GB QUIK – DENGUE IgG+IgM
(Whole blood/Serum/Plasma)

KIT NAME	KIT SIZE	CAT. NO
GB QUIK – Dengue IgG+IgM RAPID TEST KIT	25T	GBQDGM025T
GB QUIK – Dengue IgG+IgM RAPID TEST KIT	50T	GBQDGM050T

GENUINE BIOSYSTEM

INTENDED TO USE
The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to Dengue virus in human whole blood, serum, or plasma as an aid in the diagnosis of primary and secondary Dengue infections.

SUMMARY
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.

PRICIPLE
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.

KIT CONTENTS:

S. No	Component	QTY
1	Test Casette	25 nos
2	Prefilled Buffer Solution tube	25 nos
3	Sample Dropper	25 nos

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

SPECIMEN
The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.

- 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.

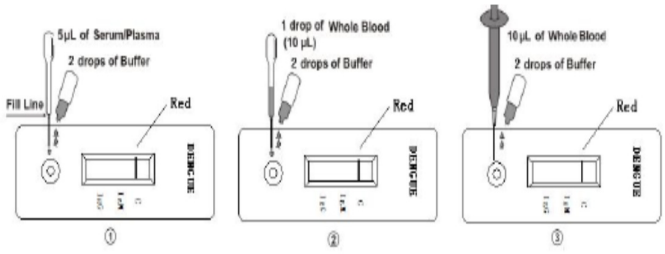
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick Whole Blood specimen to the test device by using a dropper or micropipette measuring 10µL. The dropper provided with the test dispenses approximately 10 µL in one drop even if more blood is aspirated in the dropper.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. 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. • If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST METHODS
Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

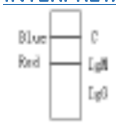
1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.

For Serum or Plasma Specimens: Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 5 µL), and transfer the specimen to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below. Avoid trapping air bubbles in the specimen well (S).

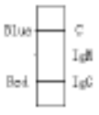
For Whole Blood (Venipuncture/Fingerstick) Specimens: To use a dropper: Hold the dropper vertically, draw the specimen 0.5-1 cm above the Fill Line, and transfer 1 drop of whole blood (approximately 10 µL) to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 uL) and start the timer. See illustration below. To use a micropipette: Pipet and dispense 10 µL of whole blood to the specimen well (S) of the test device, then add 2 drops of buffer (approximately 80 µL) and start the timer. See illustration below. 3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 15 minutes.



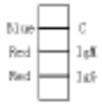
INTERPRETATION OF RESULTS



IgM POSITIVE:* The colored line in the control line region (C) changes from red to blue, and a colored line appears in test line region 1(IgM). The result is positive for Dengue virus specific-IgM and is probably indicative of primary Dengue infection.



IgG POSITIVE:* The colored line in the control line region (C) changes from red to blue, and a colored line appears in test line region 2 (IgG). The result is positive for Dengue virus specific-IgG antibodies and is indicative of secondary Dengue infection.



IgM AND IgG POSITIVE:* The colored line in the control line region (C) changes from red to blue, and two colored lines should appear in test line regions 1 and 2 (IgM and IgG). The color intensities of the lines do not have to match. The result is positive for IgM & IgG antibodies and is indicative of secondary Dengue infection.

***NOTE:** The intensity of the color in the test line region(s) (IgM and/or IgG) will vary depending on the concentration of Dengue antibodies in the specimen. Therefore, any shade of color in the test line region(s) (IgM and/or IgG) should be considered positive.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line changes from red to blue in the control line region (C), confirming sufficient buffer volume and adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested.

LIMITATIONS OF TEST METHODS

1. The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of Dengue antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Dengue antibody concentration can be determined by this qualitative test.
2. The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of Dengue antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Dengue.
3. In the early onset of fever, anti-Dengue IgM concentrations may be below detectable levels. For primary infection, an IgM antibody-capture enzyme-linked immunosorbent assay (MAC-ELISA) showed that 80% of the Dengue patients tested exhibited detectable levels of IgM antibody by the fifth day after infection, and 99% of the patients tested IgM positive by day 10.5 It is recommended that patients be tested within this time. For the secondary infection, a low molar fraction of anti-Dengue IgM and a high molar fraction of IgG that is broadly reactive to flaviviruses characterize the antibodies. 5 The IgM signal may be faint and the cross reaction in the region of IgG line may appear.
4. Serological cross-reactivity across the flavivirus group (Dengue 1, 2, 3 & 4, St. Louis encephalitis, West Nile virus, Japanese encephalitis and yellow fever viruses) is common.6,7,8 Positive results should be confirmed by other means.
5. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
6. Results from immunosuppressed patients should be interpreted with caution.
7. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
8. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Dengue infection.

EXPECTED VALUES

Primary Dengue infection is characterized by the presence of detectable IgM antibodies 3-5 days after the onset of infection. Secondary Dengue infection is characterized by the elevation of Dengue-specific IgG. In the majority of the cases, this is accompanied by elevated levels of IgM.5 The Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial Dengue ELISA test, demonstrating sensitivity of 82.4% for IgM in primary infection and >99.0% for IgG in secondary infection.

PERFORMANCE CHARACTERSTICS

Clinical Sensitivity, Specificity and Accuracy

The 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 test.

Dengue Rapid Test Device vs. ELISA

Dengue Infection	Result	Ig M	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 is 95.8%, the overall specificity is >99.0% and the overall accuracy is 99.3%

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, an IgG positive, an IgM positive and an IgM/IgG dual positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, an IgG positive, an IgM positive and an IgM/IgG dual positive. Three different lots of the Dengue IgM/IgG Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.

REFERENCE

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IVD CE

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