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CE IVD

Newscen Treponema Pallidum (TP) Antibody Rapid Test

【Colloidal gold】

THE PRODUCT NAME

The generic name: Treponema Pallidum (TP) Antibody Rapid Test (Colloidal gold).

PACKING SPECIFICATION

100 tests/kit (Strip type).

INTENDED USE

The Treponema Pallidum (TP) Antibody Rapid Test is a qualitative test for the detection of antibodies to TP in human serum/ plasma and whole blood. Syphilis is the infectious disease that caused by syphilis spirochete infection. The main route of transmission is through sexual contact or blood transfusion. It is infectious and all kinds of people are susceptible. This product is used for auxiliary diagnosis of syphilis.

PRINCIPLE

The detection reagent uses colloidal gold as indicator, adopts double antigen sandwich method, and selects multiple genetic engineering fusion antigens of syphilis (TP) as coated and colloidal gold labeled antigens. During detection, the sample is first mixed with gold colloid. If the detected sample contains TP antibody, the TP antibody will first bind with TP antigen on the gold colloid. Under the action of capillary attraction, the sample and the gold colloid mixture will flow to the membrane area together, and form antigen-antibody-antigen sandwich with TP antigen fixed at the corresponding position on the membrane, so that the reaction area will show a crimson reaction line. The film is coated with a quality control line as a control, so when a red quality control line and a reaction line appear, the test result is positive. If there is no TP antibody in the sample, only a red line appears at the position of the quality control line, and the result of this experiment is negative. To ensure the validity of the test, any valid sample will make a red quality control line appear in the quality control area of this test reagent.

COMPONENTS

1. Test cassettes: The main components are colloidal gold labeled with treponema pallidum fusion antigen and NC film coated with sheep anti-mouse IgG and treponema pallidum fusion antigen.
2. Desiccant.
3. Diluent buffer: Phosphate buffer encapsulated in dropper or drip bottle.

The components in different batches of reagents are not interchangeable. Users should prepare timers, such as clocks and watches.

STORAGE AND EXPIRY DATE

Store at 4 ~ 30℃ in the dark, and the validity period is 24 months.

Once you have taken the test cassette out of the pouch, perform the test as early as possible (within 1 hour) to avoid test cassette from becoming moist.

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. 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. Hemolytic hemoglobin > 5mg/mL, triglyceride > 8mmol/L in hyperlipidemia samples, and bilirubin > 300 μmol/L in jaundice samples may affect the detection results and cannot be used for detection. 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

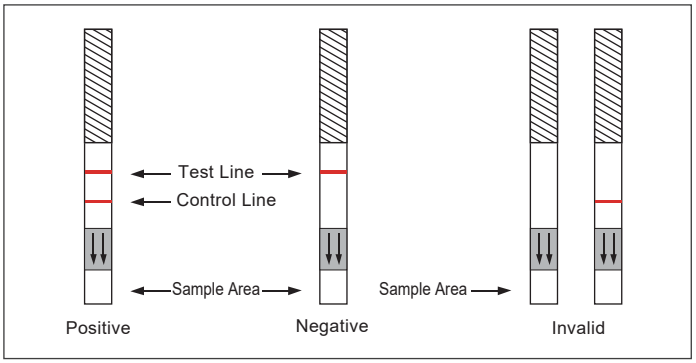
1. Balance the detection reagent to room temperature, and then tear the aluminum foil bag, take out the detection reagent.
2. Test for serum or plasma sample:

Add 50 ~ 80μ l (2 ~ 3 drops) of serum or plasma to the sample-adding end of the detection reagent, or insert the sample-adding end of the detection reagent into the sample to be detected (be careful not to exceed the MAX line), and then take it out when the sample starts to be chromatographed on NC membrane, and lay it flat on the experimental bench.

3. Test for whole blood sample: Add 1 drop of whole blood sample to the sample application end of card or strip detection reagent, and then add 1 ~ 2 drops of sample diluent.
4. Observe the result in 20 minutes. The results after 30 minutes are invalid.

Positive judgment value: The reference value (normal value) of this kit is negative.

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). This indicates that the specimen contains TP antibodies.
2. ***Negative***: No apparent line in the test zone (T), only one red line appears in the control zone (C). This indicates that no TP antibodies have been detected.
3. ***Invalid***: If no line appears in the control zone (C), regardless of the presence or absence of line in the test zone (T).This indicates that the experimental result is invalid. The test should be repeated using a new reagent strip.

Positive result is confined to qualitative diagnosis person serum, plasma and antibody of syphilis spirochete in whole blood, confirm specific experiment to seek advice to the hospital specialist doctor please.

LIMITATION

This kit is limited to the qualitative detection of treponema pallidum antibodies in samples.

PERFORMANCE CHARACTERISTICS

Product performance shall be carried out with national reference products or enterprise reference products. National reference product verification shall meet the requirements of national reference products, and enterprise reference product verification shall meet the following requirements.

1. Conformity rate of positive reference products: 10 positive serum samples of enterprise reference products were tested, and the conformity rate of positive reference products was 10/10.
2. Conformity rate of negative reference products: 20 corporate reference negative serum samples were tested, and the negative reference conformity rate was 20/20.
3. Minimum detection amount: the minimum detection of the testing is 3 copies of serum, L1 should be positive, L2 can be positive or negative, L3 should be negative.
4. Precision: 10 test reagents were tested in parallel with the precision serum of the enterprise, and the test results should be consistent and the color should be uniform.

Tests showed that the kit did not cross-react with the following positive samples: human immunodeficiency virus, hepatitis B virus, hepatitis C virus and rheumatoid factor.

WARNING

1. For in vitro diagnostic use only.
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. Repeated freeze-thaw, hemolysis, or bacteria growth of test samples should be avoided, otherwise the test results may be affected. Test reagents stored in the refrigerator should be balanced to room temperature before testing and then used in bags, otherwise the test results may be affected.
4. Beware of moisture. The detection reagent cannot be used after the aluminum foil composite packaging bag is damaged or the detection reagent is damp.
5. The small packet in the aluminum foil bag is desiccant, so you can't eat it by mistake.
6. Please strictly follow this instruction to operate and strictly control the reaction time.

REFERENCE

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