Mycobacterium tuberculosis IgG/IgM Antibody Combined Rapid Test Kit (Colloidal Gold)

【Product name】

Mycobacterium tuberculosis IgG/IgM Antibody Combined Rapid Test Kit (Colloidal Gold)

【Packing specification】

1 test/box、10 tests/box、25 tests/box、40 tests/box

【Intended use】

This product is used for in vitro qualitative detection of Mycobacterium tuberculosis IgG/IgM antibodies in human serum, plasma or whole blood samples

【Reactivity principle】

This kit adopts the principle of colloidal gold immunochromatography. The detection area of nitrocellulose membrane (G-line and M-line) was coated with mouse anti-human IgG monoclonal antibody and mouse anti-human IgM monoclonal antibody, the quality control region (C-line) was coated with Rabbit polyclonal antibody anti-Mycobacterium tuberculosis and colloidal gold labeled Recombinant Mycobacterium tuberculosis antigen (recombinant TB-Ag) on the gold-labeled pad. During the detection of positive the sample, the Human Mycobacterium tuberculosis antibody (TB-IgG or TB-IgM) in the sample combined with colloidal gold (Au) labeled Recombinant Mycobacterium tuberculosis antigen (recombinant TB-Ag) to form an (Au-TB-Ag-TB-IgG or Au-TB-Ag-TB-IgM) immune complex, which flows forward in the nitrocellulose membrane. It combined with coated mouse anti-human IgG monoclonal antibody and (or) mouse anti-human IgM monoclonal antibody to form agglutination "(Au—TB-Ag)-(TB-IgG) mouse anti-human IgG monoclonal antibody) and (or) (Au—TB-Ag)-TB-IgM)-mouse anti-human IgM monoclonal antibody" in the detection area during the test. For negative sample, the detection area (G-line) and (M-line) can't agglutination and develop color. It always develops red line in the quality control region (C-line) regardless of whether the sample contains Mycobacterium tuberculosis antibody.

【Main components】

SPEC / Component	1 test/ Box	10 tests/ Box	25 tests/ Box	40 tests/ Box	Main components
TB-IgG/IgM Rapid test kit	1 test	10 tests	25 tests	40 tests	It is composed of absorbent paper, nitrocellulose film, gold labeled pad, blood filtration membrane and sample pad. The quality control line of nitrocellulose membrane was coated with Rabbit polyclonal antibody anti-Mycobacterium tuberculosis, the detection zone was coated with mouse anti-human IgG monoclonal antibody and mouse anti-human IgM monoclonal antibody, and the gold labeled pad was coated with colloidal gold labeled Recombinant Mycobacterium tuberculosis antigen.
Sample diluent	0.5mL×1 Bottle	2mL×1 Bottle	4mL×1 Bottle	6mL×1 Bottle	20mM Phosphate buffer

【Storage conditions and expiry date】

- 4~30℃, valid for 24 months.
- When humidity is less than 60%, it should be used within 1 hour and when humidity is more than 60%, it should be used immediately.
- Expiration date and lot number are shown in the label.

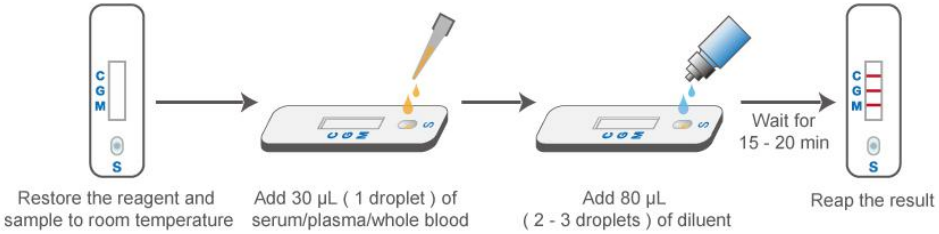
【Sample requirements】

- The whole blood should be venous blood, serum samples can be collected by vein in a conventional manner. The plasma samples can be treated with heparin, sodium citrate and EDTA. The above samples can be stored at 2-8 ℃ for 8 days. Samples under -20℃ can be stored for at least 3 months.
- Samples should avoid hemolysis or repeated freezing-thawing. If the sample is turbid or has precipitation, it should be centrifuged or filtered to clarify before testing.

【Test procedure】

This package insert must be read completely before performing the test. Please restore the reagent and sample to room temperature before inspection. Experimental humidity should be less than 60%, the experiment temperature is 18~30℃. Test procedure is as follows:

1. Remove the test card from the aluminum foil bag, mark the sample and put it on the horizontal work table.
2. Take 30μL (about 1 drop) serum, plasma or whole blood to be directly added to the sample hole then add the sample diluent 80 μL (about 2-3 drops).
3. Result should be read at 15-20 minutes; negative results must be confirmed at the end of 20 minutes.



