One Step Rapid Test for Dengue Antigen & Antibody

MaxLINE Dengue Antigen & Antibody Duo Test

Serum/Plasma Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size	Ref. No.	Pack Size
AVDEN-10	10 Tests	AVDEN-30	30 Tests
AVDEN-20	20 Tests	AVDEN-50	50 Tests
AVDEN-25	25 Tests		

INTENDED USE:

MaxLINE Dengue Duo is a rapid, qualitative immunochromatographic test for the detection of Dengue NS-1 (Dengue Non-Structural Protein-1) antigen and differential detection of IgM & IgG antibodies to Dengue virus in human serum/plasma. The test device can be used as a test for Dengue viral infection and as an aid for differential diagnosis of the primary & secondary Dengue infections.

PRODUCT FEATURES :

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen Sandwich Principle.
3. Detects Dengue (NS-1) Antigen & Antibodies (IgM/IgG).
4. Sensitivity for NS-1 : 96.0%
   IgG : 96.19, IgM : 95.37%
5. Specificity for NS-1 : 98.3%
   IgG : 98.46, IgM : 98.44%

INTRODUCTION

Dengue is a flavivirus found largely in areas of the tropic and sub tropics. There are four distinct but antigeniticaly related serotypes of dengue viruses, and transmission is by mosquito, principally Aedes aegypti and Aedes albopictus. The mosquito-born dengue viruses (serotypes1-4)cause dengue fever , a severe flu like illness. The disease is prevalent in third world tropical regions and spreading to sub tropical developed countries-including occur worldwide each year, including potentially deadly form of the disease called dengue a haemorrhagic fever(DHF)and dengue shock syndrome (DSS). Primary infection with dengue virus results in a self -limiting disease characterized by mild to high fever lasting for 3 to 7 days, severe headache with pain behind the eyes, muscle and joint pain, rash and vomiting. Secondary infection is the more common form of the disease in many parts of Southeast Asia and South America. IgM antibodies are not detectable until 5-10 days in case of primary dengue infection and until 4-5 days in secondary infection after the onset of illness. IgG appear after 14days and persist for life in case of primary infection and rise within 1-2 days after the onset ofsymptoms in secondary infection. This form of the disease is more serious and result in DHF and DSS. The major clinical symptoms can include high fever , haemorrhagic events, and circulatory failure, and the fatality rate can be high as 40% .Early diagnosis of DSS is particularly important, as patient may die within 12 to 24 hours if appropriate treatment is not administered. Primary dengue virus infection is characterized by elevation in specific NS1 antigen levels 0 to 9 days after the onset of symptoms; this generally persists upto 15 days. Earlier diagnosis of Dengue reduces risk of complication such as dengue haemorrhagic fever (DHF) and dengue shock syndrome(DSS), especially in countries where dengue is endemic.

PRINCIPLE

Dengue NS-1 is an rapid chromatographic immunoassay for the qualitative detection of Non – structural protein 1(NS1) in human serum /plasma. Dengue NS1 antigen device contains two lines; “C” (Control Line) & “NS1” (Test line). The test membrane is pre-coated with a NS-1 specific antibody on the Test line region and utilizes a separate control to assure assay flow and performance. During testing, the test sample is added directly to the sample well. The sample interact with NS1-specific monoclonal antibodies conjugated to gold nano particles. The solution migrates upward on the membrane (via capillary action) to react with the anti-NS1 antibody on the membrane. If NS1 antigen is present, a purple/pink line will appear at the test line. The purple/pink line at the control region should always appear if the assay is performed correctly.

