DENGUE NS1 Antigen Card test

BHAT Bio Scan®

For Professional Use

IVD

A Rapid Chromatographic Immunoassay for the detection of Dengue NS1 Antigen in Human Serum or Plasma

Read the pack Insert before use provided along with the kit

REF DNS1

INTENDED USE : Dengue is a flavivirus found largely in areas of the tropic and sub-tropics.There are four distinct but antigenitically 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 flue like illness. The disease is prevalent in third world tropical regions and spreading to sub tropical developed countries including the United states .WHO estimates that 50-80 million cases of dengue fever occur worldwide each year, including potentially deadly form of the disease called dengue a haemorragic 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 up to 15 days. Earlier diagnosis of Dengue reduces risk of complication such as dengue haemorragic fever (DHF) and dengue shock syndrome(DSS), especially in countries where dengue is endemic.

TEST PRINCIPLE : The Bhat Bioscan® Dengue NS1 Antigen Card test contains a membrane strip which is precoated with antibodies to Anti Dengue Ns1 antigen .This test device has a letter of T & C as "Test line" and "Control line" on the surface of the case. Both the Test Line (T) and Control line (C) in result window are not visible before applying any samples. When a sample is added to the device , Dengue NS1 antigen if present in the sample will bind to the anti -dengue NS1 gold colloid conjugate making antigen antibodies complex. This complex migrates along the membrane to the test region and forms the visible pink line at "T" as antibody-antigen. The Control Line is used for Procedural control. Control Line should always appear if the test procedure is performed properly and reagents of control line are working.

STORAGE AND STABILITY :Kit should be stored between 2-30ºC in the sealed pouch. The kit is stable until the expiry date mentioned on the pouch when stored under the above conditions.

PACK SIZE: 10 Test

Contents of the Kit

Pack Size	10 Test
Test Device	10 Nos.
Silicagel	10 Nos.
50µl Dropper	10 Nos.
Pack Insert	1 No.

MATERIAL REQUIRED BUT NOT PROVIDED:

a) Sterilized vial b) Disposable gloves c) Sodium hypochlorite solution (free available chlorine 50-500mg/L) d) Autoclaved Tips

Warnings & Precautions : In order to obtain reproducible result , the following rules must be observed :

a). Read this Pack insert carefully.

b). DO NOT FREEZE THE KITS. If refrigerated the kits should be brought to room temperature before testing . Assay should be conducted between 15 - 30ºC.

c). Do not use umbilical cord blood because it prevents colloidal gold from migrating & can interfere with result.

d). Do not use the kits beyond their expiry date.

e). Use only Serum or Plasma.

f) Carefully observe the prescribed number of drops to be added, 2drop of serum or plasma only.

g). Use the test device soon after it is removed from the pouch.

h).Do not use the test device, if the pouch seal is broken.

I). Avoid any contamination among samples; for this purpose, disposable tips and sterilized vial should be used for each sample and reagent.

j). Read the results in 20 minutes.

DO NOT INTERPRET THE RESULT AFTER 20 MINUTES.

k). Do not smoke, eat drink or apply cosmetics during the assay.

l) For in vitro Diagnostic Use only.

m). For single use only.

All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control / National Institute of Health manual “Biosafety in Microbiological and Biomedical Laboratories”,1984. Never pipette by mouth. Do not smoke, eat or drink in areas in which specimens or kit reagents are handled. Afterwards wash hands carefully. Avoid splashing or forming aerosols. Discard all materials and specimens as if capable of transmitting infection The preferred method of disposal is autoclaving for a minimum of one hour at 121ºC. Liquid waste not containing acid may be mixed with sodium hypochlorite so that the final mixture contains 50-500 mg/l available chlorine. Allow 30 minutes for decontamination.

NOTE : Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite. Spills should be wiped up throughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous waste matter for proper disposal. Reagents are stored between 2-30°C. Avoid unnecessary exposure to light. Do not use reagents after expiration date. Do not mix or interchange reagents from different kits or kit batches. Cross contamination of reagents or samples can cause erroneous results. Use a new pipette tip for each sample. Optimal results are obtained by strictly adhering to the test protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements, is essential. Once the assay has been started, all steps should be performed without interruption.

SPECIMEN : Fresh serum or plasma.

SPECIMEN COLLECTION & PREPARATIONS:

a). 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.

b). If serum is not to be assayed immediately it should be stored at 2-8ºC or if storing more than 3day, then freeze the specimen at -20ºC or below.

ASSAY PROCEDURE:

1. Bring the kit and samples to room temperature.
2. Remove the device from the pouch just prior to testing.
3. Place the device on a flat surface.
4. Add 2 drops of sample into the sample window (S)
5. Read the results in 20 minutes. DO NOT READ ANY RESULT BEYOND 20 MINUTES.
6. Any line appearing after Twenty minutes would be of no diagnostics value.

PRECAUTIONS

1. Read this Pack insert carefully.
2. DO NOT FREEZE THE KITS.
3. Do not use after the expiration date.
4. Use only serum or plasma specimen. Fourth more, do not use umbilical cord blood because it prevents colloidal gold from migration and can interfere with results.
5. Carefully observe the prescribed number of drops to be added 2 DROPS OF SERUM OR PLASMA ONLY.
6. The Dengue NS1 Antigen kit Test pack if refrigerated should be brought down to room temperature before testing. Assay should be conducted at room temperature (2- 30ºC)
7. Use the kit soon after removing from the pouch.
8. Do not use the test device, it the pouch seal is broken.
9. Frozen specimens should be brought down to room temperature before testing.
10. Specimen should not be repeatedly frozen and thawed.
11. For in vitro diagnostic use only.

ASSAY PROCEDURE :
SAMPLE ADDITION

Interpretation of Test Result :
DO NOT INTERPRET THE RESULT AFTER 20 MINUTES.
NEGATIVE: Only Red band appears in the control zone (C) of the result window. No band at test zone (T).

POSITIVE : Appearance of two colored bands, one in the test zone and another in the control zone (C), indicates that sample is positive for NS1 of dengue virus.

INVALID : If a colored band does not appears in the control zone (C) or only Test Line appears, then the result is Invalid.

EXPECTED VALUE : Primary dengue is characterized by the presence of detectable NS1 Antigen from 1st day after the onset of infection.
Sensitivity: 93.4%
Specificity: 99%.

LIMITATIONS OF THE TEST
This test detects the presence of Dengue NS1 Antigen in the Specimen during the 1st day to 9th day of the Dengue infection and should not be used as the sole criteria for the diagnosis of Dengue virus infection.
If the test result is negative and clinical symptoms persists, additional follow-up testing using other clinical methods such as Antibody MAC Elisa, HIA, Virus Inoculation tests, RT-PCR is recommended. A negative result does not preclude the possibility of an present/past infection of Dengue virus.

NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

LIMITED EXPRESSED WARRANTY OF MANUFACTURER
The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

REFERENCES :
1.Dengue haemorrhagic fever : Diagnosis, treatment, prevention and control. WHO 2nd Edition 1997.
2. Songee L. ranch and Paul N. Levett. Evaluation of four methods for detection of immunoglobulin M antibodies to dengue virus. Clin.Diagn. Lab. Immunol. Vol6 (4) p 555-557, 1999.
3.Lamm S.K. (1995), dengue haemorhagic fever. Rev. Med. Micro,6-39-48.
4.Seth, J. (1991. standardization & quality assurance. In principle and practice of immunoassay, Ed. C.P. Price & D.J. Newman. Macmillan Publishers, pp.154-189.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
2℃ 30℃	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL -	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

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