Rapid Response™

Hepatitis B Surface Antibody (HBsAb) Test Strip
(Serum/Plasma)
REF HBsAb-12S50 Product Insert

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ Hepatitis B Surface Antibody (HBsAb) Test Strip is a rapid visual immunoassay for the qualitative presumptive detection of HBsAb in human serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of HBV infection.

Introduction

Hepatitis B virus (HBV) is the most thoroughly characterized and complex hepatitis virus. The infective particle consists of a viral core plus an outer surface coat. HBV has at least 3 distinct antigen-antibody systems that can be tested: HBsAg, HBcAg, and HBeAg. HBV surface coat can be detected in serum as HBsAg. HBsAg characteristically appears during the incubation period, usually 1 to 6 weeks before clinical or biochemical illness develops, and implies infectivity of the blood. The corresponding protective antibody (anti-HBs or HBsAb) appears weeks or months later, after clinical recovery, and usually persists for life; thus, its detection indicates past HBV infection and relative immunity. Unfortunately, in 5 to 10% of patients, HBsAg persists and antibodies do not develop; these patients become asymptomatic carriers of the virus or develop chronic hepatitis. Since this antibody is recognized as the marker of immunity to HBV, the World Health Organization (WHO) includes a HBsAg diagnostic procurement program for the control of Hepatitis B. Many people, especially newborn infants, receive vaccination. The minimum standard titer of HBsAb for protective immunity to HBV is 10 mIU/mL.

Principle

The Rapid Response™ Hepatitis B Surface Antibody (HBsAb) Test Strip detects HBsAb through visual interpretation of color development on the internal strip. HBsAg is immobilized on the test region of the membrane. During testing, the specimen reacts with HBsAg conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient HBsAb in the specimen, a colored line will form at the test region of the membrane. The presence of this colored line indicates a positive result, while its absence indicates a negative result. The appearance of a colored line at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For professional *in vitro* diagnostic use only.
- Read these instructions carefully before performing the test.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- 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 standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Avoid splashes and clean up spills immediately with appropriate disinfectant.
- Do not use any other specimen than those specified. For plasma, EDTA, sodium citrate, sodium heparin or potassium oxalate can be used as anticoagulant.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Materials

Materials provided

- Individually packed test strip
- Disposable specimen dropper
- Product insert

Materials required but not provided

- Specimen collection container
- Centrifuge
- Timer

Storage and Stability

- The kit should be stored at 35.6-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze the kit.**
- Protect the kit from humidity.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

Collection and Storage of Specimens

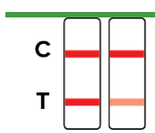
- The Rapid Response™ Hepatitis B Surface Antibody (HBsAb) Test Strip is intended for use with human serum, or plasma specimens only.
- Collect specimens according to safe phlebotomy procedure.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 35.6-46.4°F (2-8°C) for up to 7 days. For long term storage, specimens should be kept below -4°F (-20°C).
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

Test Procedure

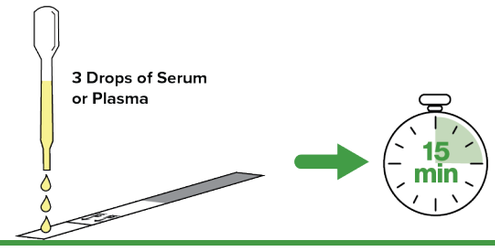
Bring tests, specimens, and/or controls to room temperature (59-86°F; 15-30°C) before use.

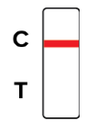
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the Strip with patient or control identification. For best results the assay should be performed within one hour.
2. Add 3 drops of serum/plasma (approximately 75 µL) with the provided disposable dropper directly into the sample pad of the strip and start the timer.
   Avoid trapping air bubbles in the sample pad, and do not add any solution to the result area.
   As the test begins to work, color will migrate across the result area in the center of the Strip.
3. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

Results Interpretation

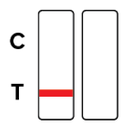


POSITIVE: Two colored lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T).





NEGATIVE: Only 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. Results from any test which has not produced a control line at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

Quality Control

- Internal procedural controls are included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Rapid Response™ Hepatitis B Surface Antibody (HBsAb) Test Strip is for professional in vitro diagnostic use, and should only be used for the qualitative detection of

HBsAb.

2. The kit will only indicate the presence of HBsAb in the specimen and should not be used as the sole criteria for the diagnosis of HBV viral infection.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.
4. A negative result does not at any time rule out the existence of HBsAb in blood, as HBsAb may be present below the minimum detection level of the test (10 mIU/mL).
5. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics

The performances of the Rapid Response™ Hepatitis B Surface Antibody (HBsAb) Test Strip have been established in comparison with EIA. The testing results were shown in the table below:

Table: Rapid Response™ Hepatitis B Surface Antibody (HBsAb) Test Strip vs. EIA

Relative Sensitivity:
100% (98.6%-100.0%)*
Relative Specificity:
99.4% (98.0%-99.8%)*
Overall Agreement:
99.7% (98.9%-99.9%)*
*95% Confidence Interval

		EIA +	EIA -	Total
Rapid Response™ Hepatitis B Surface Antibody (HBsAb) Test Strip	+	276	2	278
	-	0	352	352
Total		276	354	630

Bibliography

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]. Available from http://www.merck.com/mmpe/sec03/ch027/ch027b.html.

Glossary of Symbols

Consult instructions for use
Test per Kit
Do Not Reuse
Store between 35.6°F to 86°F
Use by
REF Catalogue #
LOT Lot Number
IVD For *in vitro* diagnostic use only

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