testing.
- Whole blood specimens should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

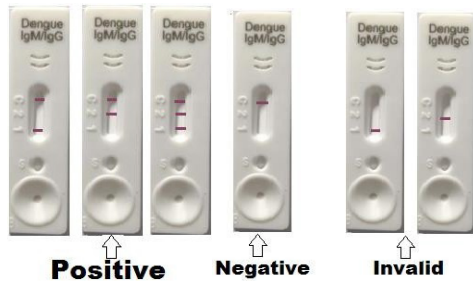
DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it.
2. Remove the test cassette from the sealed pouch and place it on flat dry surface.
3. **For Serum/Plasma OR Whole Blood Specimen:** Hold the dropper vertically and transfer **1 Drop** of Serum/Plasma or Whole Blood (**approximately 5µl**) to the specimen into the sample well (S), then add **2 Drops** of buffer (**approximately 80µl**) into the buffer well (B), and start the timer, see illustration below.
4. Wait for the colored line(s) to appear. The test result should be read at 15 minutes.

Note. Do not interpret the result after 15 minutes.

INTERPRETATION OF ASSAY RESULT



Negative: The presence of one Red band ("C" control line) within the result window indicates a negative result for IgG and IgM antibodies. Retest in 3-5 days if dengue infection is still suspected.

IgM Positive: The control line (C) and IgM line (M) (1) are visible on the test device. This is positive for IgM antibodies to Dengue virus. This is indicative of a primary dengue infection.

IgG Positive: The control line (C) and IgG line (G) (2) are visible on the test device. This is positive for IgG antibodies. This is indicative of secondary or past dengue infection.

IgG and IgM Positive: The control line, IgM (M) (1) and IgG line (G) (2) are visible on the test device. This is positive for both IgM and IgG antibodies. This is indicative of a late primary or early secondary dengue infection.

Invalid: If the control band 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.

PERFORMANCE CHARACTERISTICS

First View Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial Dengue ELISA.

Dengue Infection	Result	IgM	IgG
Primary Infection	Positive	14	0
	Negative	3	17
	Total	17	17
	Relative Sensitivity	82.4%	0%
Secondary Infection	Positive	39	55
	Negative	16	0
	Total	55	55
	Relative Sensitivity	70.9%	>99.0%
Non-Dengue Infection	Positive	0	0
	Negative	378	378
	Total	378	378
	Relative Specificity	>99.0%	>99.0%

For the primary and secondary infection, the overall

Sensitivity: 95.8%,

Specificity: 99.0%

Accuracy : 99.3%.

LIMITATIONS AND INTERFERENCES

- This product is designed for use with human serum, plasma or whole blood only.
- 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.
- The test is a qualitative assay and is not for quantitative determination of antibodies concentration levels. The intensity of the band does not have linear correlation with the antibody titer of the specimen.
- The results obtained should only be interpreted in conjunction with other diagnostic results and clinical information.

LIMITED EXPRESS WARRANTY DISCLAIMER

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REFERENCES

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