NanoEnTek

IVD

BioTracer™ Dengue IgG/IgM Rapid Card

※ Product code : 17112

▶ INTENDED PURPOSE

BioTracer™ Dengue IgG/IgM Rapid Card is intended for detection and differentiation of IgG and IgM antibodies to dengue virus (DEN 1, DEN2, DEN3, and DEN4) in human serum, plasma or human blood specimens.

▶ EXPLANATION OF THE TEST

Dengue is the most rapidly spreading mosquito-borne viral disease in the world. Dengue virus (DEN) is a small single-stranded RNA virus comprising four distinct serotypes (DEN-1 to -4). These closely related serotypes of the dengue virus belong to the genus Flavivirus, family Flaviviridae. Humans are the main amplifying host of the virus. Dengue virus circulating in the blood of viraemic humans is ingested by female mosquitoes during feeding. Serological detection is a common method for the diagnosis of infection with dengue viruses. Anti-dengue IgM starts to appear at 3 days after initial exposure and remain in the circulation for about 30-60 days. Anti-dengue IgG raise at around 7 days, peak at 2-3 weeks, and persist for life. The **BioTracer™ Dengue IgG/IgM Rapid Card** is a chromatographic immunoassay kit for rapid qualitative determination for dengue infection.

▶ PRINCIPLE OF THE METHOD

BioTracer™ Dengue IgG/IgM Rapid Card is based on the principle of an immunochromatography in vitro test for the qualitative determination of dengue virus specific IgG or IgM in serum, plasma or whole blood. When the specimens are added to the sample well and sample diluent are added to the sample pad, they move to the conjugate pad and resuspend the recombinant dengue virus envelope protein-gold conjugate. The mixtures move along the membrane by capillary action and react with the anti-human IgG or IgM antibodies immobilized in two lines on the test reaction zone. If antibodies against dengue are present enough in the sample, a colored band of dengue IgG or IgM in the test reaction zone will be appeared. If there are no antibodies against dengue or not sufficient in the sample, the area will remain colorless. The sample continues to move to the control reaction zone and forms a red or purple color, indicating the test is working properly and the result is valid.

▶ CONTENTS

1. Test device
2. Sample diluent
3. Capillary tube
4. Package insert

▶ SPECIMEN COLLECTION AND PREPARATION

1. Whole blood specimen collection
   1) Whole blood is collected in syringe or evacuated tube containing the anticoagulant.
   2) Whole blood specimens should be tested immediately after collection. In the case of storing at 2~8℃, it should be tested within 24 hours.

2. Plasma / Serum specimen collection
   1) Plasma or serum specimens should be tested immediately after collection.
   2) Do not leave the specimens at room temperature for prolonged period. Specimens may be stored at 2-8℃ for up to 3 days. For long term storage, specimens should be kept below -20℃.

   ※ Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assay.

▶ TEST PROCEDURE

Allow the specimens and sealed pouch containing the test devices to room temperature prior to use.

1. Remove the test device from the sealed pouch, and place it on a clean and flat surface.
2. Transfer 10㎕ of serum(or plasma) or whole blood in the sample well (S) of the test device using capillary tube provided in the kit or precise micropipette not provided.
3. Add 4 drops (about 120㎕) of sample diluent into the diluent well of the test device.
4. Read the test result at 15~20 minutes. Do not read the test result after 20 minutes.

※ Caution: Perform the test immediately after removing the test device from the foil pouch.

▶ READING AND INTERPRETATION OF RESULT

1. Control (C) band means that the test is working properly.
2. Test (G) and (M) band indicates the test result.

NEGATIVE:
The presence of only Control(C) band indicates a negative result.

POSITIVE:
The presence of Test band ('G' and/or 'M') with Control ('C') band indicates a positive result(refer to back page).

INVALID:
If control (C) band is not appeared in the result window after performing test, the result is considered invalid.
※ The directions may not have been followed correctly or the test device may have been deteriorated. It is recommended that the specimens be re-tested with the new device.

▶ READING AND INTERPRETATION OF RESULT

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.

▶ LIMITATIONS OF THE METHOD

A negative result does not preclude the possibility of infection with dengue. Other clinically available tests are required if questionable results are obtained.

▶ PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity
A study was performed using 312 positive and negative specimens. Each specimens were assayed with the **BioTracer™ Dengue IgG/IgM Rapid Card** and compared with Haemagglutination Inhibition(HI) test.

