Not for Sale in the USA

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INTENDED USE

For The Qualitative Assessment of HBsAg in Human Serum, Plasma or Whole Blood. This test is for In Vitro Diagnostic Use and/or professional use only. Not for Sale in the United States.

INTRODUCTION

HBsAg (RAP4868) Rapid Test is a chromatographic immunoassay for qualitative detection of the surface antigen of hepatitis B virus (HBsAg) in human whole blood samples. It is intended for use in medical institution as an aid for diagnosis and management of patients related to infection with hepatitis B as well for screening of blood donors or blood products.

SUMMARY

Hepatitis B virus is a DNA virus with four open reading frames: S, C, P and X encoding HBsAg, pre-S1, pre-S2, HBcAg, DNA polymerase and HBxAg respectively. HBcAg will be hydrolyzed into HBeAg by protease. After being infected by HBV, the corresponding antibodies including: anti-HBs, anti-S1, anti-S2, anti-HBc, anti-HBe and anti-HBx are produced in vivo and a complicated antigen-antibody system is formed. HBsAg, HBeAg, anti-HBs, anti-HBc and anti-HBe are commonly used for the diagnosis and prognosis of Hepatitis B.

PRINCIPLE OF THE ASSAY

The ***RAP4868 HBsAg*** Rapid Test employs chromatographic lateral flow device. Colloidal gold conjugated monoclonal antibodies reactive to HBsAg (sAb-Au) are dry-immobilized onto a nitrocellulose membrane strip. When the sample is added, it migrates by capillary diffusion through the strip rehydrating the gold conjugate. If present, HBsAg will bind with the gold conjugated antibodies forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti-HBs antibodies immobilized there and a visible red line appears. If there is no HBsAg in sample, no red line will appear in the Test Zone (T). The gold conjugate will continue to migrate alone until is captured in the Control Zone (C) from immobilized goat, anti-mouse IgG antibody and aggregating in a red line, which indicates the validity of the test.

REAGENT AND MATERIALS PROVIDED

1. ***HBsAg*** Test device in aluminum pouch with desiccant.
2. Package Insert

MATERIALS REQUIRED BUT NO PROVIDED

Clock or timer, safety lancets, disposable pipettes**,** specimen collection container, centrifuge, biohazard waste container

SPECIMEN COLLECTION

Fingertip of venous blood can be used. Collect the blood using standard laboratory practice procedures. If fingertip specimen is used, always wipe away the first drop of blood with sterile gauze or cotton during collection.

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STORAGE AND STABILITY

This test can be stored at room temperature (18-30□, do not freeze!) for 18 months from the date of manufacture (see label on pouch). Use immediately after opening.

PRECAUTIONS AND SAFETY

This test is for In Vitro Diagnostic Use only. This test is for professional use only.

1. All the waste and sample should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
2. Once taking the card out of the pouch, carry out your testing as early as possible (no more than 20minutes) to avoid moisture. The nitrocellulose membrane can absorb water, which can affect the test chromatography performance.
3. The performance characteristics of the test depend on sample quality and preparations. For strong positive samples, the red line corresponding to the Test Zone (T) may appear in 3-5 minutes after sample loading, but for weak positive samples, the red line may appear in the Test Zone(T) in 20 minutes. Results obtained after 30 minutes can lead to incorrect interpretation.
4. Make sure that the test is within the validity indicated.
5. Calibrate the pipette frequently to assure the accuracy. Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.
6. Do not modify the test procedure.
7. Avoid moisture.
8. Ensure that the finger is completely dry before collecting blood.
9. A test giving an invalid result should be repeated.
10. Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.
11. Do not reuse lancets, test cards, pipettes. Autoclave before disposal.

ASSAY PROCEDURE

For Test card:

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 2-3 drops (80-120 µl) of sample into the sample well.
5. Read the result between at 30 minutes

Positive sample may show positive results within a few mionutes after the sample is added. However, to confirm a negative result, please wait until 30 minutes.

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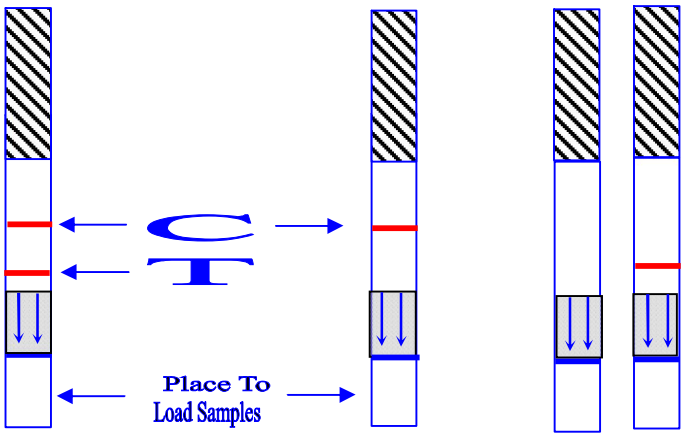
Results after 30 minutes may not be accurate.

INTERPRETATION OF RESULT

Positive Results: Two red lines appear, indicating that HBsAg has been detected using ***HBsAg*** Rapid Test.

Negative Results: Only one red line appears in the Control Zone (C), indicating that no HBsAg have been detected with this HBsAg Rapid Test. However, this does not exclude the possibility for infection with HBV.

Quality Control: One red line always appears next to Control Zone (C) If no red line appears in the Control Zone (C), the test is invalid - discard the test and repeat with new sample and new card.



Positive **Negative** **Invalid**

LIMITATION OF THE PROCEDURE

1. The positive result obtained with ***HBsAg*** rapid Test alone cannot be the final diagnosis of hepatitis B. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing with other analytical system (e.g. ELISA) is required to confirm any positive results.

2. Negative results do not rule out the possibility of hepatitis exposure or infection. Infection through recent exposure to HBV may not be detectable.

PERFORMANCE DATA AND EXPECTED RESULTS

1. Interferring factors

Presence of 0.4g/dL hemoglobin, 20mg/dL bilirubin, 1.95nmol/L triglyceride, or 6.10nmol/L cholesterol do not affect the detection of HBsAg.

2. Comparison with the ELISA method

The results of the ***HBsAg*** test card in total of 1249 samples (469 ELISA confirmed positive specimens and 780 ELISA confirmed negative specimens) is summarized.

Positive agreement(%)	Negative agreement(%)	Accuracy(%)
99.6 (467/469)	99.6 (777/780)	99.6 (1244/1249)

3. Cross reactivity with other infectious diseases

No cross reactivity was observed with specimens from patients infected with HAV, HCV, HIV, HTLV, CMV, and TP.

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