Windsor, Canada, www.bioassayplus.com

Dengue IgM/IgG rapid test cassette Assay+

Early detection of Dengue IgM and Dengue IgG in serum or plasma for in vitro diagnostic use

Introduction

Dengue virus is a mosquito-borne flavivirus, consisting of four serotypes, it is considered as a major public health problem in tropical / subtropical areas. 2.5-3.0 billion global population is estimated at risk in these regions. Annually about 50 million cases of dengue fever and more than 250,000 cases of dengue hemorrhagic fever occur based on WHO report.

Dengue virus infection includes 1. dengue fever or simple dengue fever usually seen with high fever, headache, myalgia, arthralgias, rashes and leucopenia; 2. dengue haemorrhagic fever is characterized with the acute onset, high fever, haemorrhagic diarrhea, thrombocytopenia, haemostasis and plasma leakage with a tendency to develop fatal shock (dengue shock syndrome).

Dengue infection can be also classified as primary and secondary infection. Due to the four serotypes of dengue viruses, there is no cross-protection between each subtype, multiple infections are common in the infected patients. Infants or children dengue can present with Dengue as primary infection.

Dengue IgM is usually detectable in primary infection between 5 to 7 days after fever, while dengue IgG appears after 7 days. Therefore, the appearance of dengue IgM or IgM/IgG is mostly found in the primary infection depending on the time window of test; while dengue IgG usually appears in the secondary infection in the early days of infection with or without dengue IgM. Based on the tests from different geographic regions, our dengue IgG/IgM test has the sensitivity with clear signal over 90% for all four dengue serotypes, and equal sensitivity tested in the different geographic region, the specificity is over 95%.

Assay principle

The recombinant dengue antigens are used in the test, the dengue antigens used for this test cover all four dengue serotypes. Serum or plasma from dengue infection is loaded to the device, the specific dengue antibodies in specimen will bind to gold-conjugated dengue antigens forming antibody – colloid gold-antigen complex. While the complex migrates along nitrocellulose membrane, the complex is captured by the test lines coated with anti-human IgG or IgM forming a pink to deep pink band at the IgG or IgM test line. The signal intensity is variable depending on the amount of specific antibody present in specimen. A red control line should always develop over control line indicating the proper performance.

This test device can detect all four dengue serotype infection. The sensitivity to detect dengue IgG and IgM is over 85% to 90%.

Kit Components

Each test kit contains:
1. A pouch
2. Pouch contains one cassette test device
3. One 10 ul plastic pipette
4. Each 25 tests with one 3 ml dropper bottle with assay buffer

Stability and Storage Conditions

Dengue IgG/IgM test kit is stable at room temperature between 10-28'C for one and half year in the unopened pouches.

DO NOT FREEZE the kit or expose to temperature extremes.

General Precautions

- The test is for In Vitro diagnosis 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 pipette any samples or reagents by mouth.
- All materials should be considered as potentially infectious. To disinfect, either autoclave materials at 121.5'C for 1 hour or treat with Sodium hyprochlorite (1 percent solution).
- Do not use test beyond the expiration date indicated.

Sample Collection

Serum or plasma is used for this device. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8'C after collection for up to 3 days. If testing can not be done within 3 days, serum can be stored frozen at –20'C or colder.

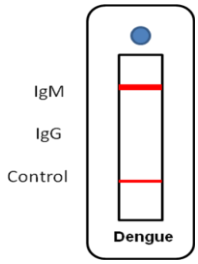
Test Procedure

1. Remove test cards from the pouches before you test, lay over a clean flat surface.
2. In case the tested samples are frozen, the sample must stay at room temperature to completely thaw, and mixed well before the tests are performed.
3. Add 10ul serum or plasma to the well over the test card using included pipette.
4. Follow adding sample, add two or three drops assay buffer from the dropper bottle.

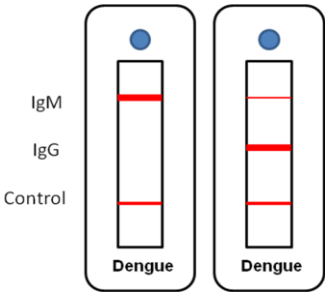
5. Results are displayed after 15 to 30 minutes, make sure control line is always positive.

Reading test results

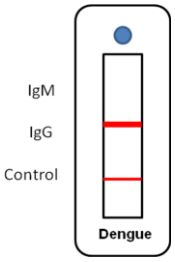
1. Dengue IgG positive



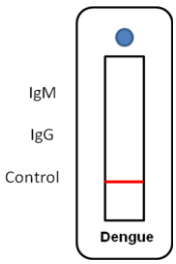
2. Dengue IgM or IgG/IgM positive



3. Dengue IgG positive



4. Dengue test negative



PLEASE NOTE: When reading this test, a clear visible line over IgG or IgM area of the card within the prescribed time limit indicates a positive result.

4. Indeterminate

Control line should always appear. If the test line is positive or negative, without positive control line, it is recommended that a fresh device be used and the test repeated carefully following the directions of the product insert.

5. Quality Control:

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

Result analysis:

1. Early dengue IgM: positive or weak positive without dengue IgG between 2 to 5 days of symptom may indicate an early stage of primary dengue infection;

2. Positive dengue IgM and IgG may occur in primary dengue infection 5 days after symptom;

3. Strong dengue IgG without dengue IgM may indicate the secondary infection;

4. Establishment of primary dengue infection has to combine clinical information for analysis, in the early stage between 1 to 3 days, the pattern is usually with positive or weak positive dengue IgM without dengue IgG; at the late stage after 5 days, it usually shows both dengue IgM and IgG; while the secondary infection, dengue IgG is not associated with dengue IgM or associated with weak IgM reaction.

Limitation of the Test

This instruction should be followed carefully and performed properly.

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

For samples that test positive by Dengue IgM/IgG test, more specific confirmatory testing may be done. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established.