

HBcAb IgM Serum Rapid Test (Cassette)

Cat. No.:DTS367

Pkg.Size:

Intended use

OneStep HBc-IgM Rapid Test is a, direct binding test for the visual detection of antibodies to Hepatitis B Core IgM in serum. It is used as an aid in the diagnosis of Hepatitis B infection. OneStep HBc-IgM Test is based on the principle of inter-second antibody immunoassay for determination of HBc-IgM specifically. This one step test is very sensitive and only takes 10-20 minutes for the result to be read. Test results are read visually without any instrument.

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. The infectious virion contains an inner "core particle" enclosing viral genome. The icosahedral core particle is made of 180 or 240 copies of core protein, alternatively known as hepatitis B core antigen, or HBcAg. During this 'window' in which the host remains infected but is successfully clearing the virus, IgM antibodies to the hepatitis B core antigen (anti-HBc IgM) may be the only serological evidence of disease. Therefore most hepatitis B diagnostic panels contain HBsAg and total anti-HBc(both IgM and IgG).

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. To dilute the serum specimen, add 3µL of sample to 10 drops (300µL) of the Diluent Solution provided. Mix well.
3. Draw 0.2 mL (about 4 drops) sample using the pipette, and dispense it into the sample well on the cassette.
4. Wait 10-20 minutes and read result. It is important that the background is clear before the result is read. Do not read results after 30 minutes.

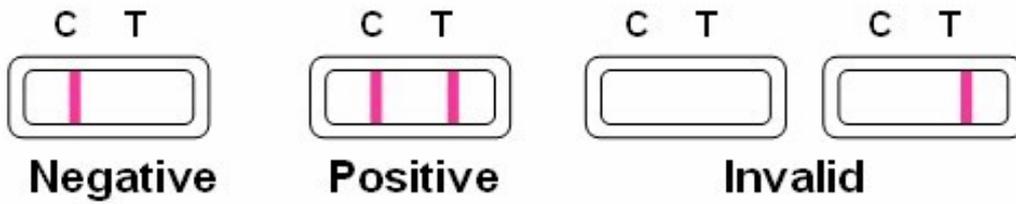
Interpretation of Results

Negative: Only one color 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 also appear in the test (T) region.

Invalid: A total absence of color in both (C) and (T) regions or no colored band appears on the control (C) region is an indication of procedure error and/or the test reagent has deteriorated. Repeat with a new test kit. 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.

Limitations

1. Only test serum and plasma samples.
2. Interfering substance in the sample and technical error will affect the results; further testing is required.
3. Only detect the presence of Anti-HBc, it cannot show the concentration of Anti-HBc in the sample.
4. As with all diagnostic 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.

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.