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Treponema Pallidum(TP) antibody

Catalog No.: BG501C BG502S

NAME AND INTENDED USE

Rapid Gold Immuno-assay Kit for Antibody to Treponema Pallidum (TP) is an in vitro immunoassay for the qualitative determination of Anti-TpP antibody in human serum or plasma in one step. It is for diagnosis of early infection and epidemic survey.

PRINCIPLE

The kit uses one step method to detect anti-TP antibodies in serum or plasma. The purified specific recombinant TP antigen is immobilized on the nitrocellulose membrane at the test line region and another specific TP Ag conjugated to the colloidal gold is coupled on the label pad. To perform the test, a sample is added to the sample well of the test card. The sample flows through to the label pad. If the sample contains Antibody to Treponema Pallidum, the antibody will bind to the antigen coated on the colloidal gold particles to form antibody-antigen-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region, and react with specific recombinant TP antigen to produce a pink color on the membrane. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If Antibody to Treponema Pallidum (TP) is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid. The pink color intensity will reflect the antibody intensity in the sample. The test is fast and easy to operate.

MATERIALS PROVIDED

Antibody to Treponema Pallidum test card/strip

Each cassette/strip contains a test strip with TP antigen on the test region of the membrane and colored Treponema Pallidum antigen-gold conjugate pad.

SAMPLE COLLECTION AND PRESERVATION

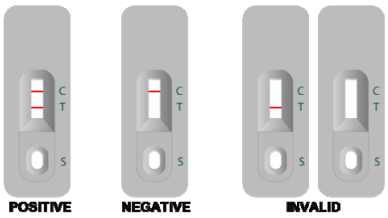
Blood serum samples are routinely prepared form vein. Blood plasma sample are routinely prepared with routine amount of anticoagulant such as heparin or sodium citrate. Samples may be stored at 2-8℃ within five days without interfering with the assay performance. For long-term storage of specimens, -20℃ or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Samples with cloud or precipitation should be centrifugated or filtered before test. Prevent serum from bacteria contamination during collection and storage.

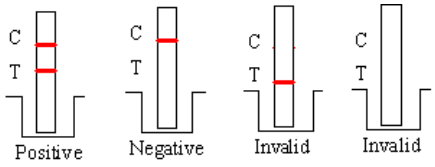
TEST PROCEDURE

1. Bring Membrane Plate and samples to room temperature (20-30 ℃) before use (approximately 30 minutes).
2. Remove the test cassette/strip from the sealed foil pouch and place the plate on flat desk.
3. Deliver 2 drops (80 -100 μL) of the sample to the sample well/sample pad.
4. Read the result between 20-25 minutes. A strong positive sample may show result earlier.

INTERPRETATION OF RESULTS

Positive Two pink lines appear in both C and T position
Negative Only one pink line appear in C position
Invalid: The control line next to the test line does not become visible within 20 minutes after the addition of the sample.





LIMITATION

The testing is for qualitative and assistant diagnosis. Confirmation of infection should refer to the clinical and other diagnosis.

PRECAUTIONS

1. Both plate and sample should be with room temperature 20-25 ℃
2. Test sample must be fresh.
3. The result after 25 minutes is invalid.
4. Diluted sample may generate false positive result
5. Bacteria contamination, serious hemolysis, jaundice and high lipid blood will cause wrong result. The sample should be re-collected.
6. Wrong result might be caused by expired kit or problematic samples.

EXPIRATION

The shelf life is 24 months. Do not use the kit beyond its expiration date.