

7. Discard the HEPACARD immediately after reading result at 20 minutes, considering it to be potentially infectious.

INTERPRETATION OF RESULT

REACTIVE :

As shown in Fig.1, appearance of pink coloured line, one each in test region "T" and control region "C" indicates that the sample is REACTIVE for HBsAg. A difference of intensity in colour

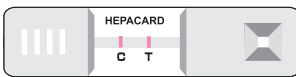


Fig. 1

may occur between the Test line & Control line depending on the concentration of the HBsAg in the serum but this does not affect interpretation of the result.

Depending on the concentration of HBsAg, positive results may be observed within 60 seconds. However, to detect concentration around 0.5 ng to 1ng/ml and to confirm a negative result, the test result should be read only at 20 minutes. If the conc. of HBsAg in the sample is very high, only test line may be observed. This is due to Hook's effect. Such samples should be diluted 1:10 or 1:20 in normal saline & again re-run the test, Diluted sample should show both control & test line. In case, if control line does not appear or is faint dilute the sample further.

In case of faint test line ('T'), centrifuging the sample at 10,000 rpm. for 15 minutes and repeat the test using fresh card. Consider a faint test line also as positive result.

NON-REACTIVE :

As shown in Fig.2 appearance of one distinct pink line in the control region "C" only, indicates that the sample is "NON REACTIVE" for HBsAg.

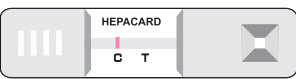


Fig. 2

INVALID :

When neither control line nor the test line appears on the membrane as shown in Fig.3, the test should be treated as invalid which may be because of following reasons:

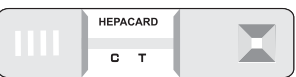


Fig. 3

- Improper storage at temperature other than the recommended temperature.
- Wrong test procedure.
- Long atmospheric exposure of the test device after opening the pouch.
- Turbid or lipaemic sample.

The test should be repeated using a new HEPACARD after centrifugation of test sample.

LIMITATIONS OF THE PROCEDURE

- The HEPACARD is for *in vitro* diagnostic use only.
- The test should be used for the detection of HBsAg in serum or plasma only and not in other body fluids.
- This is only a Screening test.** All reactive samples should be confirmed by confirmatory test. Therefore for a definitive diagnosis, the patient's clinical history, symptomatology as well as serological data, should be considered. The results should be reported only after complying with above procedure.
- Additional follow up testing using available clinical methods (along with repeat HEPACARD test) is required, if HEPACARD test is non-reactive with persisting clinical symptoms.
- False positive results can be obtained due to the presence of Rf antibodies, patients with auto-immune disease, liver problems, renal disorders and antenatal samples.

PERFORMANCE CHARACTERISTICS

(A) INHOUSE EVALUATION

- Analytical Sensitivity:** The sensitivity of Hepacard is 0.5 ng/ml
- The performance of **Hepacard** has been evaluated in house with fresh as well as frozen HBsAg negative and positive samples. The testing has been done with clinical samples, samples from random blood donors, cross reacting samples; RA, CRP, ASO, antenatal and patients with diseases related to HBV. The results of in-house studies are as follows:

No. of Samples	Status	Hepacard (+ ve)	Hepacard (- ve)
225	All ELISA +ve	225	-
3240	ALL ELISA -ve	20	3220

SENSITIVITY: 100%

SPECIFICITY: 99.38%

(B) EXTERNAL EVALUATION

External evaluations were carried out at two different centres and the results are as mentioned below:

- M/s PATH (Program for Appropriate Technology in Health), Seattle, USA.
Sensitivity : 100%
Specificity : 100%
- Christian Medical College, Vellore, India (a reference centre for Govt. of India)
Sensitivity : 100%
Specificity : 100%

This information is provided for the Scientific Community Enquiring for an independent evaluation other than company's in-house evaluation. It is not for commercial or promotional purpose.

(C) PRECISION

Within-run (Intra assay) & between-run (Interassay) precisions have been determined by testing 15 replicates of four samples: 5 negative and 10 HBsAg positive samples; 3 weak, 6 medium and 1 strong positive. The C.V.(%) of negative, weak, medium and strong positive samples were within 10% of time.

ACKNOWLEDGMENT

J. MITRA & CO. PVT. LTD. WISHES TO ACKNOWLEDGE THAT HEPACARD HAS BEEN DEVELOPED UNDER TECHNOLOGY TRANSFER AGREEMENT WITH M/s PATH (Program for Appropriate Technology in Health) SEATTLE U.S.A.

Reserve Bank of India approval for this technology transfer has been granted vide Regn. No: DFT 97 NDR 0012.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an *in vitro* diagnostic assay within the limitations and specifications as described in the product instruction-manual, when used strictly in accordance with the instructions contained therein. 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 for 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 thereof.

BIBLIOGRAPHY

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in vitro diagnostic Reagent, not for medicinal use

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