RAPINDO™
HBsAg

ONE STEP TEST FOR HBsAg

DEVICE

INTRODUCTION

RAPINDO™ HBsAg 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. For professional use.

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. **RAPINDO™ HBsAg** 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

RAPINDO™ HBsAg 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 within 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 the Agglutinating sera for HBsAg coated on the membrane leading to formation of a 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 colored band. This control band serves to validate the test results. 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

1 (one) carton of **RAPINDO™ HBsAg** contains 25 Pouch set Rapid Test Device & 1 brochure of product use instruction.

Each Rapid Test Device Pouch set consists of: 1 unit of Rapid Test Device equipped with sample applicator and silica gel.

STORAGE AND STABILITY

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

NOTE

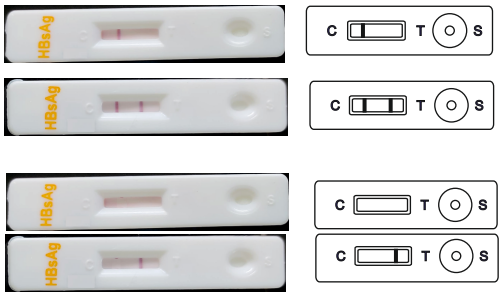
1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instruction carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. 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 2°C To 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 pouches to room temperature. Open the pouch and remove the device, applicator and desiccant. Check the colour of the desiccant. It should be blue. If it has turned colourless or pink discard the device and use another 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 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: A colored band appears at the control region 'C'.

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

INVALID : The test should be considered invalid if no colored band appears on the device. The test should also be considered invalid if a colored band appears only at the test region 'T' and not at the control region 'C'. In such cases, repeat the test with a new device,ensuring that the test procedure has been followed accurately.

PERFORMANCE CHARACTERISTIC

External Evaluation

RAPINDO™ HBsAg was evaluated using a panel of 200 samples : 50 positives & 150 negatives, in comparison with plasma panel (ECLIA) in The Center for Biomedical and Health Genomics - Ministry of Health of Republic of Indonesia . The results of the evaluation are as follows:

SPECIMEN DATA	TOTAL	RAPINDO™ HBsAg	ECLIA	Sens(%)	Spec.(%)
Number of specimens tested	200	200	200		
Number of Positives	50	50	50	100	100
Number of Negatives	150	150	150	100	100

Based on this evaluation:

Sensitivity of **RAPINDO™ HBsAg** : 100%

Specificity of **RAPINDO™ HBsAg** : 100%

The above study indicates good correlation of the results of **RAPINDO™ HBsAg** with that of ECLIA

LIMITATIONS OF THE TEST

1. Though **RAPINDO™ HBsAg** 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 **RAPINDO™ HBsAg** 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. 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 **RAPINDO™ HBsAg** 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: PT Tulip Diagnostics Indonesia.

SYMBOL KEYS

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

Manufactured & Distributed by:
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0625/VER-02