One Step
HBsAg Hepatitis B Surface Antigen
Rapid Test Kit
(Serum/Plasma)

Package Insert

A rapid, one step test for the qualitative detection of Hepatitis B virus in human serum and plasma.

For in vitro diagnostic use only.

PRODUCT NAME

HBsAg Hepatitis B Surface Antigen Rapid Test Kit (Serum/Plasma)

INTENDED USE

Used for the qualitative detection of Hepatitis B surface antigen in serum/plasma.

PRINCIPLE

The sample mixing up colloidal-gold monoclonal antibody move along the membrane to the T line, and form the T line when the human serum/plasma and whole blood contains HBsAg according to the principle of double antibody sandwich method and gold immunochromatography assay, which is a positive result. Unreacted markers move forward continually to combine with anti-mouse antibody and form a control line. If the test line does not appear, it is a negative result.

MAIN COMPONENTS

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

SAMPLE REQUIREMENTS

The test can be performed on human serum or plasma.

Serum: Collect a certain amount of venous blood into a tube that without anticoagulant, and place at room temperature for blood coagulation, take the serum after fully centrifugation for detection.

Plasma: Collect a certain amount of venous blood into a tube that has anticoagulant of Heparin or EDTA, and place at room temperature for blood stratification, take the plasma after fully centrifugation for detection.

Specimen Stability: Serum or plasma samples can be stored for 3 days at 2-8°C. If longer storage is required, freeze at -20°C. Make sure the samples come to room temperature before detection. Avoid repeated freezing and thawing.

TEST METHODS

1. *Instruction for Use* must be read carefully before taking the test. Allow the required test device to come to room temperature for 30 minutes (20℃-30℃) before use. Do not open the inner packaging (pouch) until ready, it must be used in one hour once opened (Humidity:20%~90%, Temp:10℃-50℃)

2. Test Procedure

Strip:

Dip-sample

(1) Remove the test strip from the sealed pouch.

(2) Put the end of the test strip which printed with arrows into the sample, the interface of samples should not exceed the max line.

(3) Take it out after 15 seconds and place the test strip on a clean and level surface and then start the timer.

(4) Wait for control line “C“ to appear and possibly test line “T“.

Read the test from the 15th minute onwards. Do not report a negative result before 20 minutes.

Drop-sample

(1) Take off the outer packing, put the strip onto the desk with the sample adding area up.

(2) Using the dropper, transfer two drops of sample (approx. 50-60 µl) to the sample adding area avoiding the formation of bubbles.

(3) After transferring the sample, wait for control line “C“ to appear and possibly test line “T“.

Read the test from the 15th minute onwards. Do not report a negative result before 20 minutes.

Cassette:

(1) Remove the test cassette from the sealed pouch and use it as soon as possible.

(2) Place the test device on a clean and level surface.

(3) Using the dropper, transfer three drops of sample (approx. 80µl-100µl)) to the sample well (S) of the test cassette avoiding the formation of bubbles.

(4) After transferring the sample, wait for control line “C“ to appear and possibly test line “T“.

Read the test from the 15th minute onwards. Do not report a negative result before 20 minutes*.

INTERPRETATION OF RESULTS

POSITIVE: Two distinct red lines appear. A red line in the control region (C), and another red line in the test region (T).

A pink to red line (T), even if it is very thin, indicates a positive result.

NEGATIVE: A red line appears in the control region(C). No line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons.

Review the procedure and repeat the test with a new test device.

If the problem persists, discontinue using the kit and contact your local distributor.

POSITIVE NEGATIVE INVALID

LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of HBsAg cannot be determined by this qualitative test.

2. The results of the reagent are only for clinical reference, a confirmed diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Limit of detection: The limitation should be no more than

1ng/mL. The results should all be positive when detecting the national HBsAg quality control samples of adr, adw and ay.

2. Negative specificity: The results should all be negative when detecting 20 kits of HBsAg negative quality control samples.

3. Positive specificity: The results should all be positive when detecting 3 kits of HBsAg positive quality control samples.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

5. Analytical sensitivity: 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result.

6. The reagent is not affected by the rheumatoid factor, HGV antigen, HCV antigen, HAV antigen, HBsAb, HBeAg, HBcAb, TP antigen, HEV antigen, HIV antigen and systemic lupus erythematosus.

7. Diagnostic specificity and sensitivity

A clinical evaluation was conducted comparing the results obtained using the Rapid Diagnostic Kit For Hepatitis B Surface Antigen (Colloidal Gold) and EIA HBsAg tests. The results are as follows:

HBsAg Reference Method

Method		EIA		Total Results
HBsAg Test Kit	Results	Positive	Negative	
	Positive	373	0	373
	Negative	4	120	124
Total Results		377	120	497

Relative Sensitivity: 98.94% Relative Specificity: 100%

Accuracy: 99.20%

PRECAUTION

1. The result is invalid over 20 minutes.

2. Do not use after the expiration.

3. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

4. Both deep and light color may occur during the test, even a very light brand during observation time should be judged as positive a result.

5. If the blood is too thick, and the climb speed is less than 4mm/min, add one drop buffer to the samples pad to help.

6 .Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.

BIBLIOGRAPHY

[1] MILICH D.R., Immune response to the hepatitis B virus : infection, animal models, vaccination, VIRAL HEPATITIS, 1997, 3, 63-103.

[2] HOLLINGER F.B., Hepatitis B virus, in Fields Virology, Third Edition, Lippincott-Raven Publishers, Phildelphia, 1996, 2739-2807.

[3] BLUMBERG B.S., ALTER H.J., VISNICH S. JAMA, A "New" Antigen in Leukemia Sera, 1965, 191, 541-546.

[4] PRINCE A.M., An antigen detected in blood during the incubation period of serum hepatitis, Proc Natl Acad Sci USA, 1968, 60, 814-821.

INSTRUCTIONS OF SYMBOL

	Consult instruction for use		Keep dry
	Store between		Batch number
	For single use		IVD product
	Manufacturer		Date of manufacture
	Expire date		Contains sufficient for <n> tests