



3341 SW 15<sup>th</sup> Street – Pompano Beach, FL 33069 - USA – (954) 979-3845 Fax: (954) 979-7997  
[www.healthchemdiagnostics.com](http://www.healthchemdiagnostics.com)

## **RAPID TEST DENGUE FEVER (IgG/IgM)**

---

**One Step® Assay for the simultaneous detection of IgG and IgM Antibodies to Dengue  
Virus in Serum/Plasma/Blood**

**For In Vitro Diagnostic Use**

### **DESCRIPTION:**

The Dengue virus belongs to the Flavavirus group of viruses. This virus is commonly found throughout the tropics and Australia. The symptoms of dengue fever are sudden onset fever, headache, pain in the back and limbs, lymphadenopathy, maculopapular rash and retrobulbar pain.

Dengue fever causes approximately 20,000 deaths annually with nearly 3 million children hospitalized over the past 3 decades as a result of Dengue. The virus is transmitted by a day biting mosquito (Aeder). This species is common in urban settings. Tests such as Elisa and PCR are being used to aid in the diagnosis of Dengue fever.

New serological tests such as the Rapid Test One Step® Dengue IgG/IgM rapid test are among the simplest and fastest means of identifying Dengue antibodies.

### **PRINCIPLE OF THE TEST:**

Rapid Test One Step® Dengue IgG/IgM test kit is a rapid membrane based screening test to detect the presence of antibodies to the Dengue virus. This test is the newer generation lateral flow immunochromatographic type assay. These are among the simplest and easiest to use POC (Point of Care) assays.

The test can be used either with serum or whole blood and employs the use of an antibody binding protein conjugated to a colloidal gold particle and a unique combination of Dengue antigens immobilized on the membrane.

Once the sample is added to the test cassette along with the diluents, the mixture passes through the antibody binding/gold complex, which then binds the immunoglobulins in the sample. As this complex passes over the immobilized antigens on the membrane, if any antibodies to Dengue (IgG or IgM) are present, the antigens capture them in turn. This produces a pink/purple band in the T (Test) zone of the test strip. The remaining complex continues to migrate to a control area in the test strip and produces a pink/purple band in the C area. This control band indicates that the test has been performed properly.

## **KIT COMPONENTS:**

### **Each test kit contains:**

- Test Cassette
- Diluent in dropper vial
- Directions for Use

### **Needed, but not provided:**

- Measuring pipette capable of delivering 5 $\mu$  and 10 $\mu$

## **STABILITY AND STORAGE:**

Dengue IgG/IgM test kit is stable at any room temperature between 8-30°C when in the unopened pouches.

Do Not Freeze the kit or expose to extreme temperatures.

Stability of the kit is 24 months from the date of manufacture – dating is indicated on the kit label.

## **GENERAL PRECAUTIONS :**

- The test is for In Vitro Diagnostic use only.
- Appropriate infection control and handling procedures should be followed – do not smoke, eat or drink in the area where the test is to be performed. Use suitable clothing and gloves when handling samples and when performing the test.
- Do not express (using pipette) any samples or reagents by mouth.
- All materials should be considered potentially infectious. To disinfect, either autoclave materials at 121.5°C for 1 hour, or treat with Sodium Hypochlorite (1 per cent solution).
- Do not use test beyond the expiration date indicated.

## **SAMPLE COLLECTION:**

Dengue IgG/IgM test can be run on serum or whole blood.\*

The test works best on fresh samples. If testing cannot be done immediately, samples should be stored at 2-8°C after collection, and this may remain in storage for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at -20°C, or colder. Whole blood samples cannot be frozen, nor samples collected in EDTA, and it is recommended that finger prick blood be used. Shipment of samples should comply with local regulations for transport of etiologic agents.

\* Plasma may be used dependent on anticoagulant.

## **TEST PROCEDURE:**

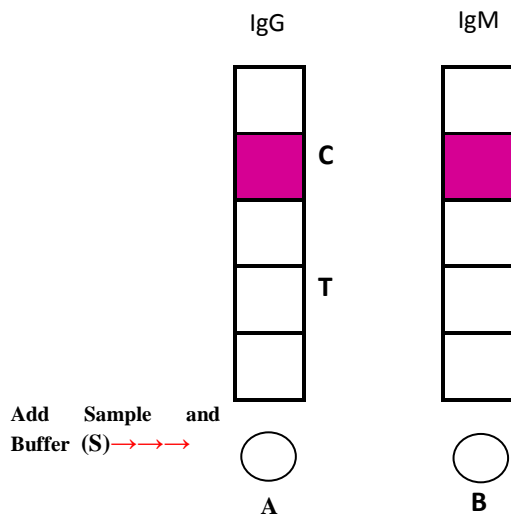
1. Remove as many test cassettes from the pouches as needed. Lay on a clean flat surface
2. *For Whole Blood* – add 10 $\mu$  of sample to the Sample Well labeled (A) of the test cassette using a measuring pipette.  
*For Serum* – add 5 $\mu$  of sample to the Sample Well labeled (A) of the test cassette using a measuring pipette.

