CHIKUNGUNYA IgM SPOT TEST

For Professional Use

BHAT Bio-Scan®

IVD

A Rapid test for the detection of IgM antibodies to Chikungunya in human serum / plasma

Read pack Insert before use provided along with the kit

REF BCSm

INTENDED USE: Chikungunya IgM Spot Test Bhat Bio-Scan® is an immuno concentration based assay for the detection of IgM antibodies to chikungunya in human serum or plasma.

INTRODUCTION: Chikungunya is a relatively rare form of viral fever caused by an alphavirus that is spread by mosquito bites from the Aedes aegypti mosquitos. Major symptoms include flu, high fever, severe back pain, joint pain (sometimes for months), rash on the trunk and limbs, vomiting and mild hemorrhaging (in children). Diagnosis can be done based on the presence of Chikungunya antigen or antibodies to Chikungunya, in the sample.

TEST PRINCIPLE: Chikungunya is diagnosed based on IgM captured immuno assay utilizing recombinant antigens (E1 and E2) derived from its structural proteins, which are immobilized on a nitrocellulose membrane. As the sample passes through the membrane, if Chikungunya IgM is present, that will bind to immobilized antigens. The bound IgM is visualized by reacting with Anti Human IgM gold conjugate, which gives distinct red spot against white background. Proper test performance is verified by the appearance of a spot next to C produced by binding of Anti human IgM gold to the control antibody immobilized next to C.

STORAGE :

The Reagent box has to be stored at 2-8°C. DO NOT FREEZE. Other contents of the kit to be stored at room temperature (25- 30°C). Reagents must be brought to room temperature prior to use.
When not in use return the Reagent Box to 2- 8°C.

STABILITY

1. The un-opened kits are stable for 1½ year from the date of manufacturing as indicated on the package.
2. Opened kits must be used with in 3 months of opening. Test device once opened from the pouch must be used immediately.
3. Repeated 'freeze-thaw cycles' i.e., bringing the kits to room temperature and back to the refrigerator several times will reduce the stability of the kit.

PACK SIZE : Available in packs of 5T, 10T, 20T and 10T Pack

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. Buffer Solution (Ready to Use)	3.0 ml	6.0 ml	12.0 ml	2 x 15.0 ml
3. Gold Conjugate (Ready to use)	1 x 0.75 ml	1 x 1.5 ml	2 x 1.5 ml	2 x 3.0 ml
4. Droppers	5 Nos.	10 Nos.	20 Nos.	50 Nos.
5. Pack Insert	1 No.	1 No.	1 No.	1 No.

MATERIALS REQUIRED BUT NOT PROVIDED

a. Sterilized Vial.
b. Disposable latex gloves.
c. Precession Pipette.
d. Sodium hypochlorite solution (free available chlorine 50-500 mg/l).
e. Autoclaved Tips.

WARNINGS

For in vitro diagnostic use only.
1.Wear disposable latex gloves while handling specimens and kit reagents. After the test, wash hands carefully.
2. Reagents to be stored between +2° C and +8° C.
3. Pre warm all reagents to 25±5 °C before use.
4.The expiration date is printed on each component and on the package.
5. Do not expose the conjugate to excessive light and high temperature.Once opened, the components must be closed tightly.
6. Do not use competitors gold conjugate or diluent. If used chances of wrong results are more.
7. Do not use different batches of gold conjugate or diluent. If used chances of wrong results are more.

SPECIMEN : Fresh Serum or Plasma.

SPECIMEN COLLECTION AND HANDLING :

1. Collect blood in a clean sterilized vial and allow it to clot. Separate the serum by centrifugation at 5000 r.p.m. for 15 min at room temperature. It is recommended that FRESH Samples should be used. If serum is not to be assayed immediately it should be stored at 2-8°C or frozen at -20°C. Serum may be stored at 2-8°C for up to 3 days and stored frozen at-20°C for 3 months. Bring specimen to room temperature (25±5° C) and mix each specimen thoroughly prior to use.
DO NOT HEAT OR REPEATEDLY FREEZE/THAW SPECIMEN.

