GB QUIK – HBsAG RAPID TEST KIT (SERUM/PLASMA)

KIT NAME	KIT SIZE	CAT. NO
GB QUIK – **HBsAG** RAPID TEST KIT	25T	GBQHbS025T
GB QUIK – **HBsAG** RAPID TEST KIT	50T	GBQHbS050T

GENUINE BIOSYSTEM

INTENDED TO USE

The HBsAg Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Hepatitis B virus (HBV). Any reactive specimen with the HBsAg Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

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. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute orchronic. 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 Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimens. The test utilises a combination of double monoclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma.

PRICIPLE

The HBsAg Rapid Test Cassette is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the test. During testing, Hepatitis B Surface Antigen in the serum or plasma specimen reacts with the particle coated with anti-HBsAg antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies 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 the proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS:

S. No	Component	QTY
1	Test Casette	25 nos
2	Prefilled Buffer Solution tube	25 nos
3	Sample Dropper	25 nos

STORAGE AND STABILITY

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

SPECIMEN

1.HBsAg Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
2.Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3.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 2-8C for up to 3 days. For long term storage, specimens should be kept below -20C.
4.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.
5.If specimens are to be shipped ,they should be packed in compliance with usual regulations for transportation of aetiological agents.

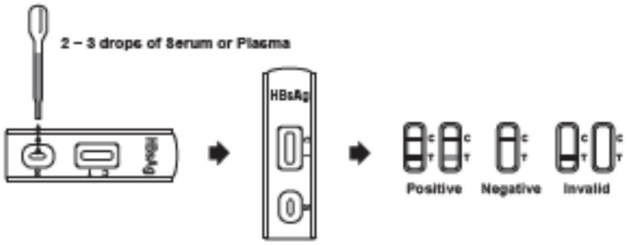
WARNING AND PRECAUTION

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. 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.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results .
8. Do not perform the test in a room with strong air flow, ie. electric fan or strong air conditioning.

TEST METHODS

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

1. Remove the test Cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2-3 drops of serum or plasma (approximately 60-90 µL) to the specimen well (S) of the test device, and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

NEGATIVE: One red 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 Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

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

LIMITATIONS OF TEST METHODS

1.Though the HBsAg Rapid Test Cassette is a reliable screening assay, it should not be used as a sole criterion for diagnosis of HBV infection.
2. The HBsAg Rapid Test Cassette is limited to the qualitative detection of HBsAg in human serum or plasma. The intensity of the test band does not have linear correlation with HBsAg titer in the specimen.
3. A negative test result does not preclude the possibility of exposure to or infection with HBV. Infection through recent exposure (seroconversion) to HBV may not be detectable.
4. A negative result can occur if the quantity of HBsAg present in the specimen is below the detection limits of the assay (lower than1 ng/mL), or the HBsAg that are detected are not present during the stage of disease in which a sample is collected.
5. Interference due to heterophile antibodies, Rheumatoid Factors and other nonanalyte substances in patient's serum,capable of binding antibodies multivalently and providing erroneous analyte detection in immunoassays, has been reported in various studies. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interference. Results that appear to be internally inconsistent or incompatible with the clinical presentation should

invoke suspicion of the presence of an endogenous artifact and lead to appropriate in vitro investigative action.
6.This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERSTICS

Sensitivity:

The HBsAg Rapid Test Cassette (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 Cassette (Serum/Plasma). The test can detect 5ng/mL of HBsAg in 10 minutes, and 1 ng/mL of HBsAg in 15 minutes.

Specificity:

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

HBsAg Rapid Test Cassette vs. EIA test

Method		EIA		Total Results
	Results	Positive	Negative	
HBsAg Rapid Test Cassette	Positive	345	5	350
	Negative	2	980	982
Total Results		347	985	1332

Relative sensitivity: 99.4%
Relative specificity: 99.5%
Accuracy: 99.5%

REFERENCE

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

IVD CE

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