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Newscen Hepatitis B Surface Antigen Diagnostic Kit (Colloidal Gold)

THE PRODUCT NAME

The generic name: Hepatitis B Surface Antigen Diagnostic Kit (Colloidal Gold).

PACKING SPECIFICATION

100 tests/kit (Strip type).

INTENDED USE

This product is used for qualitative detection of HBsAg in human serum, plasma and whole blood samples in vitro.
Hepatitis B virus (HBV) is a DNA virus belonging to hepatophilic DNA virus family. Currently, HBV is known to cause viral hepatitis B disease only in humans and orangutans. Complete hepatitis B virus is granular, divided into shell and core two parts. There are three kinds of HBV antigens: surface antigen (HBsAg), core antigen (HBcAg) and E antigen (HBeAg). HBsAg exists in the blood of infected people and is the main marker of HBV infection and detection. It has antigenicity and can induce the body to produce specific protective anti-HBS, which is also the main component of vaccine preparation. HBsAg appears in the blood circulation of patients in the early stage of hepatitis B virus infection, which can last for months, years and even life. The level of HBsAg titer can judge the infectivity of patients. Generally, the higher the titer of HBsAg, the more likely HBsAg and HBV DNA are positive, and the greater the infectivity. Testing for hepatitis B virus surface antigen can help determine whether a patient is infected with hepatitis B virus.

PRINCIPLE

This kit adopts double antibody sandwich method and colloidal gold immunochromatography technology. Colloidal gold conjugate of anti-HBsAg antibody is pre-coated to glass cellulose membrane. Anti-HBsAg antibody and anti-mouse IgG antibody are coated on the reaction line and quality control line of nitrate fiber membrane respectively. When testing, if it is the positive sample, HBsAg in the sample can combine with the gold labeled anti-HBsAg antibody to form a complex. Due to the chromatography, the complex moves forward along the strip and then combines with the antibody precoated by the reaction line to form a "gold labeled antibody ~ HBsAg ~ antibody" complex to agglutinate and display color. The nitrate fiber membrane is coated with a quality control line as a control, so when there is a red quality control line and a red reaction line, it is judged as positive. When there is no HBsAg antigen in the sample to be tested, only one red quality control line is judged as negative.

COMPONENTS

1.Test cassettes: nitrocellulose membrane coated with anti-HBsAg antibody and sheep anti-mouse IgG, gold label membrane marked with anti-HBsAg antibody, sample pad, absorption pad and lining plate.
2. Desiccant: silicone.
3. Diluent buffer: Phosphate buffer encapsulated in drip bottle.

STORAGE AND EXPIRY DATE

Store at 4 ~ 30℃ in the dark, and the validity period is 24 months.
Date of production, expiry date to see label.

APPLICABLE INSTRUMENT

This reagent does not require any instrument in the testing process.

SAMPLE COLLECTION AND TEST PREPARATION

Collection of whole blood: Fingertips, tip of earlobe or vein samples should be used as soon as possible after collection. Anticoagulant blood should be used within 24 hours to avoid hemolysis. Serum (plasma) samples were collected intravenously in the usual way, and the anticoagulant could be heparin, EDTA or sodium citrate. The blood was collected and centrifuged to obtain the samples. Samples determined within 5 days can be stored at 4℃. Samples can be stored at -20℃ for at least 3 months. Hemolysis or repeated freezing and thawing should be avoided as much as possible. Any visible particulate matter in the specimen should be removed by centrifugation or filtration before test. The serum (plasma) to be preserved should be aseptic during collection and storage, and the samples contaminated with bacteria should not be used for testing.

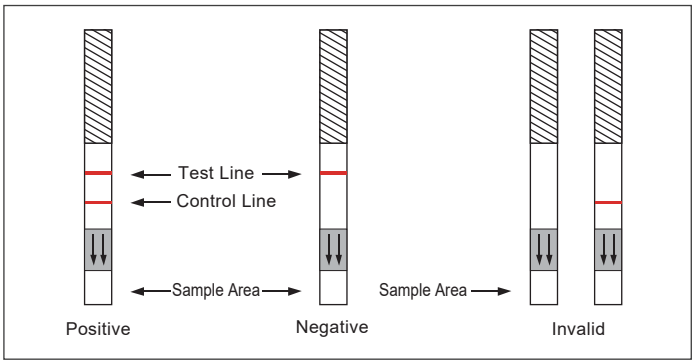
ASSAY PROCEDURE

Test for serum or plasma sample:
1. Collect 80-120μL (2-3 drops) of serum (or plasma) in a small test tube.
2. Tear the aluminum foil bag and take out the test strip.
3. Insert one end of the absorption sample of the test strip into the sample in the small test tube (the depth of the insertion of the test strip into the sample shall not exceed the mark line).
4. The results of the experiment were observed within 10 minutes (the results of strong positive samples could be shown in a few minutes). After 30 minutes, the judgment result is invalid.
Test for whole blood sample:
1. Remove the test strip from the aluminum foil bag and place it horizontally on the test table.
2. Add one drop of whole blood sample to the sample suction pad, and add 1 ~ 2 drops of sample dilution.
3. The results of the experiment were observed within 10 minutes (the results of strong positive samples could be

shown in a few minutes). After 30 minutes, the judgment result is invalid.

Positive judgment value: The reference value (normal value) of this kit is negative (Only one quality control line is displayed).

INTERPRETATION OF RESULTS



1. ***Positive***: There are two red lines, one red line in the control zone (C), a red line will appear in the test zone (T). The results are positive.
2. ***Negative***: No apparent line in the test zone (T), only one red line appears in the control zone (C). The results are negative.
3. ***Invalid***: There is no red line of quality control line or only one red line of reaction line. The experimental result is invalid and should be repeated.

LIMITATION

This kit is limited to qualitative HBsAg samples. Due to the limitation of sensitivity, samples containing very low concentrations of HBsAg (below the detection limit or gray zone) cannot be detected, resulting in false negatives, or patients whose infection is in an early window period are prone to false negatives.

PERFORMANCE CHARACTERISTICS

1. Conformity rate of positive reference products: Three standardized positive serum working standards were used for determination, and each sample was tested twice in parallel, and no false negative was allowed.
2. Conformity rate of negative reference products: 20 standardized negative serum working standards were used for determination. Each sample was tested twice in parallel, and no false positive was allowed.
3. Minimum detection amount: The positive serum P4 (2.5ng/mL) of the standardized working standard was detected, and the observation result should be positive within 30 minutes.
4. Precision: The standard working standard positive serum P5 (5ng/mL) was used to test 10 reagents in parallel, and the test results should be consistent and the color should be uniform.

WARNING

1. This test strip is a disposable product for external diagnosis only. The test results should be combined with other test indicators and medical characteristics of a comprehensive judgment.
2. Samples must be tested in a specific laboratory. Blood samples that are exposed during testing should be handled and handled in accordance with laboratory examination procedures for infectious diseases.
3. The small test tube for storing samples must be clean and not reusable to avoid contamination.
4. Try to avoid repeated freeze-thaw or bacterial growth of test samples, otherwise the test results may be affected. Test reagents or serum samples stored in the refrigerator at 2-8 ℃ should be balanced to room temperature before testing, or the test results may be affected.
5. Beware of moisture. Only open the aluminum foil bag when using, and use immediately after removing the detection reagent to avoid moisture. Do not use the test reagent when it is damp.
6. The small packet in the aluminum foil bag is desiccant, so you can't eat it by mistake.
7. Please strictly follow this instruction to operate and strictly control the reaction time.

REFERENCE

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