Windsor, Canada, www.immunoassay.ca

Dengue NS1 rapid test – cassette form *Assay+*

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 NS1 antigen is an early mark appearing on the first day after symptom both in primary and secondary infection, the proportion of dengue NS1 antigen in blood is correlated with dengue virus load in patient.

Aassayplus dengue NS1 rapid test detects all four serotype dengue NS1, the sensitivity is over 80 to 85%. Dengue NS1 test has a narrow window for 1 to 6 days, a parallel test for dengue IgG/IgM test may need for testing together.

Assay principle

80 to 120 microliter serum or plasma sample is used for the test. After specimen is loaded to the test device, dengue NS1 antigen in the specimen sample is captured by gold-conjugated monoclonal anti-dengue NS1 antibody, forming the complex with the components of dengue NS1 antibody–conjugated gold and dengue NS1 antigen, migrating along nitrocellulose membrane, the complex is captured by another dengue NS1 antibody coated on the test line to form a pink to deep pink band. The intensity of the band is variable depending on the amount of dengue NS1 antigen present in the blood sample. A red control line should always develop on the test strip indicating the proper performance.

This test device can detect all four dengue serotype virus infection and applied for the early diagnosis of dengue infection. Assayplus dengue NS1 has the sensitivity over 80% and specifity is over 95%.

Kit Components

Each test kit contains:
1. A pouch
2. one cassette test device
3. One plastic pipette

Stability and Storage Conditions

Dengue NS1 test kit is stable at room temperature between 8-30oC for one and half year when 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

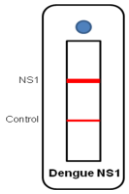
Serum or plasma is used for this device. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8°C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at –20°C or colder.

Test Procedure

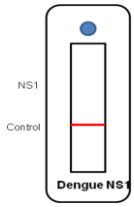
1. Remove test cards from the pouches as needed. Lay on a clean flat surface.
2. In case, the tested samples are in frozen status, the sample has to be sit in room temperature to completely thawing, and mixed well for test.
3. Slowly add 120 microliter serum or plasma drop by drop to the sample well of the test card by using an included pipette.
4. Results are read from 15 to 30 minutes, make sure control line is always positive.

Reading test results

1. Dengue NS1 positive:



2. Dengue NS1 negative:



Control line should appear always if test line is positive, if control line is negative, It is recommended that a fresh device be used and the test repeated carefully following the directions in this insert.

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.

Limitation of the test

The instructions should be followed carefully and performed properly.

Dengue NS1 antigen rapid test is designed to detect dengue NS1 antigen in serum or plasma. Testing of any other body fluids has not been validated and may not yield appropriate results.

For the samples that are tested positive by dengue NS1 rapid test, more specific confirmatory test should be done. A clinical evaluation of the patient's situation and history should also be made before a final diagnosis is established.