HBV 5-in-1 Hepatitis B Virus Markers Rapid Test Panel

(Immunochromatography)

Product Name

HBV 5-in-1 Hepatitis B Virus Markers Rapid Test Panel (Immunochromatography)

Intended Use

The reagent is used for the qualitative detection and laboratory screening of hepatitis B virus markers (HBsAg HBsAb HBeAg HBeAb HBcAb) in serum/plasma.

Test Principle

HBsAg , HBsAb & HBeAg

The sample mixing up colloidal-gold monoclonal antibody move along the membrane to the T line, and form the T line when the human serum/plasma contains HBsAg , HBsAb & HBeAg according to the principle of double antibody sandwich method and gold immunochromatography assay, which is a positive result. Unreacted markers move forward continually to combine with anti-mouse antibody and form a control line. If the test line does not appear, it is a negative result.

HBeAb & HBcAb

The test kit uses colloidal gold as a direct marker, uses the principle of competitive inhibition method for qualitative detection of HBeAb & HBcAb in serum/plasma.

Main Components

HBsAg test strip: anti-HBsAg monoclonal antibody A (solid gold standard material), anti-HBsAg monoclonal antibody B (test line), goat anti-mouse IgG (control line).

HBsAb test strip: Purified HBsAg (solid gold standard material), purified HBsAg (test line), HBsAg monoclonal antibody (control line).

HBeAg test strip: anti-HBeAg monoclonal antibody A (solid gold standard material), anti-HBeAg monoclonal antibody B (test line), goat anti-mouse IgG (control line).

HBeAb test strip: anti-HBeAg monoclonal antibody A (solid gold standard material), anti-HBeAg monoclonal antibody B (test line), goat anti-mouse IgG (control line).

HBcAb test strip: Recombinant HBcAg (solid gold standard material), anti-HBcAg monoclonal antibody A (test line), recombinant HBcAg monoclonal antibody (control line).

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

1. Collect venous blood a clean and dry container according to the standard method. Separate the serum or plasma for testing. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants

2. After collection, separate the serum and plasma as soon as possible, in order to avoid hemolysis.

3. Use fresh samples. Samples may be stored at 2-8℃ for 3 days, and should be stored at -20 ℃ if cannot be tested immediately. Do not freeze and thaw the sample repeatedly.

Test Procedure

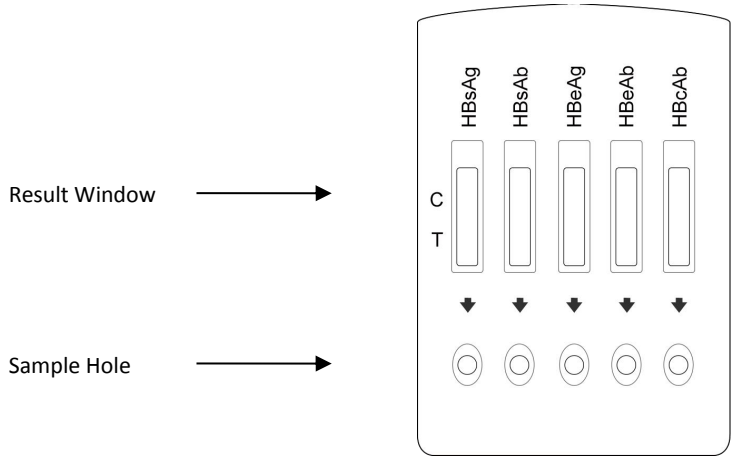
Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Cassette:

1. Take off the outer packing, put the cassette onto the desk with the sample window up.

2. Drop 3 drops of serum/plasma (80μl-100μl) vertically into the sample hole of cassette.

3. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.



Result Judgment

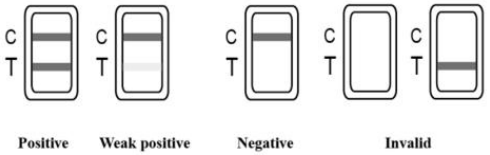
HBsAg HBsAb HBeAg：

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.

HBsAg,HBsAb,HBeAg



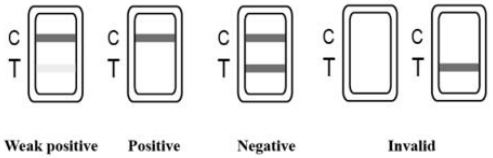
HBeAb HBcAb:

POSITIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

NEGATIVE:. Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.

HBeAb,HBcAb



Limitation

1. This reagent is designed for the qualitative screening test. Concentration of HBV cannot be determined by this qualitative test.

2. The results of the reagent are only for clinical reference, a confirmed diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

Performance Indicators

The detection limit of three subtypes of HBsAg (ADR, ADW, AY) is not more than 2.5NG/ML The detection limit of HBsAb not higher than 30.0mlu/ml.

	positive coincidence rate	negative coincidence rate
HBeAg	98.71%	100%
HBeAb	99.35%	99.86%
HBcAb	99.83%	99.50%

Precaution

1. The test result is invalid over 20 minutes, do not use after the expiration.

2. Samples may be stored at 2-8℃ for 3 days, and should be stored at -20 ℃ if cannot be tested immediately. Do not freeze and thaw the sample repeatedly.

3. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

4. Both deep and light color may occur during the test, even a very light brand during observation time should be judged as negative a result.

5. If the filtration speed is very slow or even no filtration occurs, please change the sample and test again.

6. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.