HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IHBSB-402	English

A rapid test for the qualitative detection of antibody to Hepatitis B Surface Antigen (HBsAb or anti-HBs) in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

【INTENDED USE】

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Antibody to Hepatitis B Surface Antigen in whole blood, serum or plasma.

【SUMMARY】

Viral hepatitis is a systemic disease primarily involving the liver.Most cases of acute viral hepatitis are caused by Hepatitis Avirus, Hepatitis B virus (HBV) or Hepatitis C virus. Thecomplex antigen found on the surface of HBV is called HBsAg. The presence of HBsAg in whole blood, serum or plasma is an indication ofan active Hepatitis B infection, either acute or chronic. The antibody to HBsAg, HBsAb, may not become detectable for 3-6months after acute infection. It is associated with resolution ofthe illness. This antibody is recognized as the marker ofimmunity to HBV. As a result, vaccination against HBV wasintroduced to control the morbidity and mortality associated withthe virus. As part of the World Health Organization (W.H.O)program for the control of Hepatitis B, many people, especiallynew born infants, receive vaccination. The minimum standard titer of HBsAb is 10 mIU/mL for protective immunity to HBV.[1]Unfortunately, approximately 5-15% of healthy immune competent individuals either does not exhibit an antibodyresponse to the existing recombinant vaccination or respondpoorly.[2]The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAb in whole blood, serum or plasma specimen. The testutilizes a double antigen sandwich system to detect as low as 10mIU/ml of HBsAb in whole blood, serum or plasma.

【PRINCIPLE】

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of HBsAb in whole blood, serum or plasma.The membrane is pre-coated with HBsAg on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with HBsAg. The mixture migrates upward on the membrane chromatographically by capillaryaction to react with HBsAg on the membrane and generate acolored line. The presence of this colored line in the testregion indicates a positive result, while its absence indicates anegative result. To serve as a procedural control, a colored linewill always appear in the control line region indicating thatproper volume of specimen has been added and membranewicking has occurred.

【REAGENTS】

The test device contains HBsAg particles and HBsAg coated on the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drinkor smoke in the area where the specimen or kits are handled.
3. Handle all the specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested .
5. Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The HBsAg Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 75 μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
    - Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingersticks should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials provided

•Test cassettes •Droppers •Package insert •Buffer

Materials required but not provided

•Specimen collection containers •Centrifuge •Timer

【DIRECTIONS FOR USE】

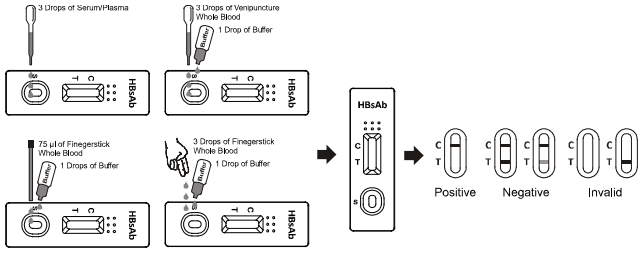
Allow test cassette, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30℃) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

   For **Serum or Plasma** specimen:
   - Hold the dropper vertically and transfer **3 drops of serum or plasma** (approximately 75 μL) to the specimen well of test Cassette and start the timer. See illustration below.

   For **Venipuncture Whole Blood** specimen:
   - Hold the dropper vertically and transfer **3 drops of whole blood** (approximately 75 μL) to the specimen area, then **add 1 drop of buffer** (approximately 40 μL), and start the timer. See illustration below.

   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 75μL of fingerstick whole blood specimen** to the specimen area of test cassette, then add **1 drop of buffer (approximately 40 μL)** and start the timer. See illustration below.
   - To use hanging drops: Allow **3 hanging drops of fingerstick whole blood s**pecimen (approximately 75 μL) to fall into the specimen area of test cassette, then add **1 drop of buffer (approximately 40 μL) a**nd start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 15 minutes.** Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAb present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A red lineappearing in the control region (C) is an internal positive proceduralcontrol. It confirms sufficient specimen volume and correctprocedural technique.

Control standards are not supplied with this kit; however, it isrecommended that positive and negative controls be tested as a goodlaboratory practice to confirm the test procedure and to verifyproper test performance.

【LIMITATIONS】

1. The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic useonly. This test should be used for the detection of HBsAb in whole blood, serum or plasma specimen.
2. The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 10mIU/ml of HBsAb in specimens.
3. As with all diagnostic tests, all results must be consideredwith other clinical information available to the physician.

【EXPECTED VALUES】

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial HBsAb EIA test. The correlation between these two systems is over 99%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested with a sensitivity panel ranging from 1mIU/ml to 40mIU/ml. The test can detect 10mIU/ml of HBsAb in 15 minutes.

Specificity

Antigen used for the HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) is highly specific for detecting HBsAb in whole blood, serum or plasma. The specificity was comparable to RIA.

Method		RIA		Total Results
HBsAb Rapid Test Cassette(Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	189	2	191
	Negative	0	341	341
Total Results		189	343	532

Relative Sensitivity: >99.9% (95%CI*: 98.4%-100%)
Relative Specificity: 99.4% (95%CI*: 97.9%-99.9%)
Accuracy: 99.6% (95%CI*: 98.6%-100%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive. The negative and positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of HBsAb in 15 independent assays. Three different lots of the HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity

Interfering Substances

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed.

In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

【BIBLIOGRAPHY】

1. David Siebert. AustPrescr. 1998;21;72-5
2. Zuckerman JN, Sabin C, Craig FM, Williams A,Zuckerman AJ. Immune response to a new hepatitis Bvaccine in healthcare workers who had not responded tostandard vaccine: randomised double blind dose-responsestudy. Br Med J 1997; 314:329-33.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		

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