RAPID DENGUE™ NS1 Ag

Test device for detection of Dengue NS1 Antigen in Serum / Plasma

BIO LAB DIAGNOSTICS
ISO 9001:2015
ISO 13485:2016
CE

INTENDED USE

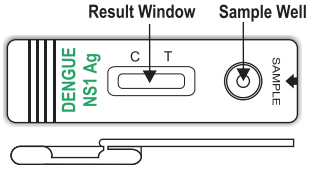
For Rapid qualitative determination of Dengue NS1 Antigen in human Serum / Plasma as an aid in diagnosis of Dengue infection.

SUMMARY AND PRINCIPAL

Dengue fever transmitted by the mosquito, *Aedes aegypti* and *Aedes albopictus*, are widely distributed throughout the tropical and subtropical area of the world. There are four known distinct serotypes (dengue virus 1, 2, 3 and 4). It usually follows symptoms of headach, fever, prostration, severe joint and muscle pain, swollen glands and rash. Dengue NS 1 (non-structural protein 1) is a highly conserved glycoprotein that is essential for the viability of Dengue virus and is produced both in membrane-associated and secretory forms by the virus. NS1 antigen is present at high concentration in the Serum / Plasma of dengue virus infected patients during the early clinical phase of the disease. Dengue NS1 Ag test detect Dengue virus NS1 antigen in human Serum / Plasma.

Biolab's Rapid Dengue NS1 Ag Test is a lateral flow chromatographic immunoassay. The test cassette consist of: 1) a burgundy colored conjugate pad containing dengue monoclonal antibody conjugated with colloidal gold and BSA-gold conjugates, 2) a nitrocellulose membrane strip containing test band "T" and a control band "C". Test band is pre-coated with mouse polyclonal antibody specific to Dengue NS1 antigen and Control band is pre-coated with Rabbit anti-BSA polyclonal antibody.

When a sample is added to the device Dengue NS1 Antigen if present in the sample will bind to the anti-Dengue NS1 Colloidal gold Conjugate. This Complex when migrates through the membrane forming antibody-antigen-antibody colloidal gold complex and produce coloured band in test zone. As procedural control Rabbit Anti-BSA gold conjugate in control zone "C" will always appear if the test procedure is performed correctly.



SAMPLE : Sample well
T : Test zone
C : Control Zone

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use the components in any other type of test kit as a substitute for the components in this kit.
4. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
5. Dispose of all specimens and materials used to perform the test as biohazardous waste.
6. Handle the Negative and Positive Control in the same manner as patient specimens.
7. The testing results should be read within 15 minutes after a specimen is applied to the sample well of the device. Reading result after 20 minutes may give erroneous results.
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

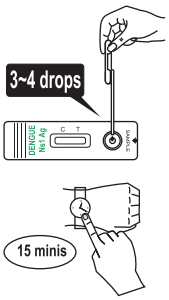
STORAGE AND STABILITY

The kit can be stored between 4-35°C. Shorter exposure to 40°C does not make any change in test result. DO NOT FREEZE. 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 use beyond the expiration date.

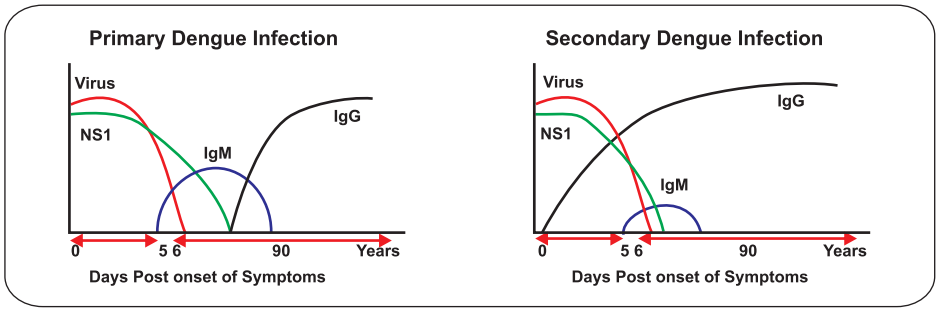
This procedure manual must be read completely before performing the test. Failure to follow the procedure manual gives inaccurate test results.

