Pariksha Biotech
A game changer in IVD

HIGH Q
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Dengue IgG/IgM cassette

CONTENTS

Dengue IgG/IgM 40 Tests

IVD **For *In-Vitro* diagnostic and professional use only**

Ordering Information

Ref./Cat. No.	Pack Size	Presentation
P - AMH-10	10 ml	

Principal

The LINEAR Dengue IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of:

1) a burgundy colored conjugate pad containing dengue recombinant envelope antigens conjugated with colloid gold (dengue conjugates) and rabbit IgG-gold conjugates,

2) a nitrocellulose membrane strip containing two test bands (G and M bands) and a control band © band).

When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-dengue virus if present in the specimen will bind to the dengue conjugates. The immunocomplex is then captured by the reagent coated on the G band, forming a burgundy colored G band, indicating a dengue virus IgG positive test result and suggesting a recent or repeat infection. IgM anti-dengue virus, if present in the specimen, will bind to the dengue conjugates. The immunocomplex is then captured by the reagent pre-coated on the M band, forming a burgundy colored M band, indicating a dengue virus IgM positive test result and suggesting a fresh infection.

REAGENT COMPOSITION

The G band is pre-coated with the antibody for the detection of IgG anti-dengue virus, M band is coated with antibody for the detection of IgM anti-dengue virus, and the C band is pre-coated with goat anti rabbit IgG.

PACKAGING CONTENTS

40	Dengue IgG/IgM test device
40	Plastic dropper
1	Sample diluent (5 mL)

STORAGE AND STABILITY

Store at 2-30°C. 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. Do not freeze the kit or expose the kit over 30°C. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Serum, (EDTA, citrate or heparin) or plasma unhemolyzed.

Test specimens as soon as possible after collecting. Store specimens at 2°C-8°C if not tested immediately.

Stable up to 5 days at 2-8°C or frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.

Store at 2-8°C if not tested immediately. The specimens must be tested within 24 hours of collection.

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

MATERIAL REQUIRED

- Timer

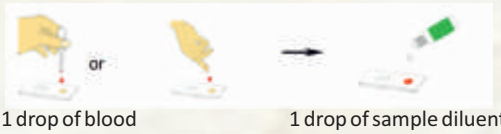
PROCEDURE

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

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Be sure to label the device with specimen's ID number.

For whole blood test

- Apply 1 drop of whole blood (40-50 µL) into the sample well.
- Then add 1 drop (35-50 µL) of Sample Diluent immediately.



1 drop of blood 1 drop of sample diluent

For serum or plasma test

Fill the pipette dropper with the specimen.

- Holding the dropper vertically, dispense 1 drop (30-45 µL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 1 drop (35-50 µL) of Sample Diluent immediately.

1 drop of specimen 1 drop of sample diluent 15 minutes

3. Set up timer.
4. Results can be read in 15 minutes.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

NEGATIVE:

If only the C band is present, the absence of any burgundy color in the both test bands (G and M) indicates that no anti- dengue virus antibodies are detected. The result is negative or non-reactive.

POSITIVE:

1. Two distinct red lines appear. In addition to the presence of C band, if only G band is developed, indicates for the presence of IgG anti- dengue virus; the result suggests past infection or re-infection of dengue virus.

2. In addition to the presence of C band, if only M band is developed, the test indicates for the presence of IgM anti-dengue virus. The result suggests fresh infection of dengue virus.

3. In addition to the presence of C band, both G and M bands are developed, indicates for the presence of IgG and IgM anti-dengue virus. The result suggests current infection or secondary infection of dengue virus.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

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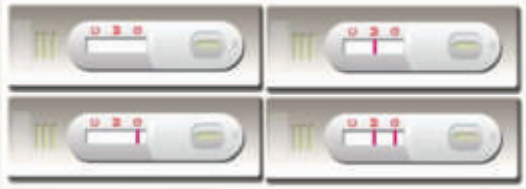
INVALID:
If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands(G and M) as indicated below. Repeat the assay with a new device.



