Dengue IgG/IgM Card Test

For Professional Use

A Rapid Card Test to detect IgM & IgG antibodies to Dengue Virus in human Serum or Plasma or Whole blood

IVD

Read the pack Insert before use provided along with the kit

REF BDC

INTENDED USE : Dengue IgG/IgM rapid card test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to dengue virus in human serum or plasma or whole blood. This test is intended for Professional use as aid in the presumptive diagnosis between primary and secondary dengue infection. This test provides only a preliminary test result. Therefore, isolation of virus, antigen detection in fixed tissues, RT-PCR and serological test like haemagglutlnation-Inhibition test, more specific alternative diagnosis method must be used in order to obtain a confirmation of dengue virus Infection. This kit can detect all 4 Dengue serotypes by using a mixture of recombinant dengue envelope proteins.

INTRODUCTION : The Dengue Virus belongs to the Flavivirus group of viruses transmitted by the mosquito, Aedes aegypti and Aedes albopictus mosquitoes, widely distributed throughout the tropical and subtropical areas of the world. The dengue fever is very common in rainy season. The symptoms of Dengue fever are sudden onset of fever, headaches, pain in the back and limbs, lymphaderopathy, maculopapular rash and retrobulbar pain. There are four known distinct serotypes (dengue virus 1,2, 3 and 4). In children infection is often subclinical or causes a self-limited febrile disease. However, if the patient is infected a second time with a different serotype a more severe disease, dengue hemorrhagic fever or dengue shock syndrome is more likely to occur. Dengue is considered to be the most important arthropod-borne viral disease due to the human morbidity and mortality it causes. Traditionally haemagglutination-inhibition (HAI) test has been the most commonly used serological assay for dengue diagnosis.

Primary Dengue infection is associated with mild to high fever, headache, muscle pain and skin rash. Immune response includes IgM antibodies produced by 5th day of symptoms and persist for 30-60 Days. IgGs appear in the 14th day and persist for life. Secondary infections often result in high fever and in many cases with hemorrhagic events and circulatory failure. Secondary infections show that IgGs rise within 1-2 days after the onset of symptoms and induce IgM after 20 days of infection. Traditionally, HAI titers have been used to classify infection. The current definitions as primary or secondary depends on an assay of paired serum specimens separated in time by at least 7 days, although any acute specimen with a HAI titer>1:2560 is defined as coming from a patient with secondary Flavavirus infection.

TEST PRINCIPLES : The Dengue IgG/IgM test kit is a sandwich immunochromalographic membrane based screening test to detect the antibodies for dengue virus. The test can be used with whole blood. The test employees the use of colloidal gold particle conjugated with IgG & IgM binding proteins and a unique combination of dengue antigen immobilized on the membrane at T. After the addition of sample and running buffer in the sample well of test device, the mixture passes through the conjugate gold and makes a immune complex.
The Immune complex will bind with the antigen immobilized at test zone(T) of the test device if antibodies to dengue present in the sample. The remaining complex continues to migrate to a control area (C) in the test device and produces a colored band In the control (C) zone. The control band indicates that the test has been performed properly and is in working condition. Appearance of pink/purple band at test (T) in addition to band at control (C) indicates that sample is positive for dengue antibodies.

STORAGE AND STABILITY : Kit should be stored between 2°C-30°C in the sealed pouch. The test kit is stable until the expiration date mentioned on the pouch when stored under these conditions. Do not use the test device, if the pouch is damaged or the seal is broken. Keep the test device in the sealed pouch until ready for use. **The opened diluent bottle is stable for 2 years.**

CONTENTS OF THE KIT :

Pack Size	5 Test	10 Test	20 Test	50 Test
1. Test Device	5 Nos.	10 Nos.	20 Nos.	50 Nos.
2. Assay Diluent	0.75 ml	1.5 ml	3.0 ml	7.5 ml
3. Silicagel	5 Nos.	10 Nos.	20 Nos.	50 Nos.
4. 5µl Dropper	5 Nos.	10 Nos.	20 Nos.	50 Nos.
5. Pack Insert	1 No.	1 No.	1 No.	1 No.

MATERIAL REQUIRED BUT NOT PROVIDED:

a) Sterilized vial b) Disposable gloves
c) Micro pipette(1-10µl) d) Sodium hypochlorite solution (free available chlorine 50-500mg/L) e) 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 whole blood.
f) Carefully serve the prescribed number of drops to be added, 5µl of serum or plasma or whole blood and 2 drops of diluent 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 result in 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.
n).Do not use the whole blood sample, which is stored for more than 3 days as it may give false positive result.

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 121°C.

Liquid wasted 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 or whole blood

Specimen collection & Preparations (Collection by Veni Puncture) :

a) Collect whole blood into a sterilized vial (Containing EDTA, Citrate or Heparin) by venipuncture.

b) If specimens are not immediately tested, they should be refrigerated at 2-8°C.

c) When stored at 2-8° C the whole blood sample should be used with in 3 days.

COLLECTION USING A LANCET :

a) Clean the area to be lanced with an alcohol swab.

b) Squeeze the end of the finger and pierce with a sterile lancet.

c) Wipe away the first drop of blood with sterile gauze or cotton.

d) Using the micropipette or dropper draw 5µl of whole blood.

ASSAY PROCEDURE :

Remove as many test units from the pouches as needed and put on flat surface. Label them with sample/patient identity.

Add 5µl of serum or plasma or whole blood to the sample window of the device.

Add 2 drops of the Diluent provided in the dropper bottle by holding the bottle vertically over the sample well.

Read the results in 20 minutes only.

INTERPRETATION OF TEST RESULT :

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 (IgM and or IgG) and another in the control zone (C), indicates that sample is positive for antibodies of dengue virus.

Positive for IgG & IgM

Positive for IgM

Positive for IgG

INVALID : If a colored band does not appears in the control zone or Only Test Line appears, then the result is Considered Invalid.

EXPECTED VALUE : Primary dengue is characterized by the presence of detectable IgM 3-5 days after the onset of infection. Secondary dengue is characterized by the elevation of specific IgG 1- 2 days after the onset of infection and in the majority of cases this is generally accompanied by an elevation of IgM.

Sensitivity: 98.4%
Specificity: 99%.

LIMITATIONS OF THE TEST

1. 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.
2. In early infections and some secondary infections, detectable levels of IgM antibodies may be low. 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.
3. 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.

REFERENCES :

1. 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.
2.Lamm S.K. (1995), dengue haemorhagic fever. Rev. Med. Micro, 6-39-48.
3. Seth, J. (1991. standardization & quality assurance. In Principle and practice of immunoassay, Ed. C.P. Price & D.J. Newman. Macmillan Publishers, pp.154-189.
4. Dengue haemorrhagic fever : Diagnosis, treatment, prevention and control. WHO 2nd Edition 1997.

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.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
2°C 30°C	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				

R-12, 2013-05-03

Manufactured in India by :
BHAT BIO - TECH INDIA (P) LTD.
11-A, 4th Cross, Veerasandra Industrial Area, Electronics City,
Bangalore - 560100, Karnataka, INDIA Tel.: +9180 3319 4000 (30 lines)
Fax : +9180 3319 4001 www.bhatbiotech.com