

Core Combo HIV-HBsAg-HCV

(Device)

INTRODUCTION

Core Combo HIV-HBsAg-HCV is an *in vitro*, rapid, self performing, qualitative two site sandwich immunoassay used for the detection of antibodies to HCV, HIV 1 / 2 virus and HBsAg in human serum / plasma or whole blood specimens.

Summary

Core Combo HIV-HBsAg-HCV is using an immunochromatography method for the detection of antibodies to HCV, HIV 1 / 2 virus and HBsAg in human serum/plasma and whole blood.

Hepatitis C virus (HCV) is a small, enveloped, and single-stranded RNA virus. It is the major cause of parenterally transmitted non-A, non-B hepatitis. Antibodies to HCV are reported in 80% of the non-A, non-B hepatitis patients.

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 within 15 minutes.

Highly purified antigen of gp 41, representing HIV- 1 and gp 36 representing HIV-2, recombinant HCV antigens (Core, NS-3, NS-4 and NS-5) and Anti HBsAg antibodies are used in this test.

Principle

Core Combo HIV-HBsAg-HCV utilizes the principle of immunochromatography, a unique two site immunoassay on a membrane.

In **Core Combo HIV-HBsAg-HCV**, a line containing a mixture Highly purified antigen of gp 41, representing HIV- 1 and gp 36 representing HIV-2 (line 1), a line of Anti HBsAg antibodies (line2) and a line of recombinant HCV antigens (line 3) are coated on the membrane in the test region and anti- Rabbit antiserum at the control region.

As the test sample flows through the membrane assembly within the test device, the colored conjugated colloidal gold complex (HIV 1 / 2 specific recombinant antigen-colloidal gold conjugate, anti-HBsAg-colloidal gold conjugate, HCV specific recombinant antigen-colloidal gold conjugate) reacts with antibodies to HIV 1 / 2, HCV and HBsAg in the sample. This complex moves further on the membrane to the test region where it is immobilized at individual lines coated with the HIV 1 / 2 Specific recombinant antigens (line 1), Anti HBsAg antibodies (line2) and recombinant HCV antigens (line 3) coated on the membrane leading to formation of a colored band which 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 antibodies coated on the membrane at the control region, forming a colored band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

Rapid Test For HIV-HBsAg-HCV kit has the following components.

- A. Individually Pouched devices
2. Disposable Plastic Dropper
3. Desiccant Pouch.
- B Sample Running Buffer.

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.

SPECIMEN COLLECTION AND PREPARATION

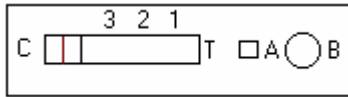
No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma/whole blood is preferable, specimens may be stored at 2-8 °C for upto 24 hours, in case of delay in testing. Blood samples collected with a suitable anticoagulant such as 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.

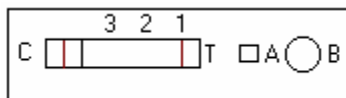
TESTING PROCEDURE AND INTERPRETATION OF RESULTS

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 drop of serum/ plasma or two drops of whole blood with the sample dropper provided in the well marked "A".
5. Add four drops of sample running buffer in the well marked "B".
6. At the end of 15 minutes read the results as follows.

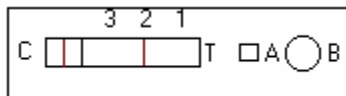


Negative : Only one coloured band appears on the control Window`C'

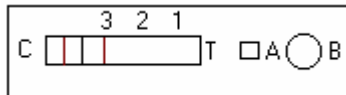
Positive In addition to the control band, a distinct colored band/bands appears on the test Window`T as follows.



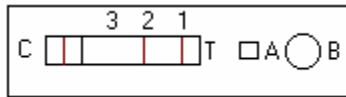
Positive for HIV 1/2



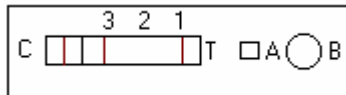
Positive for HBsAg



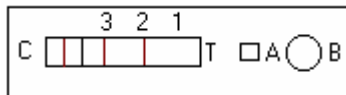
Positive for HCV



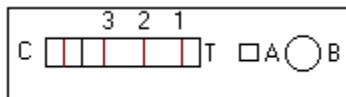
Positive for HIV 1/2 and HBsAg



Positive for HIV 1/2 and HCV



Positive for HBsAg and HCV



Positive for HIV 1/2 and HBsAg and HCV

7. The test should be considered invalid if neither the test band nor the control band appear. Repeat the test with a new device.
8. In case of a doubtful result at 15 minutes, the test may be extended upto 30 minutes to get a clear background.



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