Diagnostic Kit for IgG Antibody to Tuberculosis

(Immunochromatography)

Product Name

Diagnostic Kit for IgG Antibody to Tuberculosis (Immunochromatography)

Intended Use

The reagent is used to detect the Tuberculosis IgG antibody in serum / plasma qualitatively.

Test Principle

The test utilizes antibodies including a recombinant protein TB antigen and mouse anti-human IgG monoclonal antibody on the nitrocellulose membrane with colloidal gold marked TB antigen as anmark tracer. The reagent is used to detect the TB IgG antibody in serum / plasma according to the principle of double antibody sandwich method and gold immunochromatography assay.The sample mixing up TB antibody –marker move along the membrane to the T line, and form the T line when the sample contains TB-IgG antibody, which a positive result. Conversely, it is a negative result.

Main Components

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with mouse anti-human IgG monoclonal antibody, nitrocellulose membrane coated with recombinant protein TB antigen，control line coated with goat anti mouse IgG antibody. The sample dilution is made of 20mM phosphate buffer (PBS).

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. The reagent can be used for the serum, plasma samples.

2. 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. If blood coagulation occurs, serum samples are suggested to use.

3. Detect immediately after collecting sample. Samples may be stored at 2-8℃ for 1 week prior to assay, and at -20 ℃ for 2 years. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed.   Repeat freeze and thaw for no more than 3 times. Samples exhibiting visible precipitates, stink or muddy should not be used.

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 and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ the sample window of the cassette up.

2. Drop 1.5µl serum/plasma vertically onto the membrane in the sample hole. The pipette tip of micro dispenser is required to touch the membrane gently for an accurate operation when the sample is added.

3. Add about 3 drops (80µl-100µl) of buffer onto the sample pad of strip/the buffer hole of cassette. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

Sample Hole   Buffer Hole

Sample Hole   Buffer Hole

Result Judgment

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another 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.

Control line (C)

Test line (T)

Positive   Negative   Invalid
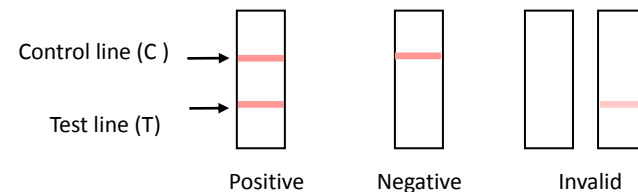
Limitation

1. This reagent is designed for the qualitative screening test. Concentration of TB-IgG cannot be determined by this qualitative test.

2. Negative result may occur when detecting short-term infected samples or window period samples, indicate that the specific antibodies of TB does not exist or the concentration is below detection limit.

3. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

4. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.

5. Abnormal results may occur according to operator error or drug use. If AIDS is still suspected, a sample should be collected later and tested again.

Performance Characteristics

1 Using internal quality control samples:

 Negative specificity: The results should all be negative when detecting 10 kits of TB-IgG negative quality control samples.

 Positive specificity: The results should all be positive when detecting 10 kits of TB-IgG positive quality control samples.(Including strong, medium and weak positive samples)

Limit of detection: The results should all be positive when detecting diluted TB-IgG positive quality control samples with the diluent rate at 1:8.

 Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. Clinical trial results

 A clinical evaluation was conducted on 1460 samples comparing the results obtained using the Diagnostic Kit for IgG Antibody to Tuberculosis and other commercially available TB tests. The results demonstrated a 99.61% positive agreement, 99.47% negative agreement, and a 99.52% overall agreement of the Diagnostic Kit for IgG Antibody to Tuberculosis when compared to the other TB-IgG test.

3. Analytical sensitivity: 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result. The reagent is not affected by the rheumatoid factor, antinuclear antibodies, anti-mitochondrial antibodies, non-specific IgG and IgM.

The addition of parainfluenza virus (mixed) , Cpn, HBV, HAV, HCV, HIV, MP and TB-IgM showed no cross-reactivity.

4. Hook effect: the hook effect will not occur even the TB-IgG concentration is 1:1024.

Precaution

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. Reagents should be used as soon as possible after opened. This reagent cannot be reused for disposable.

4. The test result is invalid over 20 minutes.

5. 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.

6. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

7. Patients used to receive monoclonal antibodies therapy may have human anti-mouse antibodies (HAMA) in blood, which does not apply to the detection of this reagent. Other detection method is suggested.

8. 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.