QUANTON BIOLIFE SCIENCES

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Dengue IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood)

QBL/DEN/RPT_43

The Dengue IgG/IgM Ab Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Dengue virus in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PDGB 01
05 Tests	PDGB 05
10 Tests	PDGB 10
25 Tests	PDGB 25
50 Tests	PDGB 50

CLINICAL SIGNIFICANCE

Dengue virus, a virus belonging to the Flavivirus group of viruses, is one of the most significant mosquito-borne diseases in the world in terms of morbidity and mortality. There are four known serotypes of dengue. Symptoms of dengue fever include high fever, headache, muscle pain and skin rash[2]. 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[1]. 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[4,5].
The Dengue IgG and IgM Rapid Test is a qualitative test for the detection of IgG and IgM antibodies to dengue virus in human serum plasma. The test provides a differential detection of anti-dengue IgG and anti-dengue-IgM antibodies and can be used for the presumptive distinction between a primary and secondary dengue infection[3]. Serum, plasma, samples may be used with this test. This test is able to detect all 4 Dengue serotypes.

PRINCIPLE

First a specimen is dispensed with sample buffer, the gold antigen conjugate will bind to anti-Dengue IgG and IgM antibodies in the specimen sample which in turn will bind with Anti-Human IgG and Anti-Human IgM coated on the membrane as two separate lines in the test region as the reagent move across the membrane. The anti-Human antibodies on the membrane will bind the IgG or IgM antigen complex at the relevant IgG and or IgM test lines causing pale or dark pink lines to form at the IgG or IgM region of the test membrane. The intensity of the lines will vary depending upon the amount of antibody present in the sample. The appearance of pink line in a specific test region (IgG or IgM) should be considered as positive for that particular antibody type (IgG or IgM).

The test contains an internal control (C band) which should exhibit a colored band of the immunocomplex goat anti mouse IgG/mouse IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only) • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The Dengue IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by vein puncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by vein puncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

To collect Fingerstick Whole Blood specimens:

- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the sample well of the test cassette by using a sample dropper. Avoid air bubbles.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

DIRECTIONS FOR USE

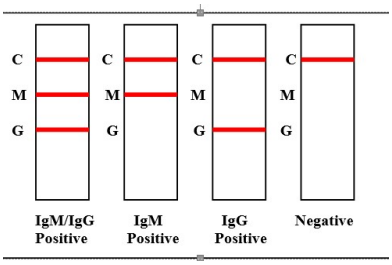
Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Place the cassette on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 5 µL) to the specimen well, then add 2 drops of buffer (approximately 80 µL) and start the timer
4. **For Venipuncture Whole Blood specimen**: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 5µL) to the specimen well, then add 2 drops of buffer (approximately 80 µL) and start the timer

For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 5 µL (1 drop) of fingerstick whole blood specimen to the specimen well of test cassette, then add 2 drops of buffer (approximately 80 µL) and start the timer.

5. Wait for the colored line(s) to appear. Read results at 15 minutes. **Note**: Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



1) **IgG POSITIVE:** Two distinct red lines appear. The control line (c) and IgG (G) line are visible on the test cassette. This is positive for IgG antibodies to Dengue Virus.

2) **IgM POSITIVE:** IgM Positive the control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to Dengue Virus.

3) **IgG/IgM POSITIVE:** IgG and IgM Positive The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to Dengue Virus.

4) **NEGATIVE:** One distinct red line appears. The control line (c) is the only line visible on the test cassette. No IgM/IgG antibodies were detected. The result does not exclude Dengue Virus infection.

5) **INVALID:** Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the IgM(M)/IgG(G) region of the cassette. Repeat the test using a new cassette.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations of the Test

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The Dengue IgG/IgM Ab Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of antibodies for Dengue Virus in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of Dengue Virus can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- Dengue antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance characteristics

A total of 356 specimens were collected (including susceptible subjects) and tested by Dengue Virus IgG/IgM Ab Rapid Test and a commercial Dengue IgG/IgM Ab Rapid Test as reference. Comparison for all subjects is showed in the following table.

	Clinical performance for IgM Test		
IgM Rapid Test	Positive	Negative	Total
Positive	31	1	32
Negative	2	287	289
Total	33	288	321

	Clinical performance for IgG Test		
IgG Rapid Test	Positive	Negative	Total
Positive	35	1	36
Negative	2	287	289
Total	37	288	325

IgM Relative Sensitivity: 96.8% (95% CI: 96.8-97.9%), IgG Relative Sensitivity: 97.2% (95% CI: 97.8-98.9%), Relative Specificity: 99.3% (95% CI: 99.8-100.0%), Overall Agreement: 99.15% (95% CI: 99.8-100.0%)

Cross-reactivity

The Dengue IgG/IgM Ab Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Dengue IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/dl

BIBLIOGRAPHY

1. Sabin, AB and Schlesinger RW. Production of immunity to Dengue with virus modified by propagation in mice: Science (1945), 101:640.
2. Lam, SK. Dengue haemorrhagic fever. Rev. Med. Micro. (1995), 6:39-48.
3. Innis, BL, Nisalak, A., et.al. An enzyme-linked immunosorbent assay to characterize dengue infections where dengue and Japanese encephalitis co-circulate. Am. J. Trap. Med. Hygiene (1989), 40:418-427.
4. CDC/NIH Guidelines. Biosafety in Microbiological and Biomedical Laboratories. 2nd Edition, 1988.
5. Siti-Strong. Diagnosis, prevention, and treatment of tropical disease, 7th ed., Philadelphia, the Ablakiston Company.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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