ACCUCARE®

ONE STEP HEPATITIS B Ag RAPID TEST

(Whole Blood/Serum/Plasma)

One step rapid Card Test for detection of Hepatitis B (HBsAg) in human Whole Blood/Serum/Plasma

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF Device
01 Test	HBSC 01
10 Tests	HBSC 10
25 Tests	HBSC 25
50 Tests	HBSC 50

CLINICAL SIGNIFICANCE

Hepatitis B surface antigen ("Australis Antigen") consists of lipid, carbohydrate and protein elements. The protein moiety provides a marker for identification of chronic and infectious HBV infections. Hepatitis B is transmitted sexually or intravenously and has an incubation period of six months. If not diagnosed properly and in time, it can develop into acute or chronic infection, liver cirrhosis and fulminant Hepatitis. This test is very useful for screening blood donors, to find out whether they are HBsAg positive before collection of blood.

PRINCIPLE

ACCUCARE® ONE STEP HEPATITIS B Ag RAPID TEST utilizes the principle of immunochromatography, a unique assay based on antigen capture or sandwich principle. The method uses monoclonal antibody conjugated to colloidal gold and polyclonal antibodies immobilized on nitrocellulose membrane in thin line. The test sample flows through the membrane assembly of the test and formed the colored monoclonal anti-HBsAg colloidal gold conjugate complexes with the HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by a polyclonal anti-HBsAg coated on the membrane leading to formation of a pink-purple colored band. The formation of first purple band (T zone) confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-rabbit IgG coated on the membrane at the control region, forming a pink-purple band. This control band serves to validate the test results.

CONTENTS

Test Device
Assay Buffer
Instruction for Use (IFU)
Disposable (Dropper) 25 µl sampling device
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. Though ACCUCARE® ONE STEP HEPATITIS B Ag RAPID TEST is a reliable screening assay, it should not be used as a sole criterion for diagnosis of Hepatitis B infection.
2. The ACCUCARE® ONE STEP HEPATITIS B Ag RAPID TEST will only indicate the presence or absence of Hepatitis B surface antigen in the specimen and other consideration like clinical symptoms should be noted before making final diagnosis.
3. For confirmation, further analysis of the specimens should be performed, such as ELISA and/or CLIA analysis. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Interference due to heterophile antibodies, RF (Rehumatoid Factors) and other non-analyte substances in high titer in patient's serum express erroneous analyte detection in immunoassays interferences. Both laboratory professionals and clinicians must be vigilant to this possibility of antibody interferences.
5. Most positive results develop within 15 minutes. However, certain sera samples may take longer time to flow. Do not read results after 20 minutes.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP HEPATITIS B Ag RAPID TEST can be performed using either Whole Blood or serum or plasma.
2. If you want to use Serum or Plasma than separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed 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 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
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, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE

1. Allow test device and specimen equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the aluminum foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

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3. Place the test device on a clean and flat surface. Carefully dispense 1 drop (appx. 25 µl) of Whole Blood/Serum/Plasma in the sample well "S" using the dropper provided.
4. After adding specimen add one drop (appx. 40 µl) assay diluent in the sample well "S".
5. Allow reaction to occur and read the results at 15 minutes. Do not interpret the results after 20 minutes.

INTERPRETATION OF RESULTS

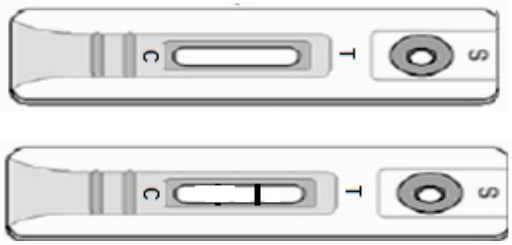
1. POSITIVE

If two color bands appear, one at control line 'C' and other at test line 'T', the specimen is positive for Hepatitis B Antigen.
ACCUCARE™ ONE STEP HEPATITIS B Ag RAPID TEST can detect Hepatitis B antigen in whole blood/serum/plasma in a concentration as low as 1.0 ng/ml

2. NEGATIVE

If only one color band appear at control line 'C' as the specimen is Negative for Hepatitis B Antigen.

3. INVALID



If no color band appear, at control line 'C' within the stipulated time then result is invalid. Repeat the test using a fresh Test Device.

NOTE: The intensity of the color band in the test line region will vary depending on the concentration of Hepatitis B Antigen present in the specimen. However, neither the quantitative value nor the rate of increase in Hepatitis B Antigen can be determined by this qualitative test.

INTERFERING SUBSTANCES

No interference in the ACCUCARE® ONE STEP HBsAg TEST was evident when the following substances were tested:

Sample Type	Number of Samples Tested	Positive	Negative
Clinical Specimens	100	01	99
Pregnant women	100	01	99
Other disease Samples*	100	00	100

*Other disease Samples: These are the samples that potentially interfere with HBsAg immunoassays. Details of the samples are as follow:

Sample Type	No. of Sample Tested
HCV Positive	20
HIV Positive	20
Syphilis Positive	15
Anti-HAV Positive	15
Rubella Positive	15
Anti-HTLV Positive	15
Total	**100**

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP HEPATITIS B Ag RAPID TEST has been evaluated with positive and negative samples confirmed by ELISA examination.

Specimen	Positive	Negative	Sensitivity
Positive	300	00	100 %

Specimen	Positive	Negative	Specificity
Negative	09	1446	99.38 %

BIBLIOGRAPHY

1. Ruben, E. (1979) Acute and chronic viral hepatitis. Federation Proceedings. 28:2665.
2. Magnius, L.O., et al. (1975) new antigen-antibody system. Clinical significance in long-term carriers of Hepatitis B surface antigen. J. American Medical Association. 231: 356.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

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