HCV Card Test

For Professional Use

HEPA-SCAN®

IVD

A Rapid Card Test for the Qualitative Detection of Antibody to Hepatitis C Virus in Human Serum/ Plasma/WHOLE BLOOD

Read the pack Insert before use provided along with the kit

REF HCC LF-WB

INTENDED USE : HEPASCAN® Hepatitis C Virus card test is an immuno chromatography based assay for the qualitative detection of Hepatitis C virus in human serum/plasma/WHOLE BLOOD.

INTRODUCTION : Hepatitis C Virus (HCV) is a small, enveloped, positive -sense, single standard RNA virus. HCV is known to be the major cause of parenterally transmitted non-A, non-B, (NANB) hepatitis. Like the hepatitis B Virus, HCV is typically transmitted parenterally. It is associated especially with the transfusion of contaminated blood and blood products. Other common routes of transmission include intravenous drug use and needle stick accidents. Present evidence indicates that sexual route is not important in the transmission of HCV. However, HCV transmission occurs more readily and with greater frequency if the sexual partner is co-infected with HIV. Prenatal transmission of HIV from mother to infant is uncommon. The risk of mother to infant transmission may be much greater if the mother is co-related with HIV. The risk of post-transfusion hepatitis was estimated to be 7 to 18%. with approximately 90% of post-transfusion hepatitis being caused by the NANB hepatitis agent. Conventional methods failed to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome made it possible to develop serological assays that use recombinant antigens.

Compared to the first generation HCV ELISA's using single recombinant antigen, multiple antigens using recombinant protein and synthetic peptides have been added in new serological tests (Third generation tests) to avoid non specific cross reactivity and to increase the sensitivity of the HCV antibody tests.

HCV Card test is indigenously developed rapid test device to qualitatively detect the presence of antibody to HCV in WHOLE BLOOD/serum or plasma specimens. This is only screening test for detection of HCV antibodies. If the sample gives positive result in this method confirmatory tests such as ELISA, Immuno Blot should be performed.

PRINCIPLE

This test is based on immuno - chromatographic principle. The test device consists of sample window containing a reagent release pad. The reagent release pad is held in contact with the porous membrane material. The membrane has three zones. The first zone is mobilized by the sample and it consists of coloured colloidal gold particles sensitized with protein A. The second zone consists of recombinant HCV antigens immobilized on the membrane (Test line). The recombinant HCV antigens used in this test include both structural (nucleocapsid) and non structural protein including NS-3, NS-4 and NS-5. The third zone (Control line) consists of control antibody,

which is also immobilized on the membrane. If HCV antibody is present in thetest sample, it will form a complex with the protein A - collodial gold conjugate and then move on, to be trapped by the test line, causing the formation of red line. The unbound colloidal gold particles continue to move along the strip by capillary action until they come in contact with the control line and are trapped, giving a red line demonstrating the validity of the test.

STORAGE & STABILITY : Store at 2-30°C. The kit is stable until the expiry date mentioned on the pouch, when stored under the above condition.

PACK SIZE : Available in packs 20s,50s and 100s.

CONTENTS OF THE KIT:

PACK SIZE	20 Tests	50 Tests	100 Tests
Test Device	20	50	100
Diluent	1.2ml	3.0ml	6.0ml
25µl Dropper	20 Nos	50 Nos	100 Nos
Silica gel	20 Nos.	50 Nos.	100 Nos.
Pack Insert	1 No.	1 No.	1 No.

MATERIAL REQUIRED BUT NOT PROVIDED :

a) Sterilized vial b) Disposable gloves C) Precission pipette d) Sodium hypochlorite solution (free available chlorine 50-500mg/L)

Warnings & Precautions :

In order to obtain reproducible results, 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 15-30° C.

C) Use only serum, plasma or WHOLE BLOOD.

D) Carefully observe the prescribed number of drops to be added 2 drops of serum or plasma for serum or plasma procedure and 1 drop(25µl) of whole blood and 1 drops of diluent only.

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

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

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

H) Read the Positive result in 10 minutes and Negative result in 20 minutes.

DO NOT INTERPRET THE RESULT AFTER 20 MINUTES.

I) For In vitro Diagnostic Use only.

J) For single use only.

K) Avoid using haemolytic, lipemic, icteric or bacterially contaminated specimens. Otherwise they may give erroneous results.

All human Serum / Whole blood &Plasma samples should be considered to be potentially infectious. 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 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/Plasma/WHOLE BLOOD can be used for testing.

SPECIMEN COLLECTION & PREPARATIONS :

a). Collect blood in a clean, dry, Serialized 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 be assayed immediately it should be stored at 2-8° C or if storing more than 3 days then freeze the specimen at - 20 °C or below.

ASSAY PROCEDURE

A. For SERUM/PLASMA

1. Bring the pouch 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 (100 µl)of Serum/Plasma 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.

B. For WHOLE BLOOD

1. Bring the pouch to room temperature.
2. Remove the device from the pouch just prior to testing.
3. Place the device on a flat surface.
4. Add 1 drop(25µl) of whole blood into the sample window(S)
5. Add 1 drop of diluent provided in the dropper bottle into the same sample window (S)
6. Read the results in 20 minutes. DO NOT READ ANY RESULT BEYOND 20 Minutes.

INTERPRETATION OF TEST RESULTS

Negative : If only one red line (Control Line) appears in the result area interpret the result as negative This shows that the specimen does not contain antibodies to HCV.

NEGATIVE

Positive : If two red line (Control and Test Line) appear in the result area, the specimen is reactive for antibodies to HCV.

POSITIVE

Invalid : If no line or only test line appears within the result window, after performing the test, the result is considered invalid. The direction may not have been followed correctly or the silicagel might have turned white. Repeat the test with a new device.

INVALID RETEST

TROUBLE SHOOTING

FLOODING OF SAMPLE	
Cause/Error	**Remedy**
Addition of more than 1 drop of diluent	Use only 1 drop of diluent

WEAK INTENSITY OF CONTROL LINE	
Cause/Error	**Remedy**
Very cold reagent	Bring the sample to room temperature before testing ($25^{\circ} \pm 5^{\circ}C$) if stored at $2\text{-}8^{\circ}C$.

POOR SENSITIVITY	
Cause/Error	Remedy
• Frozen samples is not mixed properly after thawing.	Mix the sample well and centrifuge to remove particulate matter before pipetting.
• Hooks Effect, due to too high concentration of the antibodies	Dilute the serum 10 times with negative serum and test again.
• More than25µl of sample added	Add exactly 25µl of sample by filling the sample upto the mark in the dropper.

GHOST LINE APPEARANCE	
Cause/Error	Remedy
Backflow	Read the result within the prescribed time.

PERFORMANCE CHARACTERISTICS :

ACCURACY : HepaScan ® HCV Card Test meets the requirements when tested against approved kit.

Specificity

No. of Negative Samples tested	No. of Negatives by Hepa-Scan ® HCV Card Test	Specificity (%)
481	478	99.37%

Sensitivity

No. of Positive Samples tested	No. of Positives by Hepa-Scan ® HCV Card Test	Sensitivity (%)
100	100	100

Panel Member	Result	HCV 3.0 (Abbott)
01	+	+
02	++	+++
03	+	++
04	+	++
05	++	+++

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 re-tested by using a confirmatory test for HCV, such as ELISA, Immuno Blot.
3. A negative test result does not exclude the possibility of exposure to or infection with HCV.
4. The kit works best when used fresh samples. Samples which have been frozen and thawed several times contain particles which can block the membrane, hence resulting in improper flow of reagents and high backgrouNd color which may make the interpretation of the results difficult.

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

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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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