HBsAb Serum Rapid Test (Strip 5mm)

Cat. No.:DTS381
Pkg.Size:

Intended use

The HBsAb Rapid Test is, direct binding test for the visual detection of antibodies to hepatitis B surface antigen (Anti-HBs) in serum/plasma. It is used as an aid in the diagnosis of hepatitis B infection. The HBsAb Rapid Test is based on the principle of sandwich immunoassay for determination of Anti-HBs in serum/plasma. Purified recombinant antigens are employed to identify Anti-HBs specifically. This one step test is very sensitive and only takes 10-20 minutes. Test results are read visually without any instrument.

General Description

Hepatitis B virus (HBV) is a member of the Hepadnavirus family. The virus particle, (virion) consists of an outer lipid envelope and an icosahedral nucleocapsid core composed of protein. These virions are 42 nM in diameter and are sometimes referred to as "Dane particles". The nucleocapsid encloses the viral DNA and a DNA polymerase that has reverse transcriptase activity. The outer envelope contains embedded proteins that are involved in viral binding of, and entry into, susceptible cells. The virus is one of the smallest enveloped animal viruses, but pleomorphic forms exist, including filamentous and spherical bodies lacking a core. These particles are not infectious and are composed of the lipid and protein that forms part of the surface of the virion, which is called the surface antigen (HBsAg), and is produced in excess during the life cycle of the virus. The hepatitis B surface antigen (HBsAg) is most frequently used to screen for the presence of this infection. It is the first detectable viral antigen to appear during infection. However, early in an infection, this antigen may not be present and it may be undetectable later in the infection as it is being cleared by the host.

Storage

The test kit can be stored at temperatures between 2 to 30ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

Specimen Collection And Preparation

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
If the specimen cannot be tested on the day of collection, store the specimen in a refrigerator or freezer. Stir and bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

Assay Procedure

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.
2. Following the illustration, dip the test strip with the arrow side pointing down into the vessel of serum/plasma for about 10 seconds. Do not immerse past the marker line. Take the strip out and lay it flat on a clean, dry and non-absorbent surface.
3. Wait for 10-20 minutes and read results. It is important that the background is clear before the result is read. Do not read results after more than 30 minutes.

Interpretation of Results

Negative: Only one colored band appears on the control region. No apparent band on the test region.

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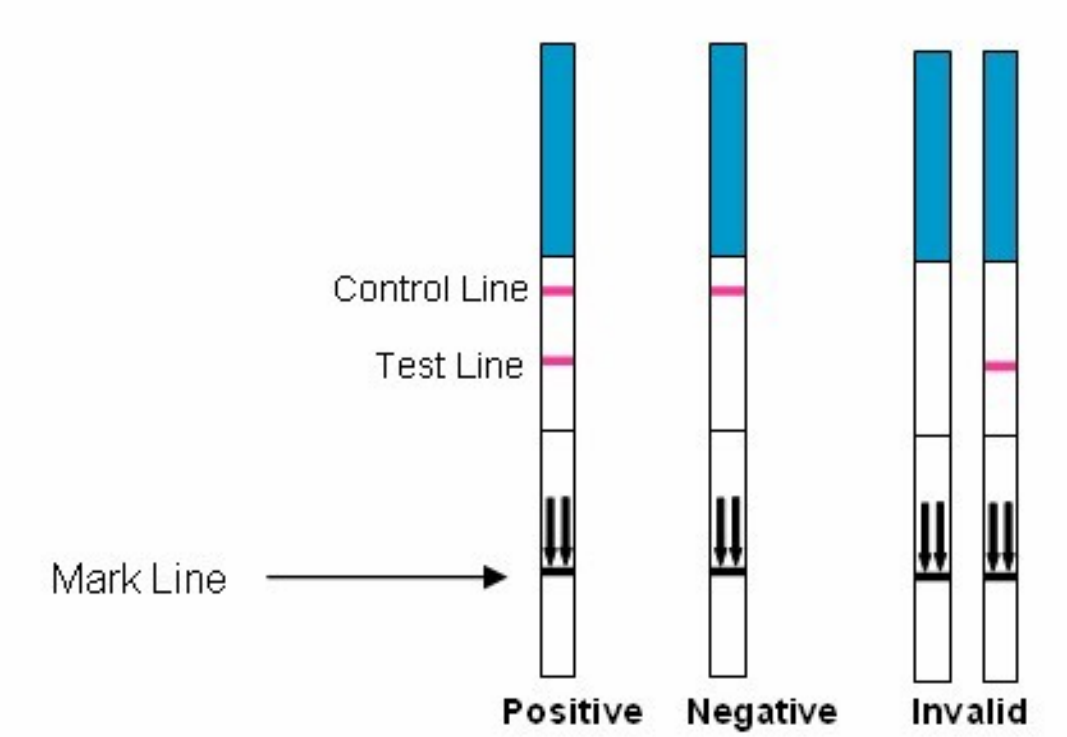
Positive: In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.
Invalid: None of line appears or no line appears in the control (C) region. An invalid result may be due to improper testing procedures or deterioration of the kit components. Repeat the assay sequence using a new device.



Precautions

1. Do not use test kit beyond expiry date.
2. The test device should not be reused.
3. Do not compare results from a different device. Serum/plasma specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.
4. Using a new specimen collection container and specimen pipette for each sample to avoid cross-contamination of samples.

Limitations

1. Only test serum and plasma samples.
2. As with all tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
3. This test is for in vitro diagnostic use only.
4. Interfering substance in the sample and technical error will affect the results; further testing is required.

REFERENCES

1. Locarnini S (2004). "Molecular virology of hepatitis B virus". Semin. Liver Dis. 24 Suppl 1: 3–10.
2. Harrison T (2009). Desk Encyclopedia of General Virology. Boston: Academic Press. p. 455.
3. Howard, C. R. (1986). "The Biology of Hepadnaviruses". Journal of General Virology 67 (7): 1215–1235.

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