Size : 137 x 218 mm

Hepaview® HBsAg

One Step Test for HBsAg

DEVICE

INTRODUCTION

HEPAVIEW - one step test for HBsAg is a rapid, qualitative, two site sandwich immunoassay for the detection of Hepatitis B surface antigen, a marker for Hepatitis B infections, in serum/plasma specimen.

SUMMARY

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B surface antigen (HBsAg), earlier known as Austrailia antigen is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter. Detection of HBV using HBsAg as a marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infection. **HEPAVIEW** - one step test for HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml.

PRINCIPLE

HEPAVIEW - one step test for HBsAg utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly of the device after addition of the clearing buffer, the colored colloidal gold conjugate of the Agglutinating Sera for HBsAg complexes with the HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by another Agglutinating Sera for HBsAg coated on the membrane leading to formation of a pink-purple coloured band which confirms a positive test result. Absence of this coloured band in the test region indicates a negative test result.

The unreacted conjugate and unbound complex if any, move further on the membrane and are subsequently immobilized by Agglutinating Sera for Rabbit globulin coated on the membrane at the control region, forming a pink-purple band. The control band formation is based on the 'Rabbit globulin / Agglutinating Sera for Rabbit globulin' system. Since it is completely independent of the analyte detection system, it facilitates formation of consistent control band signal independent of the analyte concentration. This control band serves to validate the test performance.

REAGENTS AND MATERIALS SUPPLIED

Each individual pouch contains:

1. DEVICE Test device: Contains membrane assembly predispensed with Agglutinating Sera for HBsAg - colloidal gold conjugate, Rabbit globulin colloidal gold conjugate, Agglutinating Sera for HBsAg and Agglutinating Sera for Rabbit globulin at the respective regions.
2. PIPETTE Disposable plastic sample applicator.
3. Desiccant pouch.

REF	402070025
Σ	25 Tests

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4-30^0 C till the duration of the shelf life as indicated on the pouch. DO NOT FREEZE.

NOTE

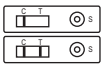
(1) For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use. (2) Do not use beyond expiry date. (3) Read the instruction carefully before performing the test. (4) Handle all specimens as potentially infectious. (5) Follow standard biosafety guidelines for handling and disposal of potentially infective material. (6) If dessicant colour at the point of opening the pouch has turned from blue to white, another test device must be run. (7).Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma is preferable, serum/plasma specimen may be stored at 2-8^0 C for upto 24 hours, in case of delay in testing. Do not use haemolysed, turbid or contaminated samples. Turbid samples should be centrifuged and clear supernatant must be used for testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed pouch to room temperature, open the pouch and remove the device. *Once opened, the device must be used immediately.*
2. Dispense two drops (50µl) of serum/plasma specimen into the sample well 'S' using the sample applicator provided. Refrigerated specimens must be brought to room temperature prior to testing.
3. At the end of fifteen minutes read the results as follows:



NEGATIVE: Only one pink-purple band appears at the control region 'C'.

POSITIVE: In addition to the control band, a pink-purple band also appears at the test region 'T'.

4. The test should be considered invalid if neither the test band nor the control band appear. *Repeat the test with a new device.*

PERFORMANCE CHARACTERISTICS

Internal Evaluation-I

In an in-house study, the performance of **HEPAVIEW** HBsAg device was evaluated using a panel of fifty known positives (of varying reactivity) and two hundred known negative specimens in comparison to two licensed ELISA kits -ELISA-I & ELISA-II. The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	HEPAVIEW	ELISA-I	ELISA-II
Number of specimens tested	250	250	250	250
Number of Positives	50	50	50	50
Number of Negatives	200	200	200	200

Based on this evaluation:
Sensitivity of **HEPAVIEW** HBsAg: 100%.
Specificity of **HEPAVIEW** HBsAg: 100%.

