Atlas Medical

**HBsAb One Step**
**Hepatitis B Surface Antibody**
**Test Strip (Serum/Plasma)**

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

IVD *For In-Vitro diagnostic and professional use only*

Store at 2-30°C

## INTENDED USE

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

## PRINCIPLE

The HBsAb One Step Hepatitis B Surface Antibody Test Strip (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.

## MATERIALS

### MATERIALS PROVIDED

- Test strips (Contain HBsAg particles and HBsAg coated on the membrane).
- Package insert.

### MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Centrifuge
- Timer

## STORAGE AND STABILITY

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

## SPECIMEN COLLECTION AND PREPARATION

- The HBsAb One Step Hepatitis B Surface Antibody Test Strip (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.

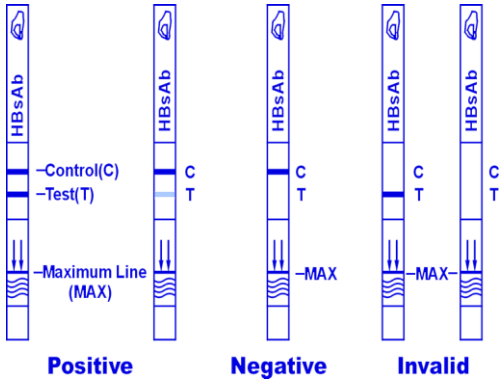
## PRECAUTIONS

- 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 or kits are handled.
- Handle all 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

## PROCEDURE

**Allow test strip, 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 strip 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. With arrows pointing toward the serum or plasma specimen, immerse the test strip vertically in the serum or plasma for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strips on a non-absorbent flat surface, start the timer and wait for the red 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**

 **POSITIVE:***

**Two distinct colored 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 HBsAb present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

 **NEGATIVE:**

**One Colored 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 control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**EXPECTED VALUES**

The HBsAb One Step Hepatitis B Surface Antibody Test Strip (Serum/Plasma) has been compared with a leading commercial HBsAb RIA test. The correlation between these two systems is over 99%.

**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.

**LIMITATION**

- The HBsAb One Step Hepatitis B Surface Antibody Test Strip (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibody to HBsAg in serum or plasma specimen.
- The HBsAb One Step Hepatitis B Surface Antibody Test Strip (Serum/Plasma) cannot detect less than 10 mIU/mL of HBsAb in specimens.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

**PERFORMANCE CHARACTERISTICS**

Relative Sensitivity: >99.0% (98.7%-100.0%)

Relative Specificity: 99.4%(98.0%-99.9%)

Overall Agreement: 99.7%(98.9%-99.9%)

*95% Confidence Interval

| | HBsAb Rapid Test | | |
|---|---|---|---|
| EIA | Positive | Negative | Total |
| + | 276 | 0 | 276 |
| - | 2 | 352 | 354 |
| | 278 | 352 | 630 |

**REFERENCES**


1. Siebert D. Hepatitis B: issues in laboratory diagnosis and vaccination. Aust Prescr. 1998 Sep; 21(3):72-5.
2. Acute Viral Hepatitis. Whitehouse Station: Merck & Co., Inc.; c2005-2008 [updated 2007 May; cited 2008 Aug].



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|---|---|---|---|
| REF | Catalogue Number | | Temperature limit |
| IVD | *In Vitro* diagnostic medical device | | Caution |
| | Contains sufficient for <n> tests and Relative size | | Consult instructions for use (IFU) |
| LOT | Batch code | | Manufacturer |
| | Do not re-use | | Use-by date |
| | Manufacturer fax number | | Do not use if package is damaged |
| | Manufacturer telephone number | | Date of Manufacture |
| | Keep away from sunlight | | Keep dry |