One Step Rapid Test for Dengue Antibody

MaxLINE Dengue IgG/IgM Antibody

Serum/Plasma Test Protocol

ORDERING INFORMATION

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

INTENDED USE:

MaxLINE Dengue Ab-IgG/IgM Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to dengue virus in serum/plasma to aid in the diagnosis of Dengue viral infection.

PRODUCT FEATURES

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen Sandwich Principle.
3. Detects IgG IgM Antibodies against Dengue Ns1
4. Sensitivity for : IgG : 96.19, IgM : 95.37%
5. Specificity for : 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 of symptoms 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 :-

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/M 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 G or M band, forming a Purple colored line (S), 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
AVDAB-10	10 Tests	10Nos.	1 No.	1 No.
AVDAB-20	20Tests	20 Nos.	1 No.	1 No.
AVDAB-25	25 Tests	25 Nos.	1 No.	1 No.
AVDAB-30	30 Tests	30 Nos.	2 No.	1 No.
AVDAB-50	50 Tests	50 Nos.	3 No.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

1. Test Device .
2. Buffer
3. Sample Dropper
4. Product Insert

2. Materials Required But Not Provided

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

PRECAUTIONS

1. Do not use test kit components after the expiration date.
2. Dispose of all used test components in a properly labeled container.
3. Read the package insert care fully before testing
4. The test result is invalid over 20 minutes.
5. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.
6. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.
7. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results

SPECIMEN COLLECTION AND STORAGE

1. **Serum:** Use disposable syringe (vacuum blood collection tube) to extract a certain amount of venous blood, and place at room temperature for blood coagulation, Separate the serum by centrifugation at 5000 r.p.m for 15 minutes at room temperature.

2. **Plasma:** Use vacuum blood collection tube with anticoagulation to extract a certain amount of venous blood, and rock repeatedly, take plasma separation for detection.

A) EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.

B) Serum and plasma samples may be stored at 2-8°C for 3 days prior to assay, and at -20°C for 2 years. Repeat freeze and thaw for no more than 3 times.

C) Testing should be performed as soon as possible after collection. Do not leave serum/Plasma at room temperature for prolonged periods.

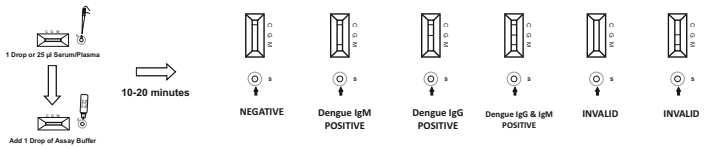
TEST PROCEDURE

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20°C-30°C) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10°C-50°C)

1. Hold the dropper vertically, add 1 drop specimen (approximately 20 µl), and transfer the specimen to the sample well “S”.
2. Add 1 drop of 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 10-20 minutes and discard the cassette after 20 minutes.
5. Do not read the results after 20 minutes.

INTERPRETATION OF RESULTS

Use Only serum and plasma



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

PERFORMANCE CHARACTERISTICS
MaxLINE Dengue Antibody (IgG/IgM) 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 IgG Ab test results

Method		MaxLINE Dengue Antibody (IgG/IgM) Test		
Dengue IgG rapid Test Cassette (Serum/Plasma)	Results	ELISA		Total results
		Positive	Negative	
	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 (IgG/IgM) Test		
Dengue IgM rapid Test Cassette (Serum/Plasma)	Results	ELISA		Total results
		Positive	Negative	
	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 IgG/IgM Ab 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 IgG IgM 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
1. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment.
2. Negative result may occur when detecting short-term infected samples or some second time infected samples, indicating that the specific antibodies of Dengue IgM does not exist or the concentration is below the detection limit. Some patients may not produce enough antibodies to be detected in their body within 7 - 10 days, it may show negative results. For some patients, if theDengue infection is still suspected, they need to do a new Dengue rapid test 3-4 days later.
3. It is common to have serological cross-reactions with Flaviviruses (ie, between dengue types 1, 2, 3, 4 and St. Louis encephalitis, West Nile, Japanese encephalitis, yellow fever virus, etc.).
4. Samples with high concentrations of Rheumatoid factor or Heterophilic antibodies may cause false positive results
5. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
6. Cannot be used for screening the general population, but can only be used for the screening of patients with clinical symptoms or when there is suspicious exposure.
7. The continued existed or not existed of antibodies cannot be used to determine if the treatment is succeeded or not.
8. The best time for dengue testing is 6 ~ 14 days after the symptom of fever.
9. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.

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.

REFERENCE

[1] Monath, Flaviviruses. In: Fields, B. N. et al. Fields Virology, 2nd ed. Vol 1, New York: Raven Press, 1990, p. 763-814.

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[3] Halstead SB. Neutralisation and antibody-dependent enhancement of dengue viruses. Advances in Virus Research 2003;60:421-67.

[4] Gubler DJ, Dengue and dengue hemorrhagic fever. Clin Microbiol Rev 11, 480, 1998

[5] Pang L, Kitsutani P, Vorndam V, Nakata M, Ayers T, Elm J, Tom T, Reiter P, Rigau-Perez JG, Hayes JM, Mills K, Napier M, Clark GG, Gubler DJ; Hawaii Dengue Outbreak Investigation Team. Dengue fever, Hawaii, 2001-2002. Emerg Infect Dis. 2005; 11(5):742-9

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

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E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875

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