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

CLINICAL SIGNIFICANCE
Dengue viruses, a family of four distinct serotypes of viruses (Den 1,2,3,4), are single-strained, enveloped, positive-sense RNA viruses. The viruses are transmitted by mosquitoes of the daytimebiting Stegemyia family, principally Aedes aegypti, and Aedes albopictus. Today, more than 2.5 billion people living in the areas of tropical Asia, Africa, Australia, and the Americas are at risk for dengue infection. An estimated 100 million cases of dengue fever and 250,000 cases of life-threatening dengue hemorrhagic fever occur annually on a worldwide basis1-3.
Serological detection is a common method for the diagnosis of infection with dengue viruses. IgM anti-dengue virus starts to appear at 3 days after initial exposure and remain in the circulation for about 30-60 days. IgG anti-dengue virus raise at around 7 days, peak at 2-3 weeks, and persist for life 4-6.
The Linear Dengue IgG/IgM Test detects IgG and IgM anti-dengue virus test within 15 minutes. The test is user-friendly, without the need for cumbersome laboratory equipment.

ANALYTICAL PERFORMANCE
Clinical Performance For IgM Test
A total of 224 patient samples from susceptible subjects were tested by theLinear Dengue IgG/IgM and by a commercial EIA. Comparison for all subjects is shown in the following table:

	Linear Dengue IgG/IgM Cassette		
IgM EIA	**Positive**	**Negative**	**Total**
Positive	22	2	24
Negative	5	195	200
Total	27	197	224

Relative Sensitivity: 91.6% , Relative Specificity: 97.5%,
Overall Agreement: 96.9%.

Clinical Performance For IgG Test
226 patient samples from susceptible subjects were tested by the Dengue IgG/IgM Cassette and by a commercial EIA. Comparison for all subjects is shown in the following table:

	Linear Dengue IgG/IgM Cassette		
IgG EIA	**Positive**	**Negative**	**Total**
Positive	25	1	26
Negative	7	193	200
Total	32	194	226

Relative Sensitivity: 96.1% , Relative Specificity: 96.5%,
Overall Agreement: 96.4%

LIMITATIONS OF TEST
1. The Assay Procedure and the Test Result Interpretation must be followed closely. Failure to follow the procedure may give inaccurate results.
2. The Linear Dengue IgG/IgM Cassette is limited to the qualitative detection of antibodies to dengue. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. The Linear Dengue IgG/IgM Cassette can not be used to differentiate if the infection is primary or secondary. No information of dengue serotypes can be provided with this test.
4. Serological cross reactivity with other flaviviruses is common (e.g., Japanese encephalitis, West Nile, yellow fever, etc.), therefore, it is possible that patients infected with these viruses may show some level of the reactivity with this test.
5. A negative or non-reactive result indicates absence of detectable dengue virus antibodies. However, a negative or non-reactive test result does not preclude the possibility of exposure to or infection with dengue virus.
6. A negative or non-reactive result can occur if the quantity of the dengue virus 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 in which a sample is collected. Therefore, a follow up test or alternative tests such antigen test or PCR test method is recommended if the clinical findings strongly suggest an infection.
7. If the symptom persists, while the result from Linear Dengue IgG/IgM Cassette is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
9. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PRECAUTIONS
1. Do not use the components in any other type of test kit as a substitute for the components in this kit.
2. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
3. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
4. Dispose of all specimens and materials used to perform the test as biohazardous waste.
5. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

REFERENCES

1. Gubler DJ, Clark GG. Dengue/dengue hemorrhagic fever. The emergence of a global health problem. Emerg Infect Dis 1995;1(2):55–57.
2. Gubler DJ, Trent DW. Emergence of epidemic dengue/dengue hemorrhagic fever as a public health problem in the Americas. Infect Agents Dis 1994;2:383–393
3. Monath TP. Dengue: The risk to developed and developing countries. Proc Natl Acad Sci U S A 1994;91:2395–2400.
4. Price DD, Wilson SR, Dengue Fever, e-medicine, http://www.emedicine.com/EMERG/topic124.htm, Jan, 2002.
5. 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.
6. Anonymous. Dengue hemorrhagic fever: diagnosis, treatment, prevention and control. 2nd ed. Geneva: World Health Organization, 1997

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