HBsAb Rapid Test Dipstick (Serum/Plasma) Package Insert

REF IHBSB-301 | English

A rapid test for the qualitative detection of antibody to Hepatitis B Surface Antigen (HBsAb or anti-HBs) in serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

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

【SUMMARY】

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

【PRINCIPLE】

The HBsAb Rapid Test Dipstick (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of HBsAb in serum or plasma. The membrane is pre-coated with HBsAg on the test line region of the strip. During testing, the serum or plasma specimen reacts with the particle coated with HBsAg. The mixture migrates upward on the membrane chromatographically by capillary action to react with HBsAg on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking 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, drink or 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】

1. The HBsAb Rapid Test Dipstick can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. 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.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials provided

•Test dipsticks •Package insert

Materials required but not provided

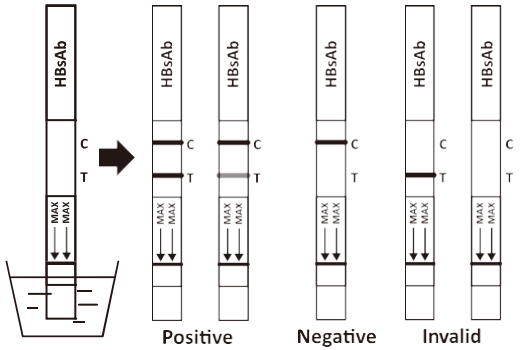
•Specimen collection containers •Centrifuge •Timer

【DIRECTIONS FOR USE】

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

1. Remove the test dipstick from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. With arrows towards pointing toward serum or plasma specimen, immerse the test Dipstick vertically in the serum or plasma for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test Dipstick when immersing the Dipstick. See illustration below.
3. Place the Dipstick on a non-absorbent flat surface, start the timer and wait for the color line (s) to appear. The result should be read at 15 minutes.

Note: A low HBsAb concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, 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 dipstick. 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 line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

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

【EXPECTED VALUES】

The HBsAb Rapid Test Dipstick (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 Dipstick (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 Dipstick (Serum/Plasma) is highly specific for detecting HBsAb in serum or plasma. The specificity was comparable to RIA.

Method		RIA		Total Results
HBsAb Rapid Test Dipstick (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 Dipstick (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 Dipstick (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 Dipstick (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. Aust Prescr. 1998;21;72-5
2. Zuckerman JN, Sabin C, Craig FM, Williams A, Zuckerman AJ. Immune response to a new hepatitis B vaccine in healthcare workers who had not responded to standard vaccine: randomized double blind dose-response study. Br Med J 1997; 314:329-33.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	2	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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