HBsAg Rapid Test Kit

Instruction for use

【Product Name】HBsAg Rapid Test Kit

REF A10019001B, A10019001C, A10019001D, A10019001E

【Specification】1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The HBsAg Rapid Test Kit is a colloidal gold immunochromatography intended for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in human serum, plasma and whole blood specimens. This test is a rapid test as an aid in the diagnosis of Hepatitis B virus infection and relative symptom.

【Summary】

Infections with Hepatitis B virus (HBV) present serious public health problems in all parts of the world. Early detection of the infection is essential. A variety of serological markers appear following infection with HBV, and the first of these is HBsAg. This antigen appears before biochemical evidence of liver disease or jaundice, persists throughout the acute disease phase, and declines during convalescence.

Procedures for the detection of HBsAg have evolved from the relatively insensitive agar gel diffusion methods to the enzyme immunoassay. In 1975, Wolters et al. published an ELISA procedure for the detection of HBsAg in micro-plates. With this procedure, the sensitivity was reported to be equivalent to radioimmunoassay on a panel of reference sera. Subsequently, the ELISA procedure has been widely applied in the detection of antigens and antibodies.

【Test Principle】

The test is a sandwich immunoassay. If there are HBsAg in the sample, it will be combined with colloidal gold labeled anti-HBsAg monoclonal antibody, form a complex. Under the action of chromatography, the complex flows on the nitrocellulose membrane. Then, the complex will combine to another anti-HBsAg monoclonal antibody (T line) coated on the nitrocellulose membrane. The control line (C line) must appear in the control area of the rod for the result to be valid. A line will appear in the test line area, indicating a positive result.

【Main Components】

Materials Provided:

Specification / Material	1 test/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	5	10	25
Whole Blood Buffer	1	1	1	1
Disposable Pipettes	1	5	10	25
Instruction for Use	1	1	1	1

Materials Optioned:

1. Alcohol pad
2. Safety lancet

Materials Required but Not Provided:

1.Timer
2.Tube rack for specimens
3.Any necessary personal protective equipment

【Storage Conditions and Validity】

1.This product should be stored in a dark and dry place at 2~30℃.The validity period of the kit is 24 months.
2.After unpacking the aluminum foil bag of the test cassette, It should be used in the specified environment (Temperature 2-35°C,Humidity 40%-90%) within 1 hour.
3.Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handing】

1. This kit is used to detect human serum/plasma/whole blood samples. The plasma and whole blood samples are recommended to use EDTA, heparin or sodium citrate for anticoagulation. Other body fluids and samples may not get accurate results.

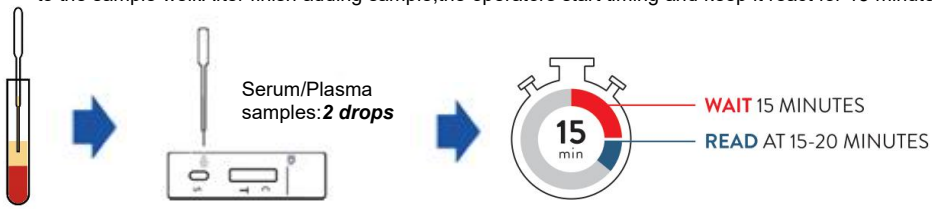
2. After the blood samples are collected, if they cannot be tested in time, the serum/plasma should be stored at 2-8°C for 7 days.The sample can be stored for 30 days under -15°C. The whole blood samples should not be frozen and can be stored for 3 days at 2-8°C.

【Test Method】

1. Read the instructions for use completely before testing
2. Before use, take out the reagents and specimens, places the reagent on a flat table and balance them to room temperature (18-25°C).
3. The operators take the test cassette out of the packaging bag and place it on the platform table.
4. Add the specimens

For serum or plasma samples

a.Collect and process blood samples according to standard operating procedures to obtain serum/plasma samples.
b.The operator uses a disposable pipette to absorb 2 drops (60 μL) of the serum or plasma sample,add it to the sample well.After finish adding sample,the operators start timing and keep it react for 15 minutes.



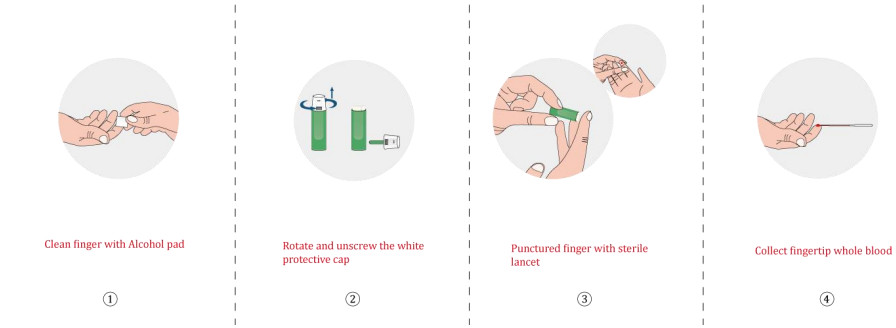
For venous whole blood samples

a.Collect and process blood samples according to standard operating procedures to obtain Venous whole blood samples.
b.The operator uses a disposable pipette to absorb 2 drops (60 μL) of the Venous whole blood sample,add it to the sample well. Immediately add 1 drop of whole blood buffer to the sample well.After finish adding sample,the operators start timing and keep it react for 15 minutes.

