HBsAg Rapid Card Test Kit

For Professional Use

HEPA-SCAN®

IVD

A Rapid Card Test for the Qualitative Detection of Hepatitis B Surface Antigen in Human Serum/ Plasma.

Read the pack Insert before use provided along with the kit

REF HBC

INTENDED USE : HBsAg Rapid Card test kit HEPA-SCAN ® is an immunochromatographic based assay for the qualitative detection of Hepatitis B surface antigen in human serum or plasma.

INTRODUCTION : The most common agent of acute hepatitis is a virus. Of all the viruses that cause hepatitis, Hepatitis B virus is responsible for the most serious form of the disease. The test is a rapid, qualitative, one-step immunoassay based on the immunochromatographic principle. This method employs unique combination of monoclonal dye conjugate (colloidal gold) and polyclonal solid phase antibodies to selectively identify Hepatitis B surface antigen with a high degree of sensitivity.

PRINCIPLE : Test is based on immunochromatographic principle,in which a unique combination of monoclonal and polyclonal antibodies are used to sandwich HBsAg from the Specimen. Monoclonal antibody is conjugated with colloidal gold and is impregnated at the sample pad. The polyclonal antibodies are selectively immobilized at the test band area. On dipping Dipstick in the Specimen, the test sample flows through the sample pad by capillary action. If the serum contains HBsAg it will form a complex with anti- HBsAg colloidal gold conjugate and allows this to be trapped by the test line, causing the formation of a 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 tests.

STORAGE & STABILITY : Store between 2 °C-30° C. Do not freeze. The kit is stable until the expiry date mentioned on the Pouch, when stored under the above condition.

PACK SIZE: Available in packs of 25, 50's & 100's.

CONTENTS OF THE KIT : One Testing Device, 2ml dropper and Silica Gel as a dehydrant.

MATERIAL REQUIRED BUT NOT PROVIDED :

a). Sterilized Vial
b). Autoclaved Tips.
c). Precision Pipette
d). Disposable gloves
e). 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). Do not use reagents after their expiry date printed on the label.
d). Do not use the kits beyond their expiry date.
e). Use only serum/plasma specimen. Further more do not use umbilical cord blood, because it prevents colloidal gold from migrating & can interfere with results.
f). Use the test device soon after it is removed from the pouch.
g). Do not use the test device, if the pouch seal is broken.
h). Specimen should not be repeatedly frozen & thawed.
I). Specimen with extremely high concentrations of red blood cells, fibrin should be re-centrifuged before using .
j.) If both test & control lines fairly week, dilute the sample 1:10 using PBS and retest with a fresh Hepa-Scan ®Card. The reason for both line appearing week is due to the phenomenon called Hook's effect whereby the HBsAg titer in the sample is abnormally high.
k). Avoid any contamination among samples; for this purpose, disposable tips should be used for each sample.
l). In order to avoid personal and environmental contamination
i).Use disposable gloves while handling potentially infectious material and while performing the assay.
ii). Do not pipette reagents by mouth.
m). Do not smoke, eat drink or apply cosmetics during the assay.
n). Avoid splashing or forming aerosols.
o). 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 wastes not containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 50-500mg/l available chlorine. Allow 30 minutes for decontamination to be completed.
p). Liquid waste containing acid must be neutralized with a proportional amount of base pair prior to the addition of sodium hypochlorite.
q). 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.
r). 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 is essential.
s). Once the assay has been started, all steps should be performed without interruption.
t). Storage and Stability : Store between 2-30° C. Do not freeze. The kit is stable until the expiry date mentioned on the pouch, when stored under the above condition.
u). For Invitro Diagnostic Use only.
v). For single use only.
w). Avoid using hemolytic, lipemic, icteric or bacterially contaminated specimens. Otherwise they may give erroneous results.

SPECIMEN :

Fresh Serum / Plasma can be used for testing.

SPECIMEN COLLECTION AND PREPARATION :

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 store at 2-8° C or if storing more than 3 days, then freeze the specimen at -20° C or below.

ASSAY PROCEDURE :

1. Bring the kit and samples to room temparature.
2. Remove the device from the pouch just before use.
3.Place the device on a flat surface.
4.Add 2-3 drops of Serum/Plasma into the sample window.
5. Read the positive result in 10 minutes and negative result in 20 min.
6. DO NOT READ AFTER 20 MINUTES. Any line appearing after 20 minutes would be of no diagnostic value.

INTERPRETATION OF TEST RESULT :

NEGATIVE : If only one line (control line) appears in the Result Area, interpret the result as NEGATIVE. This shows that the concentration of HBsAg in the specimen is under the detection limit. In case the presence of HBsAg is still in doubt, then the result should be confirmed by another method even though the result is negative.

NEGATIVE

POSITIVE : If two lines (Control and Test) appear in the Result Area, interpret the result as POSITIVE.

POSITIVE

RETEST : If no line appears in the Result Area, it is likely that not enough specimen was added or there was some other procedural mistake. Please check the procedure and retest with a new device.

INVALID (Retest)

SENSITIVITY : The HBsAg Rapid Card Test Kit HEPA-SCAN® able to detect up to 0.5ng/ml of HBsAg in a sample. 100% Sensitivity.

SPECIFICITY : Specificity of HBsAg Rapid Card Test Kit HEPA-SCAN ® is 99.5%.

LIMITATION OF THE TEST :

a).HBsAg Rapid Card Test Kit HEPA-SCAN® detects HBsAg in human serum or plasma and is only a screening test. All reactive samples should be confirmed by supplemental assays like ELISA or RIA. Therefore, for a definitive diagnosis, The patient's clinical history, symptomology as well as serological data should be considered. The results should be reported only after complying with above procedure.

b). The assay is only validated for serum and plasma from individual bleeds and not for pools of serum or other body fluids.

c). A non-reactive result does not exclude the possibility of exposure to or infection with HBsAg.

d). It should be noted that repeated false reactive results may occur due to non-specific binding of the sample to the membrane.

e). The presence of anti-HBsAg does not imply a Hepatitis B infection but may be indicative of recent and / or past infection by HBsAg.

f). Patients with auto-immune liver diseases may show falsely reactive results.

g). The kit works best when used with fresh samples and when all the kit components are at room temperature (25 ±5° c). Samples which have been frozen and thawed several times contain particulars which can block the membrane, hence resulting in improper flow of reagents and high back ground color which may make the interpretation of result difficult.

h). Optimum test performance depends on strict adherence to the test procedure as described in this manual. Any deviation from test procedure may lead to erratic result.

I). Adding more than 2-3 drops of serum/plasma will result in erratic result.

REFERENCES :

1). NCCLS Document M29-T2 (1991). Protection of laboratory workers from instrument biohazaeds. Vol. 11, No. 15.

2). Blumberg. B.S., Alter, H.J. and Visnich, S.A. "New" Antigen in Leukemia sera, J.A.M.A. 191:541-546, 1965.

3. .Cayper, H.T.M. Wiakel, I.N. Vander Poel, C.L. (1971) J. Hepatology,13,5,15.2.Halfon, Retal., (1997) J. Medical Virology. 52:391-395.3.Sarin, S.K. & Hess. G. (1998).

4. Transfusion associated Hepatitis.4.Sayers, M.H. & Gretch DR. (1993). J. Transfusion 30, 809-13.

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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℃ 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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