SPECIMEN PROCESSING : Use only serum or plasma for testing, The specimen should be clean and transparent. Viscous or turbid specimens should be centrifuged at 5,000 rpm for 15 minutes before use. Specimen should be frozen, if not used within 3 days after being collected, Do not use repeatedly frozen and thawed samples

PRECAUTIONS : For in vitro diagnostic use only.
All human serum and plasma samples should be considered as 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. Wear disposable latex gloves while handling specimens and kit reagents. 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 120°C. Liquid wastes not containing ,acid may be mixed with sodium hypochlorite in volumes such that the, final mixture contains 50-500 mg/l available chlorine. Allow 30 minutes for decontamination to be completed.
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 thoroughly 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.
Store reagents between +2°Cand +8°C. Avoid unnecessary exposure to light. The light sensitive reagents is the conjugate.
Storage of samples in self-defrosting freezers is not recommended.
Do not use reagents after the expiration date printed on the label.
Do not mix or interchange reagents from different kits or kit lots.
Cross contamination of reagents or samples can cause erroneous results. Do not interchange vial caps. Use a new dropper for each sample. Optimal results will be obtained by strict adherence to the test protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements, are essential.

Once the assay has been started, all steps should be performed without interruption.
Reusable glassware must be disinfected, washed out and rinsed free of detergents.

ASSAY PROCEDURE :

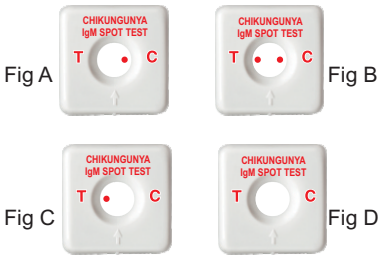
Gold Conjugate is stable for 18 months, when stored at 2-8C° and should be avoided repeated exposure to room temperature for long time. Use fresh gold conjugate vial only after finishing the one used earlier.

1. Bring all the reagents and specimens to room temperature (25-30°C).
2. Add 2 drops of buffer solution to the test device.
3. Add 2 drops of serum/plasma.
4. Add 4 drops of buffer solution
5. Add 2 drops of gold conjugate.
6. Add 4 drops of buffer solution and read the result.
7. Read the result immediately. Do not read after 5 minutes.

HOLD THE DROPPER VERTICALLY AND ENSURE FREE FALLING OF DROPS. AT EACH STEP ALLOW THE SOLUTION TO DRAIN THROUGH THE MEMBRANE BEFORE ADDING THE NEXT SOLUTION.

INTERPRETATION OF RESULTS :

1. Negative Result: If only one red spot (control spot) appears as shown in Fig A, the specimen does not contain IgM antibodies to Chikungunya.
2. Positive Result: If two red spots (control spot and test spot) appear as shown in Fig B, the specimen is reactive for IgM antibodies Chikungunya.
3. Invalid Test: If neither of the spot appears or only test spot appears after the test is complete, as shown in Fig C & Fig.D then the test has been performed incorrectly. Repeat the test with new device.



TROUBLESHOOTING

FALSE POSITIVE

Cause/Error	Remedy
Addition of more than 2 drops of sample or 2 drops of gold conjugate	Use only 2 drops of sample and 2 drops of gold conjugate

WEAK INTENSITY OF CONTROL SPOT

Cause/Error	Remedy
Very cold reagent	Bring the sample, test device, buffer and gold conjugate to room temperature before testing (25±5° C).

POOR SENSITIVITY

Cause/Error	Remedy
Frozen sample not mixed properly after thawing.	Mix well sample before pipetting.

PERFORMANCE CHARACTERISTICS

Accuracy : Chikungunya IgM Spot Test Bhat Bio-Scan® meets the requirements when tested against DCI approved Kit.

SPECIFICITY

No. of Negatives Tested	No. of Negatives by Chikungunya IgM Spot TestBhat Bio-Scan®	Specificity (%)
68	68	100

SENSITIVITY

No. of Positive Samples Tested	No. of Positives by Chikungunya IgM Spot Test Bhat Bio-Scan®	Sensitivity (%)
42	40	95.2

LIMITATIONS OF THE TEST :

1. Assay procedure and the interpretation must be followed exactly to avoid erratic results.
2. Because a variety of factors may cause non-specific reactions, samples found to be reactive must be retested by using a confirmatory test for Chickungunya, such as Elisa, PCR.

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				

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