

HBsAg

One step Hepatitis B Surface Antigen Test Device (Serum/Plasma)

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.

INTENDED USE:

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 Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg.

PRINCIPLE:

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 precoated 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 coated on the membrane.

PRECAUTIONS

- For 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 microbiology 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 (4-30°C). The test device is stable through the expiration dated printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Don't use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- 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 haemolysis. 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 4-30°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 transportation of etiologic agents.

MATERIALS PROVIDED

- Test devices.
- Disposable specimen droppers.
- Package insert.

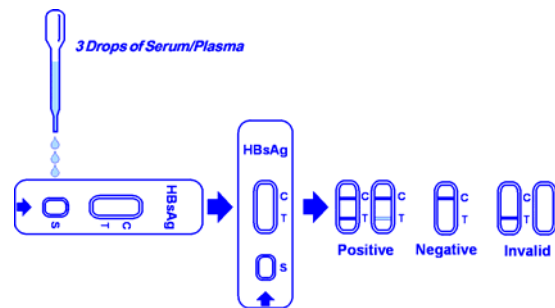
MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container.
- Centrifuge (for plasma only)
- Timer.

DIRECTIONS FOR USE

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

- 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.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 100ul) 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.
- 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).

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 device. 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 red line appearing in the control region (C) is the internal procedural 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.

LIMITATION:

- 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.
- 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.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- 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%.

Fax: ++44 (0) 1223 858 524

PERFORMANCE CHARACTERISTICS:

Sensitivity:

HBs Ag 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 result 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.

PPI146A01

Revision A (5.12.2004)

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	Result	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, 1 ng/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

ATLAS Medical

William James House,

Cowley Road, Cambridge, CB4 4WX, UK

Tel: ++44 (0) 1223 858 910