HBsAg Rapid Quantitative Test

Catalog No.BT21101

INTENDED USE

The HBsAg Rapid Quantitative Test is an in vitro immunoassay for the quantitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of Hepatitis B Virus infection.
-Fluorescent immunoassay
-Hepatitis B Virus infection
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Hepatitis b is a disease endemic throughout the world caused by the hepatitis b virus (HBV), this virus may cause acute and chronic hepatitis infections, possibly be evolving to cirrhosis or primary liver cancer.
The average incubation period for HBV infection is 6 to 8 weeks (range 1 to 6 months). HBsAg is the first antigen to appear following infection with hepatitis B virus and is generally detected 1 to 10 weeks before the onset of clinical symptoms.
Hepatitis b virus is transmitted through direct contact with blood and body fluids, such as blood transfusion, mother-neonate contact during birth and sexual contact. Common clinical symptoms include malaise, fever, gastroenteritis, and icterus. HBV infection can result in typical icteric hepatitis, subclinical anicteric hepatitis, fulminant hepatitis, or chronic or persistent hepatitis.
About 80%-90% of infants infected with HBV in the first year of life may develop chronic hepatitis, 30% and 50% of children infected with HBV before age 6 will become chronic infection. Less than 5% of adults infected with HBV will become chronic carriers, 20%-30% of these people can lead to cirrhosis or liver cancer.
Hepatitis b surface antigen (HBsAg) is the coat protein of HBV, and a unique serological marker of acute or chronic hepatitis b infection. The HBsAg test is commonly used to diagnose suspected HBV infection and to monitor the status of an infected person to determine whether the virus has been cleared or the patient has become a chronic carrier. In patients that recover from HBV infection, HBsAg levels disappear 3 to 5 months after the onset of the infection. In patients with chronic HBV infection, HBsAg levels remain detectable for life. In addition, HBsAg assays are used to evaluate the efficacy of anti-viral drugs by monitoring the levels of HBsAg in patient serum or plasma. Prenatal HBsAg screening has been recommended so that newborns from HBV carrier mothers may obtain prophylactic treatment.

PRINCIPLE

This reagent is based on fluorescent lateral flow immunoassay competition method.
HBsAg in specimen reacted with detector antibody labeled with fluorescent microsphere(contain Europium) on the fiberglass, forming antigen-antibody complexes. The complex migrates across the membrane and captured by the other immobilized-antibody on test strip, and gives fluorescent signal upon stimulation. Thus the fluorescent signals are positively correlated with the concentrations of HBsAg. The fluorescent signal will be quantified and calculated according to the calibration curve (provided with the reagents) to represent concentration of HBsAg in specimen.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

MATERIAL

Material Provided
1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD card 1 piece/kit
4. Instruction for use 1 copy/kit

Material Required But Not Provided
1. Biotime FIA Analyzer
2. Transfer Pipette Set(range 5~50 μ L and 10~100 μ L size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, and the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with plasma and serum sample using EDTA, immune tube or pro-coagulant tube.
2. The collecting of the sample: The venipuncture for human serum or plasma blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected timely, it can be stored in refrigerator at 2-8℃ for 6 days，or at -20℃ for 6 months.
3. Separate the plasma or serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the operation manual of Biotime FIA analyzers for details.
The test should be operated at room temperature (~25℃).
Step 1: Preparation
Check the lot number and insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
For plasma/serum:Take 40μL of plasma or serum with a transfer pipette and add it to the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.
Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

INTERPRETATION OF RESULTS

Cut off：1.0 IU/mL; Negative：＜1.0 IU/mL; Positive：≥1.0 IU/mL
Note: When the concentration of HBsAg is above 250.0 IU/mL，the value will be flagged as ＞250.0 IU/mL。
The cut-off is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be serum and plasma
2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies[4-5].
3. Other factors also can induce the false results, include the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy
Test cartridges from same batch were tested with HBsAg control of three different levels of concentration, mean and Bias% were calculated, Bias% was within 10%.
Assay Range and Detection Limit
Assay Range: 0.5-250.0 IU/mL
The Lowest Detection Limit: 0.5 IU/mL
Linearity
A serial concentration of HBsAg controls at 0.5-250.0 IU/mL were tested, the Correlation Coefficient (R) is≥0.99.
Precision
Intra-Lot Precision
Within-run precision has been determined by using 10 replicates from same batch to test with HBsAg control. C.V. is ≤ 15%.
Inter-Lot Precision
Between-run precision has been determined by using 3 replicates from random 3 continuous batches to test with HBsAg control. C.V. is ≤20%.
Specificity
Cross-reactivity
There was no false positive result from 156 samples containing potentially interfering substances with the HBsAg Quantitative Rapid Test. The overall specificity was 100 %.

Clinical category		HBsAg Quantitative Rapid Test results	
		Negative	Positive
CMV	10	10	0
EBV	10	10	0

HAV	10	10	0
HSV	10	10	0
HIV-1	10	10	0
HCV	10	10	0
Rubella	10	10	0
VZV	10	10	0
Syphilis	10	10	0
ANA	10	10	0
RF	10	10	0
Early stage of pregnancy	21	21	0
Middle stage of pregnancy	15	15	0
Total	156	156	0

Interference
There was no significant interference from these material with the HBsAg Quantitative Rapid Test.

Materials	Concentration
Heparin	100,000 U/L
EDTA	5 μM
Sodium citrate	25 mg/mL
Bilirubin	0.5 mM/L
Hemoglobin	2 g/L
Triglycerides	1.5 mg/mL
Cholesterol	20 mM
Albumin	60 mg/mL

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use
	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer	2℃ 30℃	Temperature limit
	Do not re-use	Σ	Contains sufficient for <n> tests
	Caution		Do not use if package is damaged

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