For fingertip whole blood samples

a.Clean the puncture site with the alcohol pad
b.After the alcohol is dried, the fingertips are punctured with safety lancet to form blood droplets
c.The operator uses a disposable pipette to absorb 2 drops (60 μL) of the Fingertip whole blood sample,add it to the sample well. Immediately add 1 drop of whole blood buffer to the sample well. After finish adding sample, the operators start timing and keep it react for 15 minutes.

NOTE：After the formation of blood drops, should wipe the first drop of blood before using a disposable pipette dropper to take fingertip blood samples.

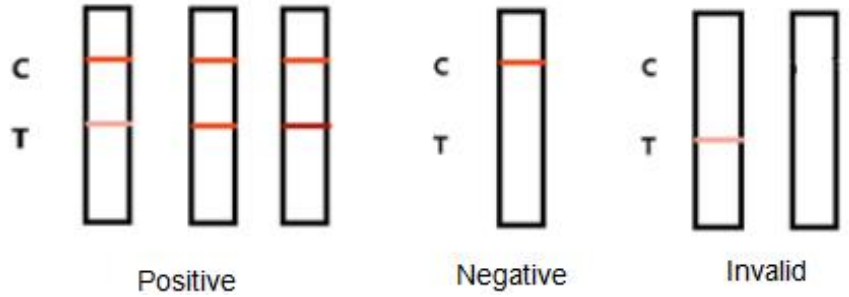


【Interpretation of Test Results】

Positive(+):There is coloration on line C,and a colored line appeared T line.

Negative(-): There is coloration on line C only showing as following picture

Invalid:There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.



【Reporting of Results】

Positive test:

If any Positive, there is currently a suspicion of Hepatitis B virus infection. contact your doctor or local health department immediately. Perform another test to confirm the result.

Negative test:

Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with Hepatitis B virus. It is recommended that these results be confirmed by other testing methods, if necessary, for patient management Control.

Invalid:

If the control line C is not visible, the result is invalid. An invalid result may have been caused by the incorrect execution of the test. Please perform a new test with a new sample and a new test cassette. If the result is invalid again, you should consult a doctor or a test center.

【Limitation of The Test】

1. The kit can be used for the detection of human serum,plasma or whole blood samples.The reliability of the determination of this substance in other types of samples has not been fully confirmed.
2. Positive test results do not rule out co-infections with other pathogens.
3. Results of HBsAg test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
4. A false-negative test result may occur if the level of viral in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of Hepatitis B virus infection.
5. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

【Performance Characteristics】

1. **Sensitivity and Specificity**

The clinical performance of HBsAg Rapid Test Kit was evaluated in comparison to a commercial HBsAg test using clinical specimens. The results are shown in the following tables.

HBsAg Rapid Test Kit	Commercial HBsAg test		
	Positive	Negative	Total
Positive	1158(a)	11(b)	1169(a+b)
Negative	15(c)	1624(d)	1639(c+d)
Total	1173(a+c)	1635(b+d)	2808(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.72%	97.90%~99.28%	
Clinical specificity	99.33%	98.80%~99.66%	
Total coincidence rate	99.07%	98.65%~99.39%	

2. **Limitation of Detection (LoD)**

The LoD of HBsAg Rapid Test Kit is 0.5 ng/mL.

3. **Cross-reactivity**

HBsAg Rapid Test Kit does not cross with the following common Potential Cross-Reactants.

S.N.	Potential Cross-Reactant	S.N.	Potential Cross-Reactant
1	Dengue virus	7	H. pylori
2	HAV	8	Syphilis
3	HCV	9	Rubella
4	HIV	10	Plasmodium falciparum
5	EBV	11	HTLV
6	HSV	12	CMV

4. **Interfering substances**:The Concentrations of triglycerides 40mmol/L,hemoglobin 2g/L,rheumatoid factor 1000IU/mL,bilirubin 350μmol/L and HAMA 600ng/mL have no effect on the test results.

【Precautions】

1. After opening the package, the kit should be ready for use as soon as possible and avoid placing it in a high temperature (over 30°C) and high humidity environment for a long time.
2. All samples (whole blood, serum and plasma) and test cassettes after use should be considered potentially dangerous and should be treated as infectious materials, and the waste should be disposed of in accordance with the regulations of the hospital or environmental protection department.
3. The test strips with any color lines before the test should not be used and the reagents with damaged packaging bags or invalid seals should not be used.
4. The kit is for in vitro diagnostic use only.The kit is for single-use,please do not use the product after it expires.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
	Do not use if package is damaged and consult instructions for use		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30°C 2°C	Temperature limit	LOT	Batch code

	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests

【Basic Information】

Anbio (Xiamen) Biotechnology Co.,Ltd.
Add: No.2016,Wengjiao West Road, Xinyang Street, Haicang District, Xiamen,Fujian,China.
Tel:+86-592-6312399,Email:info@anbio.com

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