AVECON
Transforming Research into Innovations

One Step Rapid Test for Dengue NS-1 Antigen

MaxLINE Dengue NS1 Antigen Test

Serum/Plasma Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVDNS1-10	10 Tests
AVDNS1-20	20 Tests
AVDNS1-25	25 Tests
AVDNS1-30	30 Tests
AVDNS1-50	50 Tests

INTENDED USE:

MaxLINE dengue NS1 Antigen is an rapid chromatographic immunoassay for the qualitative detection of Dengue Non – structural protein 1(NS1) in human serum /plasma.

PRODUCT FEATURES

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen Sandwich Principle.
3. Detects NS1 Antigen.
4. Sensitivity: 96.15%
5. Specificity: 98.3%

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

MaxLINE Dengue NS-1 is an rapid chromatographic immunoassay for the qualitative detection of Non – structural protein 1(NS1) in human serum /plasma. Dengue NS-1 antigen device contains two lines; “C” (Control Line) & “NS1” (Test line). The test membrane is pre-coated with a NS1 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 (viacapillary 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.

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	Product Insert
AVDNS1-10	10 Tests	10Nos.	1 No.
AVDNS1-20	20Tests	20 Nos.	1 No.
AVDNS1-25	25 Tests	25 Nos.	1 No.
AVDNS1-30	30 Tests	30 Nos.	1 No.
AVDNS1-50	50 Tests	50 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

a) Individually packed test strip
b) Sample Dropper
c) 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.

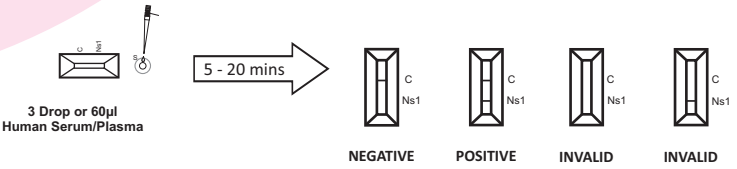
SPECIMEN COLLECTION AND STORAGE

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. The samples may be stored at 2-8°C for up to 7 days or frozen at -20°C or lower for up to 30 days.

TEST PROCEDURE

1. Remove the cassette from the foil pouch by tearing at the "notch" and place it on a flat surface.
2. Holding a sample dropper vertically, add exactly 3 drops or 60 µl of serum /plasma to the sample port.
3. Read results between 5-20 minutes and discard the cassette after 20 minutes.
4. Do not read the results after 20 minutes.

INTERPRETATION OF RESULTS



1. **Negative :** One coloured band appears in the control region (C).
2. **Positive :** Two coloured bands appear one in the test region (NS1) and other in the control region (C).
3. **Invalid :** Non appearance of any coloured bands indicates inconclusive result.

Note : In the case of invalid test should be repeated with fresh cassette.

QUALITY CONTROL

A procedural control is included in the test. A red 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 NS1Ag Rapid Test (Serum/ Plasma) has been compared with a leading commercial Dengue NS1 test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS
1225 Samples whose result were earlier confirmed by Elisa Test were tested with MaxLINE dengue NS1, The Result are Given below :-

Specimen	Number of sample	Positive	Negative
Dengue NS1 Positive	125	120	5
Negative	1100	18	1082

Sensitivity : 96.15 %
Specificity: 98.3 %

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 NS1 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 Ns1 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
This test detects the presence of antibodies to dengue in The Specimen and should not be used as the sole criteria for the diagnosis of Dengue virus infection.

1. 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.
2. 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.
3. Halstead SB. Neutralisation and antibody-dependentenhancement of dengue viruses. Advances in Virus Research 2003;60:421-67.
4. Lamm S.K. (1995), dengue haemorhagic fever. Rev. Med. Micro,6-39-48..Seth, J. (1991. standardization & quality assurance. In principle and practice of immunoassay, Ed. C.P. Price & D.J. Newman. Macmillan Publishers, pp.154-189.

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

GMP 5th Schedule MDR 2017

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