Dengue IgG/IgM Rapid Test (WB/S/P)

Labgene biotech

INTENDED USE

Labgene Dengue IgG/IgM Rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection and differentiation of the IgG and IgM antibodies against Dengue virus in human whole blood/serum/plasma samples.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Assay Buffer	Dropper & Sillica Gel	Lancets & Alcohol Swabs
LG010-10T	10	1 X 2 mL	01 in an individual pouch	-
LG010-25T	25	1 X 3 mL		
LG010-30T	30	1 X 3 mL		
LG010-40T	40	2 X 2 mL		
LG010-50T	50	2 X 3 mL		
LG010-100T	100	4 X 3 mL		
LG010LS-10T	10	1 X 2 mL		10
LG010LS-25T	25	1 X 3 mL		25
LG010LS-30T	30	1 X 3 mL		30
LG010LS-40T	40	2 X 2 mL		40
LG010LS-50T	50	2 X 3 mL		50
LG010LS-100T	100	4 X 3 mL		100
*IFU: O1 in an individual carton box				

INTRODUCTION

Dengue virus belongs to the Flavivirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. It is 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. Occasionally it develops into a potentially lethal complication called severe dengue (dengue hemorrhagic fever or dengue shock syndrome). There is no specific treatment for Dengue/ severe Dengue, but early detection and access to proper medical care lowers fatality rates to below 1%. Usually IgM starts to become detectable after 3 to 4 days after the onset of illness in cases of primary dengue infection and until 4 to 5 days after onset of illness in secondary infections. In primary infections, IgG appears on the 14th day and persist for life. Secondary infections shows that IgG rise within 1-2 days after the onset of symptoms and induces IgM response after 20 days of infection.

PRINCIPLE

Labgene Dengue IgG/IgM Rapid test kit is a lateral flow chromatographic immunoassay designed for the qualitative detection and differentiation of the IgG and IgM antibodies against Dengue virus in human whole blood/serum/plasma samples. When a specimen sample is dispensed into the sample well, the sample flows through the filter efficiently after adding buffer solution. The gold-antigen conjugate will bind to Dengue antibodies if present in the sample specimen which in turn will bind with anti-human IgG & anti-human IgM antibodies coated on the membrane as two separate lines in the test region as the reagent move across the membrane. The anti-human IgG & anti-human IgM antibodies on the membrane will bind the Dengue antibody-gold-antigen complex at the relevant G and or M test lines causing pale or dark pink or red lines to form at the G or M region of the test membrane. The intensity of the lines will vary depending upon the amount of antibodies present in the sample. The appearance of the colored line in a specific test region (G or M) should be considered as positive for that particular Dengue antibody type (IgG or IgM). If no band is present in the Control area, the test is invalid and another test must be run using a fresh device, regardless of the presence or absence of band in the Test area.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Centrifuge
- Micropipette

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves or eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.
- Do not use expired lancet.
- Do not share used lancet.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

The Dengue IgG/IgM Rapid Test can be performed using either serum, plasma or whole blood.

Plasma :

- Collect blood specimen into collection tube containing EDTA, Citrate or Heparin.
- Separate the plasma by centrifugation.
- Carefully withdraw the plasma into a new pre-labeled tube.

Serum :

- Collect blood specimen into a collection tube containing no anticoagulants.
- Allow the blood to clot.
- Separate the serum by centrifugation,
- Carefully withdraw the serum into a new Pre-Labeled Tube.

Test the specimens as soon as possible after collections. Store serum/ plasma at 2°C-8°C for up to three days if the tests cannot be performed immediately. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature and mix gently. Do not use haemolysed sample.

Whole Blood :

Venipuncture:

- Collect the whole blood into the collection tube (containing EDTA, citrate or heparin) by Venipuncture.
- Transfer the sample to sample well of device using sample pipette.
- Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The whole blood must be tested within 24 hours of collection.

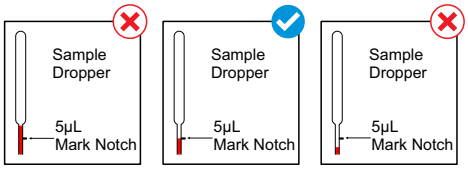
Collection using a lancet:

- Clean the area to be lanced with the alcohol swab.
- Squeeze the fingertip then prick the lateral side of the finger with a lancet provided .
- Wipe away the first blood drop. And immerse the open end of a micropipette and release the pressure to draw blood into it.

