SPECTRUM

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HBsAg

Hepatitis B Surface Antigen Test Device (Serum/Plasma)

REF: 1160 001 25 test
REF: 1160 002 50 test

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

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

INTENDED USE

The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of 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. Previous designations included the Australia or Au antigen .[1] The presence of HBsAg in 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 One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

PRINCIPLE

The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) is a qualitative,lateral flow immunoassay for the detection of HBsAg in serum or plasma. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. 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 device contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

PRECAUTIONS

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

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

- The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below - 20°C.
- 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 federal, state or local regulations for the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

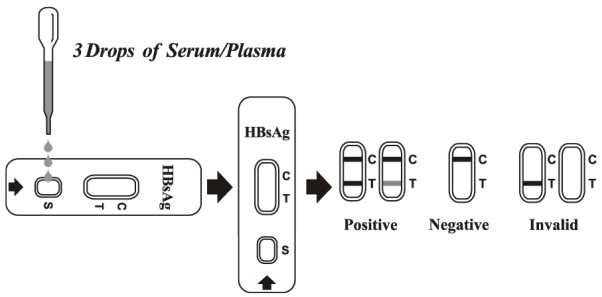
Materials Required But Not Provided

- Specimen collection containers
- Centrifuge
- Timer

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 15 minutes.
   Note: A low HBsAg 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 30 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

NEGATIVE: One red line appears in the control region (C). No apparent red or pink 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 ontrol line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control

It is recommended that a positive and negative external control be run every 20 tests, and as deemed necessary by internal laboratory procedures. Some commercial controls may contain interfering preservatives; therefore, interpretation of results with external quality controls should be done with caution.

Procedure for External Quality Control Testing

1. Hold the Control vial vertically and add 2 full drops of Control to the Specimen well (S) as in procedure Step 2.
2. Continue with Step 3 of Directions For Use. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATION

1. The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of HBsAg in serum or plasma specimen.
2. The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) 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.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) cannot detect less than 1 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.

EXPECTED VALUES

The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) has been compared with a leading commercial HBsAg EIA test. The correlation between these two systems is over 98%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/mL. All 10 HBsAg subtypes produced positive results on the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma). The test can detect 5ng/mL of HBsAg in 15 minutes, and 1 ng/mL of HBsAg in 30 minutes.

Specificity

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

HBsAg Reference Method

Method		EIA		Total Results
HBsAg Test Device	Results	Positive	Negative	
	Positive	145	5	150
	Negative	0	150	150
Total Results		145	155	300

Relative Sensitivity: > 99.0%
Relative Specificity: 96.7%
Accuracy: 98.3%

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens containing 0 ng/mL, 1 ng/mL and 5 ng/mL of HBsAg. The negative and positive values were correctly identified 98% of the time.

Inter-Assay

Between-run precision has been determined by using the same three specimens of 0 ng/mL, 1ng/mL and 5 ng/mL of HBsAg in 15 independent assays. Three different lots of the HBsAg One Step Hepatitis B Surface Antigen Test Device (Serum/Plasma) has been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 98% of the time.

BIBLIOGRAPHY

1. Blumberg, B.S. The Discovery of Australian Antigen and its relation to viral hepatitis. Vitro. 1971; 7: 223

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
1160 001	25 test
1160 002	50 test

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