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				

EC REP
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Revision - 6, 2013-05-17

HEPA-SCAN®

HBsAb Card Test

For Professional Use

A Rapid One Step Visual Test for the qualitative detection of antibody to Hepatitis B Surface antigen in human serum or plasma

CE 1023

IVD

Read pack Insert before use provided along with the kit

CATALOGUE No. : HBsAb-LF

Intended Use : HEPA-SCAN HBsAb card is an immunochromatographic based assay for the qualitative detection of antibody to Hepatitis B surface antigen in human serum or plasma.

INTRODUCTION :

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infecttion, either acute or chronic. The antibody to HBaAg, HBsAb, may not become detectable for 3-6 months after acute infection. It is associated with resolution of the illness. This antibody is recognized as the marker of immunity to HBV. As a result, vaccination against HBV was introduced to control the morbidity and mortality associated with the virus. As part of the World Health Organization (W.H.O) program for the control of hepatitis B, many people, especially new born infants, receive vaccination. The minimum standard titer of HBsAb is 10 mIU/mL for protective immunity to HBV. [1] Unfortunately, approximately 5-15% of healthy immuno-competent individuals either does not exhibit an antibody response to the existing recombinant vaccination or respond poorly.[2]

The HBsAb One Step Hepatitis B Surface Antibody test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAb in serum or plasma specimen. The test utilizes a double antigen sandwich system to detect as low as 10 mIU/mL of HBsAb in serum or plasma.

PRINCIPLE :

The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of HBsAb in serum or plasma. The membrane is pre-coated with HBsAg on the test line region of the strip. During testing, the serum serum or plasma specimen reacts with the particle coated with HBsAg. The mixture migrates upward on the membrane chromatographically by capillary action to react with HBsAg on this membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE & STABILITY :

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

PACK SIZE : Available in packs of 20's, 50's, & 100's.

CONTENTS OF THE KIT :

One Testing Device, One 2ml Dropper and Silica Gel as a dehydrant.

MATERIAL REQUIRED BUT NOT PROVIDED :

a). Sterilised Vial
b). Autoclaved Tips.
c). Precission 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 below 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).Carefully observe the prescribed number of drops to be added, 2 DROPS 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). Specimen should not be repeatedly frogen & thawed.

j). Specimen with extremely high concentrations of red blood cells, fibrin should be re-centrifuged before using .

k). Avoid using hemolytic, lipaemic, ecteric or bacterially contaminated specimens. Otherwise they may give erroneous results.

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 121C. Liquid wastes notcontaining acid may be mixed with sodium hypochlorite in volumes such that the finalmixture contains 50-500 mg/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 2-30C. Do not freeze. The kit is stable until the expiry date mentioned on the pouch, when stored under theabove condition.

u). For Invitro Diagnostic Use only.

v). For single use only.

w).Avoid any contamination among samples; for this purpose, disposable tips should be used for each sample.

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 -20C or below.

ASSAY PROCEDURE :

a). Bring the kit and samples to room temperature.

b). Remove the device from the pouch just prior to testing.

c). Place the device on a flat surface.

d). Add 2 Drops of serum/plasma into the sample window.

e). Read the positive in results in 15 minutes & Negative results in 20 minutes.
DO NOT READ ANY RESULT BEYOND TWENTY MINUTES.

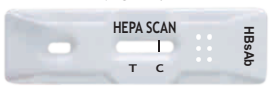
f). Any line appearing after 20 minutes would be of no diagnostic value.

INTERPRETATION OF TEST RESULT :

Negative

The presence of only one Band at "C" within the result window indicates a Negative Result.

NEGATIVE



Positive

The presence of two Bands at "C" & "T" within the Result window indicates the Positive Result.

POSITIVE

Invalid

If no lines appear 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)

Sensitivity : The HEPA-SCAN HBsAb Test Device kit is able to detect upto 10mIU/ml of HBsAb in a sample. 99% Sensitivity.

Specificity : Specificity of HEPA-SCAN HBsAb Card test device is 98.7%.

LIMITATIONS :

1. The HBsAb One Step Hepatitis B Surface Antiboby Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of HBsAb in serum or plasma specimen.
2. The HBsAb One Step Hepatitis B Surface Antiboby Test Device (Serum/Plasma) cannot detect less than 10 mIU/mL of HBsAb in specimens.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

REFERENCE :

1. David Siebert. Aust Prescr. 1998;21;72-5.
2. Zuckerman AJ. Immune response to a new hepatitis B vaccine in healthcare workers who had not responded to standard vaccine: randomised double blind dose-responsed study. Br Med J 1997; 314;329-33.