

HbeAg Rapid Test (Strip) Serum (5mm)

Cat. No.:DTS384

Pkg.Size:

Intended use

The OneStep HBeAg Rapid Test is a direct binding test for the visual detection of hepatitis B e antigen (HBeAg) in serum, to be used as an aid in the diagnosis of hepatitis B infection. The OneStep HBeAg Rapid Test is based on the principle of sandwich immunoassay for the determination of HBeAg in serum. Monoclonal and polyclonal antibodies are employed to identify HBeAg specifically. This one step test is very sensitive and only takes 10-20 minutes. Test results are read visually without any need for additional instrumentation.

General Description

Hepatitis B is an infectious inflammatory illness of the liver caused by the hepatitis B virus (HBV) that affects hominoidea, including humans. About a third of the world population has been infected at one point in their lives, including 350 million who are chronic carriers. HBeAg is produced by proteolytic processing of the pre-core protein. Shortly after the appearance of the HBsAg, another antigen called hepatitis B e antigen (HBeAg) will appear. Traditionally, the presence of HBeAg in a host's serum is associated with much higher rates of viral replication and enhanced infectivity; however, variants of the hepatitis B virus do not produce the 'e' antigen, so this rule does not always hold true. During the natural course of an infection, the HBeAg may be cleared, and antibodies to the 'e' antigen (anti-HBe) will arise immediately afterwards. This conversion is usually associated with a dramatic decline in viral replication.

Storage

The test kit can be stored at temperatures between 2 to 30°C 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

For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum 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

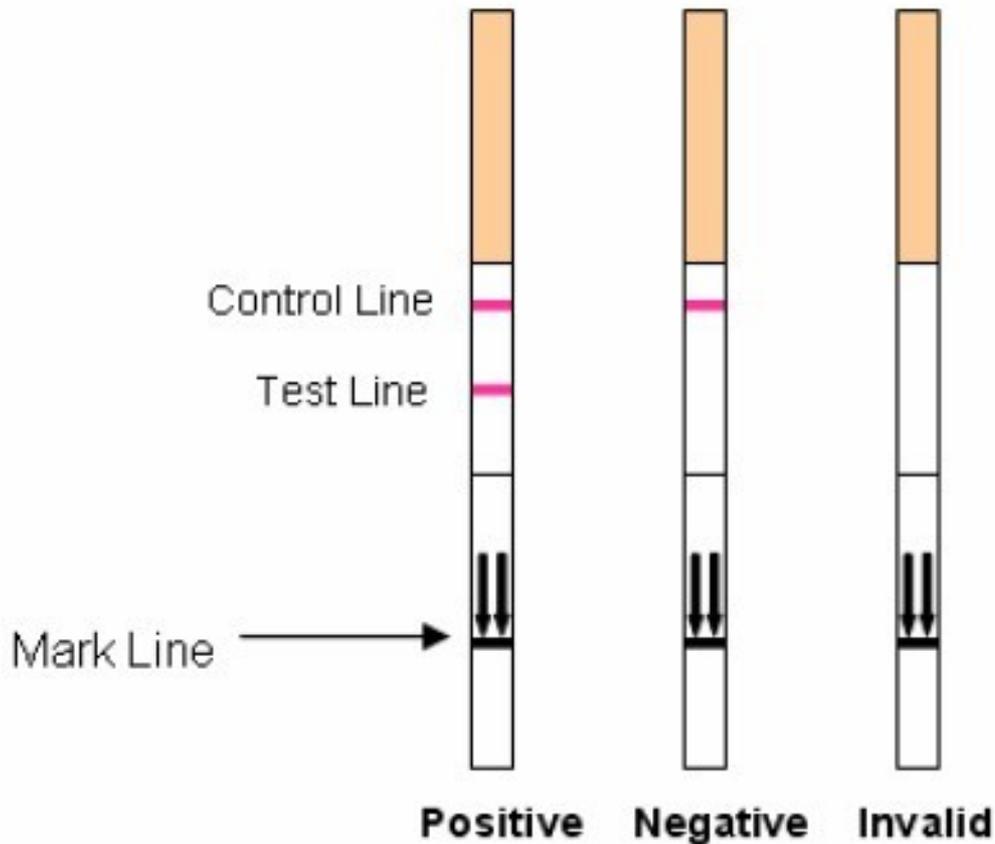
1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.
2. Following the illustration, dip the test strip with the arrow side pointing down into the vessel of serum for about 10 seconds. Do not immerse 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 (C) region. No apparent band on the test (T) region.

Positive: In addition to a pink colored control (C) band, a distinct pink colored band will appear in the test (T) region.

Invalid: A total absence of color in both regions or no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Precautions

1. Do not use test kit beyond expiry date.
2. The test device should not be reused.
3. Keep out of the reach of children.

Limitations

1. As with all CD 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.
2. This test should be used for the detection of HBeAg in serum specimen.
3. This test kit will only indicate the presence of HBeAg in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
4. This test kit cannot detect less than 1 ng/mL of HBeAg in specimens. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Hepatitis B infection.

REFERENCES

1. Hunt, Richard (2007-11-21). "Hepatitis viruses". University of Southern California, Department of Pathology and Microbiology.
2. Locarnini S (2004). "Molecular virology of hepatitis B virus". *Semin. Liver Dis.* 24 (Suppl 1): 3–10
3. Howard CR (1986). "The biology of hepadnaviruses". *J. Gen. Virol.* 67 (7): 1215–35.