Size : 137 x 218 mm

SENSA Hep-B

ONE STEP TEST FOR HBsAg

DEVICE

INTRODUCTION

Sensa Hep-B - 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 Australia antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter. Detection of HBV using HBsAg as the 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. Sensa Hep B - one step test for HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.3 ng/ml.

PRINCIPLE

Sensa Hep-B - 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 test device, the colored Agglutinating sera for HBsAg-colloidal gold conjugate 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 colored band which confirms a positive test result. Absence of this colored 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 the Agglutinating sera for rabbit globulin coated on the membrane at the control region, forming a pink-purple band. This control band serves to validate the test results.

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 coated at the respective regions.
2. PIPETTE Disposable plastic sample applicator.
3. Desiccant pouch.

REF	402150025
Σ	25 Tests

OPTIONAL MATERIAL REQUIRED BUT NOT PROVIDED

Disinfectant, Disposable gloves, Biohazard waste container, Micropipette.

STORAGE AND STABILITY

Sensa Hep-B is stable upto expiry date mentioned on the label when stored at 4°C to 30°C. Once the pouch is opened, the device must be used immediately. DO NOT FREEZE.

NOTE

1. For in vitro diagnostic use only. NOT FOR MEDICINAL 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 desiccant 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.

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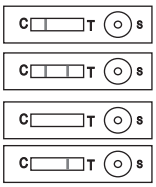
SPECIMEN COLLECTION AND PREPARATION

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 2-8°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 150 µl (3 drops) of serum/plasma into the sample port 'S' using a micropipette. Refrigerated specimens must be brought to room temperature prior to testing.
3. At the end of 20 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'.

INVALID: The test should be considered invalid if neither the test band nor the control band appear. Repeat the test with a new device if only test band appears.

PERFORMANCE CHARACTERISTICS

Internal Evaluation

In an in-house study, the performance of **Sensa Hep-B** device was evaluated using a panel of 100 known positives (of varying reactivity) and 200 known negative specimens in comparison with Other licensed kit and ELISA. The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	Sensa Hep-B	Other Licensed kit	ELISA
Number of specimens tested	300	300	300	300
Number of Positives	100	100	100	100
Number of Negatives	200	200	200	200

Based on this evaluation:
Sensitivity of **Sensa Hep-B** : 100%
Specificity of **Sensa Hep-B** : 100%

Evaluation of Sensa Hep-B using 1st INTERNATIONAL REFERENCE PANEL 2003 (NIBSC)
(WHO HBsAg subtype adw2, genotype A Reference Panel)
2.6 IU = 0.5ng/ml
(WHO HBsAg 2nd IS) (French or UK-Standard)

Dilutions of Genotype A Reference Panel	Sensa Hep-B Device		Remarks
	TL	CL	
Sample A (8.25 IU/ml) ≅ (1.58ng/ml)	1+	4+	Positive results with Genotype A ≅ 1.58ng/ml
Sample B (2.0625 IU/ml) ≅ (0.4ng/ml)	1w	4+	Positive results with Genotype A ≅ 0.4 ng/ml
Diluted Sample B (1.5468 IU/ml) ≅ (0.3ng/ml)	1w	4+	Positive results with Genotype A ≅ 0.3 ng/ml
Sample C (0.5156 IU/ml) ≅ (0.1 ng/ml)	0	4+	NA
Sample D (0.1289 IU/ml) ≅ (0.025ng/ml)	0	4+	NA
Sample E (HBsAg Negative Sample)	0	4+	Negative

NA – Not Applicable

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The Sensitivity of SENSA Hep-B is 0.3ng/ml.

Evaluation of Sensa Hep-B using HBV Worldwide Performance Panel

Name of Panel: HBV Worldwide Accuset™ Performance Panel
Catalogue no.: 0805-0247

Sr. No.	Genotype[1]	Sensa Hep-B	
		TL	CL
1	A	4+	4+
2	B	+/-	4+
3	C	4+	4+
4	D	4+	4+
5	E	4+	4+
6	F	1+	4+
7	H	4+	4+

All 7 genotypes of HBV have been detected by **SENSA Hep-B.**

LIMITATIONS OF THE TEST

1. Though **Sensa Hep-B** 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 **Sensa Hep-B** 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 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. 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 Sensa Hep B 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

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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 359-362.
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): 1165-1169.
4. Data on File: Qualpro Diagnostics.

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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.

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