For IgG/IgM Test :The test device consists of: 1) a purple colored conjugate pad containing dengue recombinant envelope antigens conjugated with Colloid gold (dengue conjugates), 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). When an adequate volume of test sample is dispensed into the sample well of the test cassette, the sample migrates by capillary action across the cassette. IgG/IgM anti-dengue, if present in the sample, will bind to the dengue conjugates. The immunocomplex is then captured by the reagent pre-coated on the Test Lines forming a purple colored Test line, indicating a dengue IgG/IgM positive test result and suggesting a recent or repeat infection. Absence of any Test lines suggests a negative result.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C). 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 FREEZE. Do not use beyond the expiration date.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Buffer Vial	Product Insert
AVDEN-10	10 Tests	10Nos.	1 No.	1 No.
AVDEN-20	20Tests	20 Nos.	1 No.	1 No.
AVDEN-25	25 Tests	25 Nos.	1 No.	1 No.
AVDEN-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVDEN-50	50 Tests	50 Nos.	3 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

1. Dengue Combo antigen & antibody test Device.
2. Assay Buffer (For Dengue IgG/IgM test only)
3. Sample Dropper for Ns1
4. Sample Dropper for IgM/IgG
5. Product Insert

2. Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for serum/ plasma separation only)
- Stop Watch

PRECAUTIONS

1. For Professional use only, not to be used by the general public.
2. Bring all the reagents & specimen room temperature before use.
3. Wear protective cloth such as laboratory cloths disposable gloves and eye protection.
4. Do not use test kit components after the expiration date.
4. Dispose of all used test components in a properly labeled container.
5. Read the package insert care fully before testing.
6. Humidity & temperature can adversely affect results.

SPECIMEN COLLECTION AND STORAGE

1. Human Serum /Plasma must be used with this assay and usual precautions for venipuncture should be observed.
2. Collect blood in a clean, dry, sterilized vial and allow it to clot. Separate the serum by centrifugation at 5000 r.p.m for 15 minutes at room temperature.
3. Testing should be performed as soon as possible after collection. Do not leave Serum/Plasma at room temperature for prolonged periods.
4. Preferably use fresh sample may be stored at 2-8°C for up to 3 days or frozen at -20°C or lower for long period.

TEST PROCEDURE :-

1. Bring the sealed pouch to room temperature before use.
2. Remove the test cassette from the foil pouch by tearing at the "notch" and place it on a level flat surface.

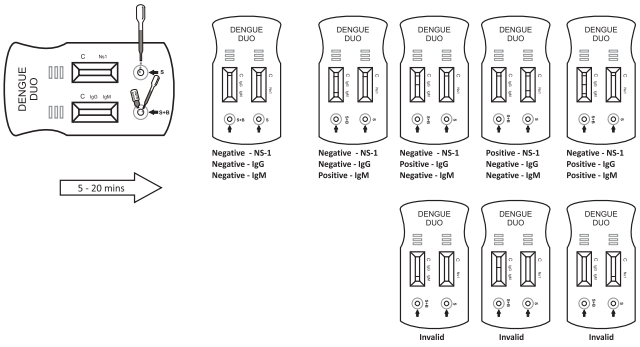
A. Testing Procedure for Dengue Ns1

1. Holding a sample dropper vertically, add exactly 3 drops or 60 µl of serum /plasma to the sample well “s”.
2. Read results between 5-20 minutes and discard the cassette after 20 minutes.
3. Do not read the results after 20 minutes.

B. Testing Procedure for Dengue Antibody (IgM/IgG)

1. Hold the dropper vertically and **transfer 1 drop** (approximately 20 µl) serum/plasma to the speciemen well (S) of the test device.
2. Add 1 drop of assay buffer (approximately 35 µl), avoid trapping air bubbles in the specimen well.
3. Start the timer and wait for the colour lines to appear in the window.
4. Read results between 5-20 minutes and discard the cassette after 20 minutes.
5. Do not read the results after 20 minutes.

INTERPRETATION OF RESULTS



1. **Negative** : One coloured band appears in the control region C. The result should be considered negative for dengue antibody & antigen.
2. **Positive** : Appearance of coloured bands at IgM & C' regions indicates that specimen is positive for IgM Dengue antibody. Appearance of coloured bands at IgG & C' regions indicates that specimen is positive for IgG Dengue antibody. Appearance of bands at NS-1 & C regions indicates that specimen is positive Dengue NS-1 antigen. Appearance of coloured bands at IgM, IgG & C regions indicates that specimen is positive for Dengue antibody IgM/IgG or both.
3. **Invalid** : Appearance of no coloured bands in the control line region "C", the assay should be considered invalid regardless of any coloured band in the region IgM & IgG in Dengue antibody test or NS-1 in the Dengue antigen test. Repeat the test with new card.