PROCEDURE

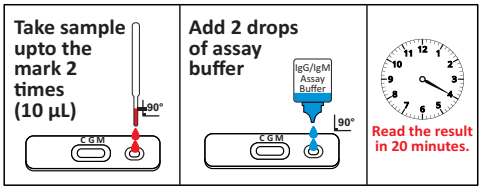
1. Allow test device, specimen, to reach room temperature (15°C- 30°C) prior to testing.
2. Place the test device on a clean and level surface.
3. **For serum/plasma specimen :** Hold the dropper vertically and **take the sample specimen upto the mark (5µL)** as shown in the diagram below and transfer the sample to the specimen well of the test device, then **add 2 drops of assay buffer (about 80 µL)** into the well.
4. **For whole blood specimen :** Hold the dropper vertically and take the **sample specimen upto the mark 2 times (10 µL)** as shown in the diagram below and transfer the sample to the specimen well of the test device, then **add 2 drops of assay buffer (about 80 µL)** into the well.
5. Read the result at the end of 20 minutes. Read results as shown under interpretation of Results.

⚠ **Do not read the results after 25 minutes. For each sample, Strong positive specimens may produce positive result in as little as 1 minutes.**

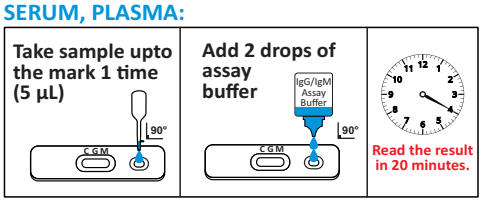


Incorrect Sample Volume | **Correct Sample Volume** | Incorrect Sample Volume

WHOLE BLOOD:



SERUM, PLASMA:



INTERPRETATION OF RESULTS

POSITIVE:

IgG and IgM positive: In addition to the band in the control area marked 'C', appearance of two pink-red coloured bands in the test region 'G' and region 'M', indicates the presence of Dengue virus specific IgG and IgM antibodies.

IgM positive: In addition to the control band in the control area marked 'C', appearance of a pink-red coloured band in the test region 'M', indicates the presence of Dengue virus specific IgM antibodies.

IgG positive: In addition to the control band in the control area marked 'C', the appearance of a pink-red coloured band in the test region 'G', indicates the presence of Dengue virus specific IgG antibodies.

NEGATIVE: Only one colored line appears in the control line region (C). No apparent colored line appears in the test line regions (G or M), indicates the absence of specific antibodies against Dengue virus or that the amount of antibodies is below the detection limit of the test.

INVALID: No visible band appears at the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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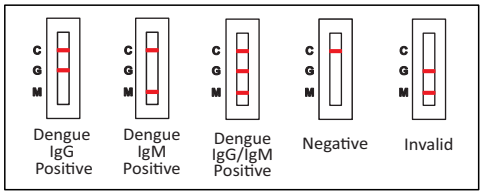
RESULTS:



LIMITATIONS

- The Dengue IgG/IgM Rapid test is for in vitro diagnostic use only.
- Humidity and temperature can adversely affect results.
- This test should be used for the detection of Dengue IgG/IgM Rapid test in human whole blood, serum or plasma specimens only.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results.

PERFORMANCE CHARACTERISTICS

- Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

Dengue IgG Samples	Positive	Negative	Total
Positive	25	00	25
Negative	01	49	50
Total	26	49	75

Relative Sensitivity: 98.00%,
Relative Specificity: 98.00%,
Overall agreement: 100.00%

Dengue IgM Samples	Positive	Negative	Total
Positive	10	00	10
Negative	00	50	50
Total	10	50	60

Relative Sensitivity: 100%,
Relative Specificity: 100%,
Overall agreement: 100%

REFERENCES

1. Current Global Status of Dengue Diagnostics: Miranda D. S. et. al., Journal of Advance in Biology and Biotechnology, 2015.
2. Innis BL, and Nisalak A, et al. An enzyme-linked immunosorbent assay to characterize dengue infections where denude and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene. 1989: 40: 418-427.
3. Clinical Evaluation of a rapid Immunochromatographic test for the diagnosis of Dengue virus infection, Chew Theng Sang. Lim Siew Hoon, Andrea Cuzzubbo, Peter Devine. Clinical and Diagnostic Laboratory Immunology, May 1998, Vol.5, No.3 p.407-409.
4. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.

INDEX OF SYMBOLS

REF	Product Reference No.	ISO ISO 13485	International Organization or Standardization
	Manufacturer		Keep out of Sunlight
	Expiry date	IVD	For invitro diagnostic use only
LOT	Lot (batch) number		Read product insert before use.
2°C 30°C	Store between 2-30°c		Do not use if package is damaged
	Do not reuse		Keep Away From Moisture
	Contains sufficient for test	ART/IFU-010-04	

Manufactured by:

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