PROCEDURE

1. Bring all kit components and specimen to room temperature prior to testing.
2. Remove cassette device from sealed pouch immediately before use and label with patients ID. Place on a Flat table top.
3. Add 3-4 drops (100 µL) of Patient's serum or Plasma using sample dispensing device or micro pipette to the Sample well.
4. Observe the results within 15 minutes and interpret as per the test result interpretation column.



Caution :
Strong Positive result could appear immediately on sample with high levels of NS1 Antigen. A very weak positive sample could react in as late as 20 minutes.
Do not interpret result after 30 mins.



MATERIALS

Materials Provided

1. Cassette device
2. Desiccant
3. Sample dispensing device
4. Procedure manual

Materials Not Provided

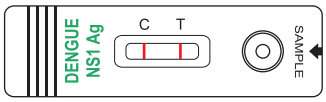
Known Positive and Negative Controls, Timer, Sample collection and handling kits.

SAMPLE COLLECTION AND HANDLING

Sample may be plasma, serum which has no sign of hemolysis. Common anticoagulants have no interference with this test. If the test is not performed immediately, samples should be kept refrigerated. Do Not Freeze. (All samples should be handled as potential infective agents as no laboratory methods make conclusive finding for its safety. Therefore, adequate protective laboratory measures should be taken while handling such materials).

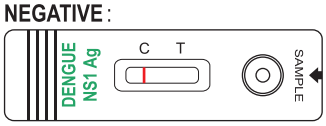
RESULTS INTERPRETATION

POSITIVE:



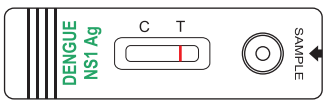
The presence of Two bands at position "C" and "T" respectively indicate a positive result.

NEGATIVE :



The presence of only one band at position "C" indicates a negative result.

INVALID:



Absence of band in position "C" regardless of the band present at position "T" indicates the test is invalid and to be repeated with new test device. Any Shades of line appear after 30 minutes to be reassured with new test device and or sample.

LIMITATIONS AND INTERFERENCES

1. For professional in vitro diagnostic use only.
2. Humidity and temperature can adversely affect results. Similarly avoid excessive air flow or strong air-conditioning while performing the test.
3. Less or Excess sample volume can completely alter the test result.
4. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of Dengue NS1 antigen in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
5. Rapid Dengue NS1 Antigen Test is limited to the qualitative detection of Dengue NS1 Antigen in human serum or plasma. The intensity of the test band does not indicate linear correlation with the antigen titer in the specimen.
6. A negative result for an individual subject indicates absence of detectable Dengue NS1 Antigen. However, a negative test result does not preclude the possibility of exposure to or infection with Dengue Virus.
7. A negative result can occur if the quantity of the Dengue NS1 Antigen present in the specimen is below the detection limits of the assay, or the antigens that are detected are not present during the stage of disease in which a sample is collected.
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.

BIBLIOGRAPHY

1. V. Kumarasamy, A.H. Abdul Wahab, S.K. Chua, Z. Hassan, Y.K. Chem,M. Mohamad, K.B. Chua. Evaluation of a commercial dengue NS1 antigen-capture ELISA for laboratory. J Virol Methods. 2007 Mar;140(1-2):75-9.2.
2. Kassim FM, Izati MN, TgRogayah TA, Apandi YM, Saat Z. Use of dengue NS1 antigen for early diagnosis of dengue virus infection. Southeast Asia J Trop Med Public Health. 2011 May;42(3):562-9.

BIOLAB DIAGNOSTICS (I) PVT. LTD.
J-245, MIDC, Tarapur, Boisar – 401 501, MS.
E-mail : biolab@vsnl.com / www.biolabdiagnostics.com
Customer Care : (+ 9122) 28088243