

HBsAg Hepatitis B Surface Antigen Rapid Test Kit (Colloidal Gold Chromatography)

Product Name

HBsAg Hepatitis B Surface Antigen Rapid Test Kit(Colloidal Gold Chromatography)

Intended Use

Used for the qualitative detection of Hepatitis B surface antigen in serum/plasma and whole blood.

Test Principle

The specimen mixing up colloidal-gold monoclonal antibody move along the membrane to the T line, and form the T line when the human serum/plasma and whole blood contains HBsAg 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.

Main Components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

Specimen 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. (only for serum/plasma test kit)
3. Use fresh specimens. Specimens 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 specimen repeatedly.

Storage and Expiry

Store as packaged in the sealed pouch at room temperature (4-30℃), avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE.

Test Procedure

Collect the patient's venous blood and make it contracted in a natural way. Place the reagent at room temperature for 30 minutes before use, and return to room temperature (20℃-30℃). Instructions must be read entirely before taking the test. Do not open the inner packaging until ready, it must be used as soon as possible if opened. (Humidity:20%~90%,Temp:10℃-50℃).

Strip: 1. Take off the outer packing, put the stripe onto the desk with the sample adding area up.

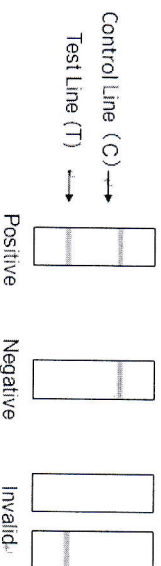
2. Drop 2 drops of serum/plasma/whole blood(50µl-60µl)vertically into the sample adding area up.
 3. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.
- Cassette:** 1. Take off the outer packing, put the cassette onto the desk with the sample window up.
2. Drop 2 drops of serum or plasma (50µl-60µl) vertically into the circular groove of cassette, add 1 drop of buffer (55-60µl) into the circular groove of cassette.
 3. Observe the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

Interpretation of Result

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 bands 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.



Limitations

1. This reagent is designed for the qualitative screening test. Concentration of HBsAg 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.

Attention

1. The result is invalid over 20 minutes.
2. Do not use after the expiration.
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 positive a result.
5. If the blood is too thick, and the climb speed is less than 4mm/min, add one drop buffer to the samples pad to help.