Mycoplasma Pneumoniae IgM Antibody Rapid Test Kit (Colloidal Gold)
User manual

【Product name】
Mycoplasma Pneumoniae IgM Antibody Rapid Test Kit (Colloidal Gold)

【Package specification】
25 Tests/kit

【Intended use】
It is used for qualitative detection of mycoplasma pneumoniae IgM antibody in human serum, plasma, and whole blood samples. It is applicable to the auxiliary diagnosis of mycoplasma pneumoniae infection.

【Inspection principle】
The principle of chromatographic capture method is applied to qualitatively detect Mycoplasma pneumoniae IgM antibody in human plasma, serum and whole blood. After the sample is added into the sample hole, the anti Mycoplasma pneumoniae antibody (IgM) in the sample will bind to the gold labeled Mycoplasma pneumoniae antigen after re dissolution and migrate upward by chromatography. When it migrates to the detection line, it will bind to the anti human IgM (u-chain) antibody on the detection line, Form a visible gold labeled Mycoplasma pneumoniae antigen anti Mycoplasma pneumoniae IgM antibody anti human IgM antibody complex. Anti Mycoplasma pneumoniae IgM antibody negative samples did not form gold labeled complexes.

【Components】

Name	Quantity	Component
Test cards	25	a) Anti human IgM (U chain) antibody (fixed in the T region of nitrocellulose membrane); b) Sheep anti human Mycoplasma pneumoniae antigen polyclonal antibody (fixed in the C region of nitrocellulose membrane); c) Colloidal gold labeled Mycoplasma pneumoniae antigen; d) Other test strip supports.
Sample diluent	25（1mL/tube）	Phosphate buffer

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】
The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.
The production date, batch number and expiration date are shown in the outer package of the product.

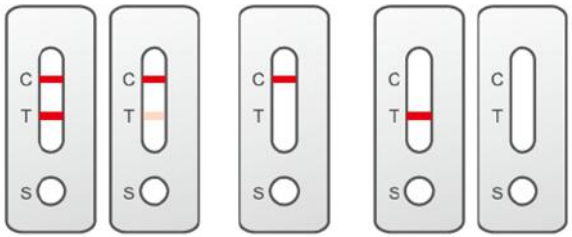
【Sample requirements】
1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃ ~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15 ℃ ~30 ℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】
Please read the operating instructions carefully before testing. Before the test, please restore all reagents to room temperature, and the reagents shall be carried out at room temperature.
1. Open it along the opening of the aluminum foil bag, take out the reagent card and place it flat.
2. Add 10 μL of serum or plasma to be tested (20 μL of whole blood) into the sampling hole of the test card, and slowly add 3 drop (or 80 μL) of sample buffer.
3. Observe the displayed results within 15 ~ 20 minutes, and the displayed results after more than 20 minutes are invalid.

【Interpretation of results】
1. (a) Both the control line and the test line were positive; (b) Only the control line is negative; (c) The control line is not displayed, so this experiment is invalid.
2. The positive results show that the sample contains Mycoplasma pneumoniae IgM antibody. It

should also be combined with other clinical indicators to determine whether the patient is infected with Mycoplasma pneumoniae.

3. The negative result shows that no Mycoplasma pneumoniae IgM antibody is detected, but if the content of Mycoplasma pneumoniae IgM antibody in the sample is too low, which is lower than the detection limit of this kit, although the test result is negative, the possibility of infection with Mycoplasma pneumoniae is not ruled out.



Positive Negative Invalid

【Limitations of methods】

1. This reagent is only used for testing serum, plasma and whole blood samples.

2. The test results of this reagent are only for clinical reference and shall not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients shall be comprehensively considered in combination with their symptoms / signs, medical history, other laboratory tests and treatment reactions.

3. The substance detected in this test card is MP IgM antibody. In the window period of MP acute infection or when the titer of MP IgM in the sample is lower than the detection limit of this kit, incorrect negative results may be obtained, and the patient should be prompted to recheck within 7-14 days.

4. MP IgM positive not only occurred in the primary interference of Mycoplasma pneumoniae, but also in the secondary infection.

5. Cross reactivity: no cross reactivity with serum samples of patients infected with Ureaplasma urealyticum, Mycoplasma genitalium, Mycoplasma hominis, Streptococcus pneumoniae, Chlamydia pneumoniae, Haemophilus influenzae, Klebsiella pneumoniae, Staphylococcus aureus, Mycobacterium tuberculosis, Legionella pneumophila and Pseudomonas aeruginosa, and no cross reactivity with syncytial virus, adenovirus, influenza virus There was no cross reaction in serum samples of patients infected with parainfluenza virus.

6. When the content of triglyceride in the sample does not exceed 15mg / ml, the content of hemoglobin does not exceed 5mg / ml, the content of bilirubin does not exceed 0.5mg/ml, and the RF concentration is less than 2000iu / ml, it has no effect on the test results.

7. When the human anti mouse concentration in the sample is less than 50NG / ml, HAMA effect will not occur.

【Performance】

1. Positive coincidence rate: all 10 positive quality control samples were positive, and the positive coincidence rate was 100%.

2. Negative coincidence rate: all 10 negative quality control samples were positive, and the negative coincidence rate was 100%.

3. Repeatability: the judgment results of yin and Yang of the same reference material shall be consistent, and the apparent chromaticity shall be consistent.

4. Difference between batches: the test results between batches shall be completely consistent, and the apparent chromaticity shall be consistent.

5. Detection limit: not higher than 5IU/ml.

【Note】

1. This product is a disposable in vitro diagnostic reagent. Do not use expired products.

2. There is no color band on the quality control line and inspection line, indicating that there is an error and the detection should be retried.

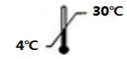
3. Avoid the high temperature of the test environment. The test card stored at low temperature needs to be restored to room temperature and then opened to avoid moisture absorption.

4. It is recommended to use fresh samples instead of repeated freeze-thaw samples.

5. If the virus sampling solution is used to treat the sample, it can be detected directly without diluting the sample extraction solution.

6. Pay attention to safety measures during operation, such as wearing protective clothing, gloves, etc.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

[1] Fraser C. WHO Rapid Pandemic Assessment Collaboration. Pandemic Potential of a Strain of Influenza A (H1N1) [J]. Early Findings. Science, 2009, 324.

[2] Yuan, Liu, Aihua, et al. Detection of 3-phenoxybenzoic acid in river water with a colloidal gold-based lateral flow immunoassay [J]. Analytical Biochemistry, 2015.

【Essential information】
Registered/manufacturer name: WWHS Biotech. Inc
Address: Rm505, 1st building, Shenzhen Biomedical Innovation Industrial Park, No. 14th, Jinhui Road, East Jinxiu Road, Kengzi Street, Pingshan District, Shenzhen
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