Diagnostic Kit for Treponema Pallidum Antibody

(Immunochromatography)

Product Name

Diagnostic Kit for Treponema Pallidum Antibody (Immunochromatography)

Intended Use

The reagent is used to detect the treponema pallidum antibody in serum / plasma qualitatively.

Test Principle

The test kit uses colloidal gold as a direct marker, uses the principle of double antigen sandwich method for qualitative detection of Treponema Pallidum antibody in serum or plasma.

Main Components

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

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. A serum / plasma sample must be collected in a clean and dry container. 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. Samples may be stored at 2-8℃ for 3 days prior to assay, and store at -20 ℃ if cannot be used immediately.

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℃)

Strip: Remove the test device from the sealed pouch, put the end of the test strip print with arrow into the sample, the interface of serum/plasma should not exceed the max line, take it out and place the test device on a clean and level surface after 15 seconds. Observe the test results immediately within 10~20 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. Add 2-3 drops of（80~120μl）serum or plasma with a dropper vertically into the sample hole of cassette.

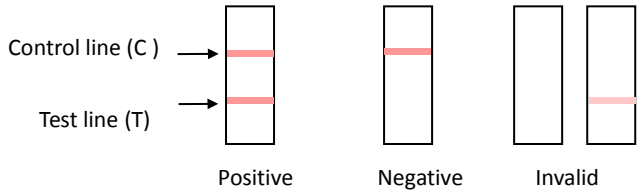
3. Observe the test results immediately within 10-20 minutes, the result is invalid over 20 minutes.

Result Judgment

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.



Limitation

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

Precaution

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 20 minutes.

4. Hyperlipidemia and jaundice samples have no effect on the detection results.

5. Slight hemolysis samples have no effect to the detection results, but serious hemolysis samples can produce background, impact the observation of test line (T), other test method are suggested.

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.