Reference method (HI test)	BioTracer™ Dengue IgG/IgM Rapid Card			Total
	IgM Positive	IgG Positive	Negative	
Dengue IgM Positive	25	0	5	30
Dengue IgG Positive	0	59	3	62
Negative	12	8	230	250
Total	37	67	238	342

The relative serological sensitivity was 91.3% (84/92) and the relative serological specificity was 92.0% (230/250).

2. Reproducibility
1) Within run performance test was determined by one analyst with ten devices of one lot for 1 negative and 3 different positive control specimens. There was no variation within the test devices of one lot.
2) Between run performance test was determined by three analyst with 3 different lots for 1 negative and 3 different positive control specimens. There was no variation between different analyst.

▶ WARNING AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterward.
4. Do not use test kit if the packing is damaged or the seal is broken.
5. Avoid splashing or aerosol formation while handling specimens.
6. Clean up spilled specimens thoroughly using an appropriate disinfectant.
7. Decontaminate and dispose of all specimens, tested kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

▶ STORAGE AND SHELF LIFE

BioTracer™ Dengue IgG/IgM Rapid Card should be stored at 1~30℃ (34~86°F). The test device is sensitive to humidity as well as to heat. Do not use it beyond the expiration date, printed on the sealed pouch.

▶ LITERATURE REFERENCE

1. 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
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. Dengue Guidelines for Diagnosis, Treatment, Prevention and Control. WHO. 2009

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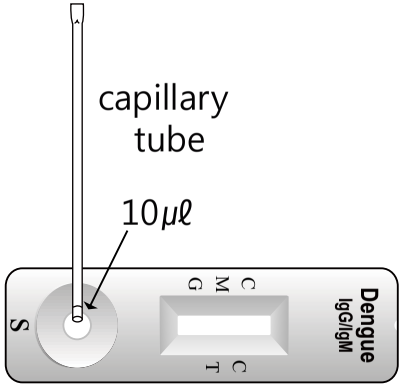
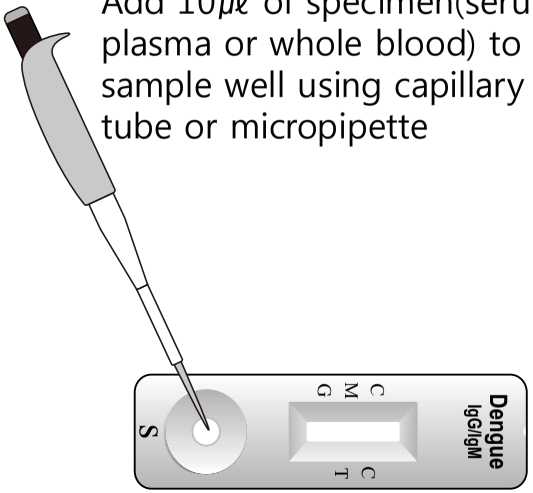
BioTracer™ Dengue IgG/IgM Rapid Card

▶ TEST PROCEDURE AND INTERPRETATION OF RESULT

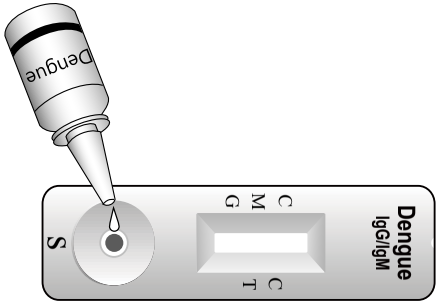
1. Load Specimen



Add 10㎕ of specimen(serum, plasma or whole blood) to sample well using capillary tube or micropipette



2. Load Sample Diluent



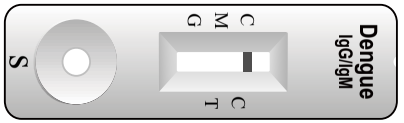
Add 4 drops (120 ㎕) of sample diluent to diluent well

15~20 min

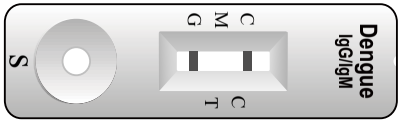
Read

3. Read & Interpret

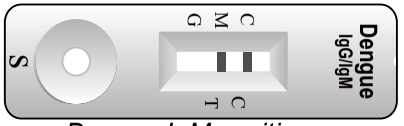
Negative



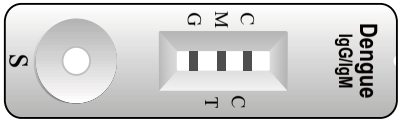
Positive



Dengue IgG positive



Dengue IgM positive



Dengue IgG/IgM positive

Invalid