SPECTRUM

The Creative Approach to Bioscience

HBsAg Rapid Test Dipstick (Whole Blood/Serum/Plasma) Package Insert

REF: 1218 001 50 test

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

INTENTED USE

The HBsAg Rapid Test Dipstick is a rapid chromatographic immunoassay for the qualitative detection of 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 A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen.1The presence of HBsAg in whole blood, serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

The HBsAg Rapid Test Dipstick is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

PRINCIPLE

The HBsAg Rapid Test Dipstick is a qualitative, solid phase, two-site sandwich immunoassay for the detection of HBsAg in whole blood, serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the Dipstick. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies 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 Dipstick contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

PRECAUTION]

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. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

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 uses beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HBsAg Rapid Test Dipstick 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 Dipstick.
- 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 fingerstick 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.

EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

MATERIALS

Materials provided

Test dipsticks • Droppers • Test cards
Buffer • Package insert

Materials required but not provided

Specimen collection containers • Centrifuge
Lancets (for fingerstick whole blood only) • Timer
Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

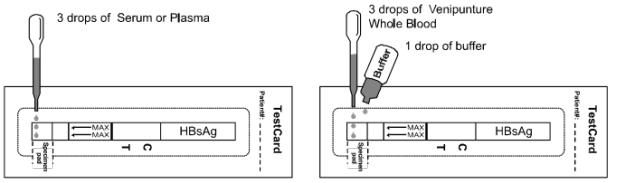
DIRECTIONS FOR USE

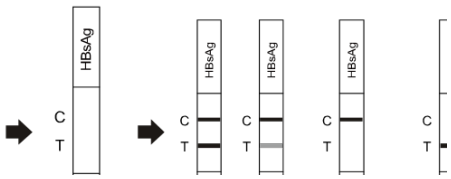
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test Dipstick from the sealed pouch and use it within one hour.
2. Place the test card on a clean and level desk, then peel off the strip label of the test card, stick the test dipstick onto it as soon as possible before testing.
   For **Serum or Plasma** specimen:
   Hold the dropper vertically and transfer 3 **drops of serum or plasma (approximately 75 μL)** to the specimen area of test Dipstick 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 Finger stick Whole Blood specimen:
   To use a capillary tube: Fill the capillary tube and transfer approximately **75 μL of finger stick whole blood specimen** to the specimen area of test Dipstick, then add **1 drop of buffer** (approximately 40 μL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 15~30 minutes. Do not interpret the result after 30 minutes.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.





(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 HBsAg 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

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal quality control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control (containing 10 ng/mL HBsAg) and a negative control (containing 0 ng/mL HBsAg) be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

The HBsAg Rapid Test Dipstick is for professional in vitro diagnostic use only. The test should be used for the detection of HBsAg in whole blood, serum or plasma specimen. Neither the quantitative value nor the rate of HBsAg concentration can be determined by this qualitative test.
The HBsAg Rapid Test Dipstick will only indicate the presence of HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
The HBsAg Rapid Test Dipstick cannot detect less than 1PEI ng/ml of HBsAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.
5.The hematocrit of the whole blood should be between 25% and 65%.

EXPECTED VALUES

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

PERFORMANCE CHARACTERISTICS

Sensitivity

The HBsAg Rapid Test Dipstick (Whole Blood/Serum/Plasma) was tested against a sensitivity panel including both ad and ay subtypes with concentrations ranging from 0 to 300ng/mL. The test can detect 1PEI ng/ml of HBsAg in whole blood, serum or plasma in 15 minutes.

Specificity

Antibodies used for the HBsAg Rapid Test Dipstick (Whole Blood/Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Dipstick (Whole Blood/Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

Method		ELISA		Total Results
HBsAg Rapid Test Dipstick(Whole Blood/Serum/Plasma)	Results	Positive	Negative	
	Positive	149	1	150
	Negative	1	409	410
Total Results		150	410	560

Relative Sensitivity: 99.3% (95%CI:*96.3%-99.9%)
Relative Specificity: 99.8% (95%CI:*98.6%-99.9%)
Overall accuracy: 99.6% (95%CI:*98.7%-99.9%) *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of 5 specimens containing 0ng/ml, 2ng/ml, 5ng/ml, 12ng/ml and 20ng/ml of HBsAg. The negative and positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using the same 5 specimens of 0ng/ml, 2ng/ml, 5ng/ml, 12ng/ml and 20ng/ml of HBsAg in 3 independent assays. Three different lots of the HBsAg Rapid Test Dipstick (Whole Blood/Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The HBsAg Rapid Test Dipstick (Whole Blood/Serum/Plasma) has been tested for anti-HAV IgM, anti-HIV IgG, anti-HCV IgG, anti-HEV IgG, anti-Syphilis IgG, anti-HAMA IgM, anti-Rheumatoid Factor IgG, anti-H. Pylori IgG, anti-CMV IgG,anti-CMV IgM, anti-Rubella IgG, anti-Rubella IgM, anti-Toxo IgG and anti-Toxo IgM positive specimens. The results showed no cross-reactivity.

Interfering Substances

The HBsAg Rapid Test Dipstick (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 2,000mg/dl Hemoglobin,1000 mg/dl Bilirubin, and 2000 mg/dl human serum Albumin.

BIBLIOGRAPHY

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