







SYMBOLS USED ON THE

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
IVD	In vitro diagnostic medical device
CARD	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Sample running buffer
	Manufactured By
	Date of Manufacture
	Contains sufficient <n> tests



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Version En1 - 10/2004.

Core™ HBsAg

Rapid test for the detection of Hepatitis B Surface Antigen (HBsAg) in serum, plasma and whole blood.
CAT N°: HBsAg-150020

INTRODUCTION

Core HBsAg is a rapid, self performing, qualitative, two site sandwich immunoassay for the determination of Hepatitis B surface antigen, a marker for Hepatitis B infection, in serum/plasma specimens or whole blood specimens.

SUMMARY

Blood containing the Hepatitis B Virus (HBV) is potentially infectious. Hepatitis B Surface Antigen (HBsAg), earlier known as Australia Antigen, is among the first serological markers that circulate in the blood of infected persons even two to three weeks prior to the appearance of clinical symptoms. The levels of HBsAg are especially elevated during the symptomatic phase and decline thereafter. Detection of HBV using HBsAg as the marker to screen blood donors is essential to reduce the risk of transmission of Hepatitis B by blood transfusion. HBsAg detection is also useful for screening high risk groups for HBV and for differential diagnosis of Hepatitis infections. Core HBsAg detects the presence of HBsAg in serum/plasma specimens, qualitatively, at concentrations as low as 0.5 ng/ml with in 15 minutes.

PRINCIPLE

Core HBsAg utilizes the principle of Immunochromatography, a unique two site immunoassay on a membrane. As the test sample flows through the membrane assembly within the test device, the colored anti-HBsAg-colloidal gold conjugate complexes with HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-HBsAg coated on the membrane leading to formation of a pink-purple colored band which confirms a positive test results. 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-mouse antibodies coated on the membrane at the control region, forming a pink-purple colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Core HBsAg kit has the following components.

- A. Individually Pouched devices comprising of :-
1. Test Device : Comprising of Anti-HBsAg Ab-colloidal gold conjugate, Mouse IgG- colloidal gold conjugate, membrane assembly pre-dispensed with Anti-HBsAg Ab and anti-mouse antiserum coated at the respective regions.
 2. Disposable Plastic Dropper
 3. Desiccant Pouch.
- B Sample Running Buffer.

STORAGE AND STABILITY

The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4°C to 30°C. Do not freeze the kit or components.

NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Sample running buffer contains sodium azide (0.1%). Avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.
7. If the pouch of the test device is damaged, discard the device and take a new one for the test.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma/whole blood is preferable, specimens may be stored at 2-8 °C for upto 24 hours, in case of delay in testing. Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate can also be used. Fresh blood from finger prick / puncture may also be used as a test specimen. Do not freeze whole blood samples. Do not use turbid, lipamic and haemolysed specimens. Do not use haemolysed, clotted or contaminated blood samples .

Precautions under the HBV regulations:

1. For professional use only, not to be used by the general public.
2. Negative result may not have detected recently acquired HBV infection.
3. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the device. Once opened, the device must be used immediately.
3. Label the test device with patients identity.
4. Add two drops of serum using the sample dropper provided, in the well marked "A" . A lab micropipette can also be used.
5. Add four drops of sample running buffer in the well marked "B" using the dropper vial.
6. At the end of 15 minutes read the results as follows:

NEGATIVE:



POSITIVE:



Negative: Only one colored band appears on the control region 'C'

Positive: In addition to the control band, a distinct colored band also appears on the test region "T"

7. The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new device.
8. Although, depending on the concentration of HBsAg in the specimen, positive results may start appearing as early as 2 minutes, negative results must be confirmed only at the end of fifteen minutes.
9. In case of a doubtful results at 15 minutes, the test may be extended up to, but no longer than, 30 minutes to get a clear background.

REMARK:

To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. Diagnostic specificity:

A total of 250 samples were tested with the Core HBsAg. The diagnostic specificity is determined as 100%.

Centre	Number of samples tested	Core HBsAg	
		Negative	Positive
A	250	250	0
Total	250	250	0

2. Diagnostic sensitivity:

150 HBsAg positive samples were tested with the Core HBsAg, all of them were found positive.

The diagnostic sensitivity is determined as 100%.

HBsAg Type	Number of samples tested	Core HBsAg	
		negative	positive
HBsAg	150	0	150

3. Precision

Repeatability and reproducibility (inter-assay and inter-lot) were evaluated on a number of negative and positive HBsAg samples. No variations were found in the outcome of the different tests.

LIMITATIONS OF THE TEST

1. Presence of elevated levels of other antigens such as RF and cross reacting auto antibodies such as antibodies to HLA DR4 may yield false positive results. This may occur in less than 1% of the specimens. For confirmation of results, a confirmatory test must be used.
2. This test detects the presence of HBsAg in the specimen and hence should not be used as the sole criterion for the diagnosis of Hepatitis infection.
3. As with all diagnostic tests, the result must be correlated with clinical findings.

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