Note : The intensity of the colour in the test line regions (NS-1, IgM & IgG) will vary depending on the concentration of Dengue antigen/antibodies in the specimen.

QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

EXPECTED VALUES

The Dengue Ag & Ab Rapid Test (Serum/ Plasma) has been compared with a leading commercial Dengue Ag & Ab test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS

MaxLINE Dengue Antigen (NS1) & Antibody (IgM/IgG) Duo Test has been evaluated with specimen obtained from a population of symptomatic and asymptomatic individuals. Results were confirmed by a leading commercial Dengue ELISA test. The Result show that the over all relatives sensitivity from the primary & secondary infection of the Dengue rapid test cassette.1225 Samples whose result were earlier confirmed by ELISA Test were tested with Dengue Ns1. Six hundered Samples whose result were earlier confirmed by ELISA Test were tested with Dengue IgG/IgM Antibody. The Result are Given below :-

Dengue NS1(Antigen)

Method		MaxLINE Dengue Antigen (NS1) Test		
	Results	ELISA		Total results
		Positive	Negative	
Dengue NS1 rapid Test Cassette (Serum/Plasma)	Positive	120	5	125
	Negative	18	1082	1100

Sensitivity: 96.0 % Specificity: 98.3 %

Dengue IgG Ab test results

Method		MaxLINE Dengue Antibody (IgM/IgG) Test		
	Results	ELISA		Total results
		Positive	Negative	
Dengue IgG rapid Test Cassette (Serum/Plasma)	Positive	101	3	104
	Negative	4	192	196
Total Results		105	195	300

Sensitivity: 96.19 % (101/105) Specificity: 98.46 %(192/195)

Dengue IgM Ab test results

Method		MaxLINE Dengue Antibody (IgM/IgG) Test		
	Results	ELISA		Total results
		Positive	Negative	
Dengue IgM rapid Test Cassette (Serum/Plasma)	Positive	103	3	106
	Negative	5	189	194
Total Results		108	192	300

Sensitivity: 95.37% (103/108) Specificity: 98.44% (189/192)

PRECISION

Intra-Assay

Within-run precision has been determined by testing 15 replicates of three specimens : a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by testing 15 replicates on the same three specimens : a negative, a low positive and a high positive. Three different lots of the Dengue Duo Rapid Test (Serum/Plasma) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to Dengue Duo negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATIONS OF THE TEST

1. MaxLINE Dengue Antigen (NS1) & Antibody (IgM/IgG) Duo test is an *in vitro* diagnostic test. The test should be used for qualitative detection of Dengue antigen NS-1 and Dengue antibodies IgG & IgM in human serum or plasma.
2. The test detects the presence of Dengue Ns1 antigen & IgM/IgG antibodies to Dengue virus in the specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
3. A negative result occur if the quantity of dengue virus Ns1 antigen or IgM/IgG antibodies present in the specimen is below the detection limit of the assay.
4. Some patients may not produce detectable levels of antibody within the first 7-10 days after infection. Where symptoms persist, patients should be retested 3-4 days after the first specimen.
5. If the test result is negative and clinical symptoms persists, additional follow-up testing using other clinical methods is recommended. A negative result does not preclude the possibility of an early infection of Dengue virus.

DISCLAIMER:

The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.

WARNING:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

REFERENCES:

1. Monath, Flaviviruses. In: Fields, B. N. et al. Fields Virology, 2nd ed. Vol 1,New York: Raven Press, 1990, p. 763-814
2. Effler PV, Halstead SB. Immune enhancement of viral infection. Progress in Allergy 1982;31:301-64

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test

ISO 13485 Certified Company

5^Schedule MDR 2017

Manufactured in India by :

AVECON Healthcare Pvt. Ltd.
Transforming Research into Innovations
Plot No.: 338, Sector-2, Industrial Growth Centre, Saha, Ambala, Haryana (INDIA)-133104
E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com
Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875

Ver. : 05/10-25