3. Follow sample addition with 3 drops of the diluent provided in the dropper bottle by holding the bottle vertically over the (S) well.
4. Results are then read in as little as 5 minutes for strong positives, or up to 30 minutes for weaker positives and to make sure negatives are confirmed.

Note: If the dye has not cleared the membrane, or blood is still present, one or two more drops of diluents may be added to the (S) well.

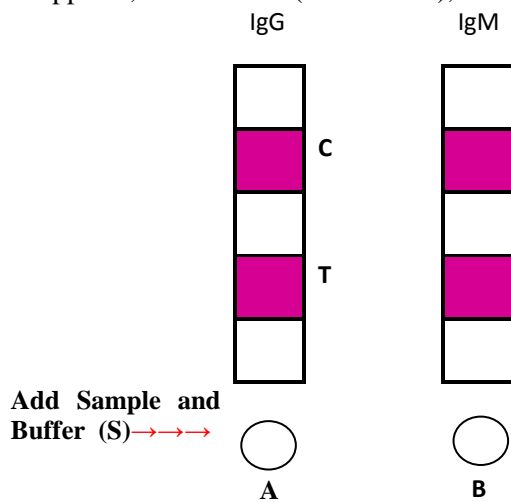
## READING THE TEST RESULTS

**NEGATIVE:** Only one pink/purple band appears in the C (Control) line area of the test cassette;



**Negative Result**

**POSITIVE:** Two pink/purple band appears, one in the C (control line), and one in the T (test line) area of the test strip;



**Positive Result**

**Please Note:** When reading this test, any visible colored line in the T (Test) area of the strip within the prescribed time limit of the test indicates a POSITIVE result.

INDETERMINATE: If only one band appears in the T well – Test area, or no band appears at all in the C well – Control area, it is then recommended that a fresh device be used and the test repeated, carefully following the directions in this insert.

### Rapid Test One Step® Dengue IgG/IgM test vs. ELISA Test

|                   |          | Rapid Test One Step® Dengue Test |          |
|-------------------|----------|----------------------------------|----------|
|                   |          | Positive                         | Negative |
| ELISA }<br>Test } | Positive | 58                               | 1        |
|                   | Negative | 1                                | 65       |

Sensitivity – 98.0%

Specification – 98.0%

### QUALITY CONTROL

A known positive and negative control should be run to insure proper performance. All controls should be handled in the same manner as patient samples.

### LIMITATIONS OF THE TEST

The Instructions for Use and reading of the test instructions must be followed carefully for the test to perform properly.

Dengue IgG/IgM test is designed to detect antibodies against the Dengue virus in serum or whole blood. Testing of any other body fluids has not been validated and may not yield appropriate results.

For samples that test Positive by the Dengue IgG/IgM test, more specific confirmatory testing should be done. A clinical evaluation of the patient’s situation and history should also be made before a final diagnosis is established. The use of a rapid test alone is not sufficient to diagnose Dengue fever even if antibodies are present. Also, a Negative result does not preclude the possibility of infection with Dengue virus.

### PERFORMANCE CHARACTERISTICS

As there are no true standards established for determining the absence or presence of Dengue IgG or IgM antibodies in serum or whole blood samples, it is recommended that the performance of the kit be compared to established serum panels or reference materials. The Dengue IgG/IgM kit is tested against characterized serum samples and has shown to be highly sensitive and specific for Dengue IgG and IgM antibodies.

Manufactured in the USA by:

**HEALTH-CHEM DIAGNOSTICS LLC,**  
**3341 SW 15<sup>th</sup> STREET, POMPANO BEACH, FL - USA**  
[www.healthchemdiagnostics.com](http://www.healthchemdiagnostics.com)  
 Certified ISO CMDCAS 13485:2003



FM77504 - Quality Award  
 FDA Registration No.: 1048532