Sensit HBs Ag Rapid Test

Cat NO.: S027-01

In vitro Diagnostics

INTENDED USE

Sensit HBs Ag Rapid Test Kit is a rapid and convenient immunochromatographic assay for the qualitative detection of surface antigen of Hepatitis-B virus (HBV) in whole blood, Serum or Plasma from Humans. Sensit HBs Ag Test is only intended for preliminary analysis and reactive samples should be confirmed by a supplemental assay such as ELISA.

SUMMARY & TEST DESCRIPTION

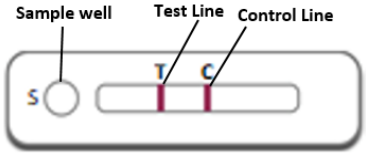
Hepatitis B virus (HBV) is a partially double stranded DNA that cause acute or chronic hepatitis, which gets transmitted through exposure of infectious body fluids or blood, blood transfusion and use of contaminated needles or syringes. Hepatitis B surface antigen (HBsAg) is the first marker to appear in the blood in acute hepatitis B, being detected 1 week to 2 months after exposure and 2 weeks to 2 months before the onset of symptoms. HBsAg consists of Lipid, carbohydrate and protein elements: the protein moiety provides a marker for the identification of Chronic, infectious HBV infections. If not diagnosed properly and in time, it can develop in to acute or chronic infection, liver cirrhosis and fulminant hepatitis.

This test is very useful for screening of blood donors, to diagnose them for HBs Ag before the collection of Blood.

Sensit HBs Ag Rapid is a Test captures the antigen developed during the infection. The captured antigen is detected using colloidal gold conjugate.

TEST PRINCIPLE

Sensit HBs Ag Rapid Test works on chromatographic immunoassay. Basic components of test strip include: a) Conjugate pad which includes Anti- HBV, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines T: Monoclonal Antibody to HBV and C: Goat Anti Mouse.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where HBs antigen present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized HBV antibody (on test line) producing a visible line on the membrane. If the respective antigen is not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each sealed in a foil pouch containing following items:
   a. One Test card
   b. Desiccant
   c. Dropper
2. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening pouch.
2. Do not touch result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Do not reuse the test device; each test can be used ONLY SINGLE TIME.
6. Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION & PREPARATION

Whole Blood:

- Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.

Serum:

- Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.

Note:

- *If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.*
- *For storage period longer than 5 days, freezing is recommended. Store at -20°C*
- *The specimen should be brought to room temperature prior to use.*

Treat the specimen as infectious and handle with standard biosafety measures.

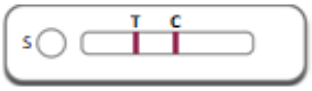
TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 3 drops of specimen without air bubble to the Sample well "S".
3. Wait for 10-15 minutes and interpret results. Do not read the result after 15 minutes. All results where control band does not appear are considered invalid.

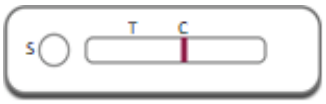
INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS 'C' & 'T' ON THE DEVICE AS SHOWN BELOW.

Positive: Color bands at position C and T. HBS antigen is present in the sample



Negative: Color band at position C. HBS antigen is not present in the sample



Invalid: Color band at C does not appear

Reference:

1. MILICH D.R., Immune Response to the Hepatitis-B virus: Infection, Animal models, Vaccination, VIRAL HEPATITIS, 1997, 3,63-103.
2. HOLLINGER F.B., Hepatitis-B virus, in fields virology, Third edition. Lippincott-Raven Publishers, Philadelphia. 1996, 2739-2807.

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