Internal Evaluation-II

HEPAVIEW was evaluated with a serial dilution of known concentration of HBsAg positive sample. It was observed that **HEPAVIEW** was able to detect all the dilutions with HBsAg concentration of > 0.5 ng/ml.
Therefore the detection limit of **HEPAVIEW** is 0.5 ng/ml.
With a low titre performance panel (PHA 104) from BOSTON BIOMEDICA Inc., USA, **HEPAVIEW** showed (±) reactivity with a sample that contained as low as 0.3 ng/ml of HBsAg. In the same panel, with another sample of 0.6 ng/ml, **HEPAVIEW** showed (+) reactivity.

Independent External Evaluation

In another independent study, the performance of **HEPAVIEW** was evaluated using a panel of 50 samples - 20 positives and 30 negatives, in comparison with commercially available Immunochromatographic Test (ICT), Enzyme Immunoassay (EIA) and Microparticle Enzyme Immunoassay (MEIA). The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	HEPAVIEW	ICT	EIA	MEIA
Number of specimens tested	50	50	50	50	50
Number of Positives	20	19	18	20	20
Number of Negatives	30	31	32	30	30

The above study indicates good correlation of the results of **HEPAVIEW** with that of EIA & MEIA.

LIMITATIONS OF THE TEST

1. Though **HEPAVIEW** is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.
2. Interference due to heterophile antibodies, Rheumatoid factors and other nonanalyte substances in patient's serum, capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies.Though **HEPAVIEW** uses sufficient amounts of HETEROPHILIC BLOCKING REAGENT (HBR) to inhibit the majority of this interference; nevertheless, some samples with high titres may still express clinically important assay interference. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
3. Do not compare the intensity of the test lines and the control lines to judge the concentration of HBsAg in the test specimen.
4. Since various tests of HBsAg differ in their performance characteristics and antibody composition, their reactivity patterns may differ.
5. Testing of pooled samples is not recommended.

6. The membrane is laminated with an adhesive tape to prevent surface evaporation. Air pockets or patches may appear, which do not interfere with the test results. Presence of a band at the test region, even if low in intensity or formation, is a positive result.
7. Most positive results develop within 15 minutes. However, certain sera sample may take a longer time to flow. Therefore, negatives should be confirmed only at 30 minutes. Do not read results after 30 minutes.
8. HBsAg is coded for by the S gene and the common antigenic epitopes of all subtypes of HBsAg are found in the same 'a' determinant. The antibodies used in **HEPAVIEW** are directed against this 'a' determinant so that all subtypes of HBsAg can be detected. However, a few patients infected with HBV may show negative for HBsAg inspite of a positive test for HBV-DNA or HBV polymerase chain reaction. These rare cases are due to antigenically divergent variants. Therefore, the existence of such variants should be considered before taking clinical decisions.
9. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Kim, C. Y., Tillis, J. G. 1973, Purification of Biophysical characterization of Hepatitis A antigen, J. Clin. Invest, 52, May 1973, Pgs. 1176-1186. (2) Kee Myung Lee et.al., Emergence of Vaccine- induced escape mutant of Hepatitis B Virus with Multiple surface gene mutations in a Korean child, J.Korean. Med.Sci., 2001, 16, Pgs 356-361. (3) Koyanagi T et al. Analysis of HBs antigen negative variant of hepatitis B virus: Unique Substitutions, Glu 129 to Asp and Gly 145 to Ala in the surface antigen gene. Med Sci Monit, 2000; 6(6): Pgs1165-1169. (4) Data on File: Qualpro Diagnostics.

Size : 137 x 218 mm

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use		Date of Manufacture
Manufacturer	Use by	This side up	Do not reuse
IVD — *In vitro* Diagnostic Medical Device	REF — Catalogue Number		DEVICE — Device
Σ — Contains sufficient for <n> tests	LOT — Batch Number / Lot Number		PIPETTE — Disposable Plastic Sample Applicator

Manufactured by:

Qualpro Diagnostics

A Division of Tulip Diagnostics (P) Ltd.

88/89, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

0317/VER-01