Accu-Screen HBsAg Rapid Test Device (Serum/Plasma) Package Insert

A rapid test for the qualitative detection of hepatitis B surface antigen in human serum/plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The HBsAg Rapid Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in serum,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 HBV is called HBsAg.Previous designations included the Australia or Au antigen.[1]The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection,either acute or chronic.In a typical Hepatitis B infection,HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop.HBsAg has four principal subtypes:adw,ayw,adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

The HBsAg Rapid Test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in serum,plasma specimen.The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum, plasma.

PRINCIPLE

This test device contains a membrane strip,which is pre-coated with mouse monoclonal anti-HBsAg capture antibody on test band region. The mouse monoclonal anti-HBsAg-colloid gold conjugate and sample moves along the membrane chromatographically to the test region (T) and forms a visible line as the antibody-antigen-antibody gold particle complex forms. Both the Test Line and Control Line are not visible before applying any samples. The Control Line is used for procedural control.Control line should always appear if the test procedure is performed properly and the reagents of control line are working.

REAGENTS

The test contains anti-HBsAg particles and anti-HBsAg coated on the membrane.

PRECAUTIONS

- Please read all the information in this package insert before performing the test.
- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test, including test Device, dropper, buffer and so on, should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30℃).The test is stable through the expiration date printed on the sealed pouch.The test must remain in the sealed pouch until use.**DO NOT FREEZE**.Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HBsAg Rapid Test Device (Serum/Plasma) can be performed using serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected.Do not leave the specimens at room temperature for prolonged periods.Serum and plasma 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 local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

- Test Device
- Droppers
- Package insert

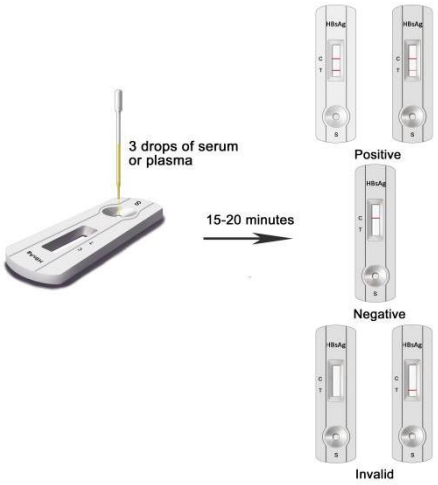
Materials required but not provided

- Specimen collection containers
- Timer
- Centrifuge
- Heparinized capillary tubes and dispensing bulb

DIRECTIONS FOR USE

Allow the test, specimen,buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it.Remove the test Device from the sealed pouch and use it as soon as possible.
2. Place the Device on a clean and level surface.
3. Hold the dropper vertically and **transfer 3 drops of serum or plasma (approximately 75ul)** to the specimen area and start the timer. See illustration below.
4. Wait for the colored line(s) to appear.**Read results at 10 minutes.**Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:*Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

***NOTE:**The intensity of color in the test line region (T) will vary depending on the concentration of HBsAg antibody present in the specimen.Therefore,any shade in the test region indicates positive result.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test.If the result is still invalid, stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control.

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.

LIMITATIONS

1. The HBsAg Rapid Test Device (Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of Hepatitis B surface Antigen in Serum/Plasma specimens only. Neither the quantitative value nor the rate of increase in Hepatitis B surface Antigen can be determined by this qualitative test.
2. The HBsAg Rapid Test Device (Serum/Plasma) will only indicate the presence of Hepatitis B surface Antigen in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B infection.
3. As with all diagnostic tests,all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.A negative result does not at any time preclude the possibility of Hepatitis B infection.

EXPECTED VALUES

The HBsAg Rapid Test Device (Serum/Plasma) has been compared with another leading commercial rapid test. The correlation between these two systems is 99%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The HBsAg Rapid Test Device (Serum/Plasma) has been tested with a sensitivity panel ranging from 0 to 300 ng/ml. All 10 HBsAg subtypes produced positive results on the HBsAg Rapid Test Device (Serum/Plasma).The test can detect 1 PEI ng/ml of HBsAg in serum/plasma.

Specificity Antibodies used for the HBsAg Rapid Rapid Test Device (Serum/Plasma) were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the HBsAg Rapid Test Device (Serum/Plasma) was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

Method		EIA		Total Results
HBsAg Rapid Test Device (Serum/Plasma)	**Results**	**Positive**	**Negative**	
	Positive	129	1	130
	Negative	0	370	370
Total Results		129	371	500

Relative Sensitivity: ＞99.9% (95%CI*: 97.7%~100%) *Confidence Intervals
Relative Specificity: 99.7% (95%CI*: 98.5%~100%)
Overall Accuracy:99.8% (95%CI*: 98.9%~100%)

Cross-reactivity

The HBsAg Rapid Test Device(Serum/Plasma) has been tested by HAMA,Rheumatoid factor(RF), HAV,Syphilis,HIV,H.Pylori,MONO,CMV,Rubella and TOXO positive specimens.The results showed no cross-reactivity

Specificity

The HBsAg Rapid Test Device(Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens.No interference was observed. In addition, no interference was observed in specimens containing up to 2,000 mg/dl Hemoglobin,1000 mg/dl Bilirubin, and 2000 maldl human serum Albumin.

BIBLIOGRAPHY

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

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number	Σ	Contains sufficient for <n> tests

Hangzhou Realy Tech Co., Ltd.
#2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Website: www.realytech.com

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