HBsAg Rapid Test Cassette

HBsAg Rapid Test Device
Package Insert

Cat: SP-216
Specimens: Whole Blood/Serum/Plasma **For professional *in vitro* diagnostic use only**

INTENDED USE

The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of HBsAg in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of HBV infection.

INTRODUCTION

Hepatitis B virus (HBV) is the prototypic member of the hepadnaviruses. In the lipid envelope of this small DNA virus the hepatitis B surface antigen (HBsAg) is located. During the replicative phase of the virus this surface antigen is produced in excess and detectable in the blood of infected person. The antigens HBcAg and HBeAg are parts of the nucleocapsid. The incubation period of HBV is 6 weeks to 6 months.

PRINCIPLE

The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect the HBsAg through visual interpretation of color development in the strip. The membrane was immobilized with anti-HBsAg antibodies on the test region. During the test, the specimen is allowed to react with colored anti-HBsAg antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough HBsAg in specimens, a colored band will from at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

1 Package insert
40 Individually packed test devices
1 Buffer
40 Disposable pipettes
40 Alcohol pads
40 Lancet

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use.
Timer	For timing use.
Centrifuge	For preparation of clear specimens

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its 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 totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- 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.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit should be stored at 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.**
- Cares should be taken to protect components in this 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.

SPECIMEN COLLECTION AND STORAGE

- The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. 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. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

PROCEDURE

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

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.
Transfer 2 drops of serum/plasma to the specimen well of the device with a disposable pipette provided in the kit and then start the timer.

OR

Transfer 2 drop of whole blood to the specimen well of the device with a disposable pipette provided in the kit, then add 1 drop of buffer and start the timer.

OR

Allow 2 hanging drop of fingerstick whole blood specimen to fall into the center of the
specimen well (S) on the device, then add 1 drop of buffer and start the timer.
Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.
As the test begins to work, you will see color move across the membrane.
2. Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not
interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

* A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT:

One colored band appears in the control band region (C). No band
appears in the test band region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading 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 the color in test region (T) may vary depending on the concentration of aimed
substances present in the specimen. Therefore, any shade of color in the test region should be
considered positive. Besides, the antibodies level can not be determined by this qualitative
test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are
the most likely reasons for control band failure.

QUALITY CONTROL

・ Internal procedural controls are included in the test. A colored band appearing in the control
region (C) is considered an internal positive procedural control. It confirms 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 OF THE TEST

1. The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro
diagnostic use, and should be used for the qualitative detection of HBsAg only.
2. The HBsAg Rapid Test Device (Whole Blood/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. If the test result is negative and clinical symptoms persist, additional testing using other
clinical methods is recommended. A negative result does not at anytime rule out the existence
of HBsAg in blood, because the HBsAg may be absent or below the minimum detection level of
the test.
4. Like 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

Table: HBsAg Rapid Test vs. EIA

Relative Sensitivity: 99.9% (99.3%-100.0%)*
Relative Specificity: >99.9% (99.7%-100.0%)*
Overall Agreement: 99.9% (99.8%-99.9%)*
***95% Confidence Interval**

EIA	HBsAg Rapid Test +	HBsAg Rapid Test -	Total
+	820	1	821
-	1	2134	2135
	821	2135	2956

LITERATURE REFERENCES

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

CE

	Storage temperature	LOT	Lot number
IVD	In vitro diagnostic device		Expiry date
	Read instruction before use		Manufacturer
	Protect from light and moisture		Do not reuse

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