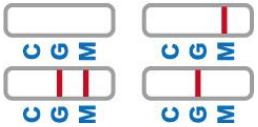
【Interpretation of assay result】

1. IgG Positive: There are two red lines in G line and C line, indicating that the sample has detected Mycobacterium tuberculosis IgG antibodies which may be in the stage of infection or previous infection, and it needs to be confirmed in combination with clinical symptoms.

2. IgM Positive: There are two red lines in M line and C line, indicating that the sample has detected Mycobacterium tuberculosis IgM antibodies, which may be in the stage of acute infection, and it needs to be confirmed in combination with clinical symptoms

3. IgG、IgM Positive: There are three red lines in G line, M line and C line, indicating that the sample contains Mycobacterium tuberculosis IgM and IgG antibodies, which may be in the stage of infection and need to be finally confirmed in combination with clinical symptoms.

4. Negative: only a red line appeared on the C line in the test window, indicating that the samples did not detect Mycobacterium tuberculosis IgM and IgG antibodies, and it was necessary to retest after 7-14 days according to the clinical symptoms.



5. Invalid: no red C line appears in the test window, which means that the test result is invalid, and the invalid result should be retested, and it should be carried out in strict accordance with the instructions. If the retest result is still invalid, then contact the local supplier or contact the customer service of our company to conduct technical consultation to determine whether there is a problem with the product.

【Limitations of the test method】

1. The product is only used for the detection of whole blood, serum or plasma, do not test for saliva, urine or other body fluids.
2. This kit is only used for qualitative detection and can not be used for the determination of antibody content.
3. The test results of this product are only for clinical reference and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered comprehensively with the information of symptoms / signs, medical history, other laboratory examinations, treatment response and epidemiology.
4. The results of sample testing are related to factors such as sample collection, testing, transportation and storage. Any error will affect the accuracy of the results.
5. Interfering substances: 1) When the bilirubin concentration≤50mg/dL, the hemoglobin content≤ 500mg/dL, and the triglyceride content≤1500mg/dL, it will not interfere with the test results of this product; 2) when the antinuclear antibody titer≤1:320, rheumatism factor ≤500IU/mL will not interfere with the test results of this product.
6. Cross reaction: Hepatitis B virus antibody, hepatitis C virus antibody, Treponema pallidum antibody, HIV antibody, hepatitis A virus IgM antibody, hepatitis E virus IgM antibody and anti-mitochondrial antibody positive will not interfere with this product.

【Product performance indicator】

1. The coincidence rate of positive reference samples: the coincidence rate of positive reference samples should be 8 to 8.
2. The coincidence rate of negative reference samples: the coincidence rate of negative reference samples should be 10 to 10.
3. Minimum detection limit：The minimum detection limit for quality control products is not less than 1:8.
4. Repeatability：Test internal repetition quality control material for 10 times, and the result should be positive.
5. Statistics of 305 human serum were statistically analyzed. The positive rate detection of IgG was 93.85%，95% confidence interval was [85.22%-97.58%]，negative detection coincidence rate was 96.67%，95% confidence interval was [93.56%-98.30%]，Total coincidence rate was 96.07%，95% confidence interval was [93.25%-97.74%]；The positive rate detection of IgM was 92.59%，95% confidence interval was [76.63%-97.94%]，negative detection coincidence rate was 97.48%，95% confidence interval was [94.89%-98.78%]，Total coincidence rate was 97.05%，95% confidence interval was [94.49%-98.44%]

【Cautions】

1. If the state of the kit and sample is not restored to 18~30 ℃, the operation should not be carried out, otherwise the accuracy of the results will be affected.
2. The positive samples obtained by rapid test should be confirmed by other methods.
3. The test reagent should be sealed and stored in a dry place. The test card should be tested as soon as possible after it is removed from the package, so as not to stay in the air for too long and cause moisture.
4. The color of the test line is not necessarily related to the titer of the antibody in the sample, and the interpretation result is invalid after 20 minutes.
5. The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and treatment.
6. Waste samples and test should be treated as potential infectious agents.
7. The time of occurrence of the quality control line should not be used as the time basis for judging the results of the test line. The color results should be observed and judged within 15-20 minutes.
8. The rapid test is only used for in vitro diagnosis.

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Index of Symbol

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Store between 4-30℃		Consult instructions for use
	Use by	LOT	Lot number
	Do not use if package is damaged	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturing date		Manufacturer

EC REP

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