

## Chlamydia Pneumoniae IgM Rapid Test

Cat. No.: DTS626

Pkg. Size: 40T

### Intended use

This kit is used to qualitatively detect the existence of Cpn-IgM antibodies in serum or plasma sample, as an auxiliary clinical diagnostic reagent of (Chlamydia Pneumoniae) Cpn infection in early stage.

### General Description

Chlamydia pneumoniae (Cpn) is a species of Chlamydophila, an obligate intracellular bacterium that infects humans and a major cause of pneumonia. It is mainly infected through the respiratory transmission and can breed in human alveolar macrophages, epithelial cells, endothelial cells, smooth muscle cells and neutrophils. Chlamydia pneumoniae is the main cause of the human atypical pneumonia, bronchitis, pharyngitis, sinusitis, otitis media, iritis, myocarditis and other diseases. 5-10% of the community acquired pneumonia, bronchitis and sinusitis was caused by chlamydia pneumoniae. In addition, epidemiology and aetiology research shows that the chlamydia pneumoniae infection is associated with cardiovascular disease.

### Principle of the Test

This kit is based on colloidal gold immunochromatography to qualitative test the Cpn-IgM antibody of serum or plasma samples. The Cpn-IgM antibodies in positive sample can combine with colloidal gold labeled mouse anti human IgM immobilized on conjugate pad to form immune complex, and move along the membrane strip by chromatography. Some of the complex is caught by recombinant Cpn Ag pre-coated on T line to form "gold labeled mouse anti human IgM-Cpn IgM Ab-Cpn Ag" and develop color. The remaining free complex will be caught by the goat anti-mouse IgG antibody coated on the C line to develop color. As for negative samples, in which have no Cpn-IgM antibodies, cannot form immune complexes and show color on the T line, and C line appears only.

### Reagents and Materials Provided

- 1, Test Card: 40 T
- 2, Sample diluent: 1 bottle (5 ml)
- 3, Kit Insert: 1 pcs

### Storage

Store at 4 ~ 30°C, dry places for 24 months. Use test card within 1 hour once open to atmosphere when the humidity is below 60%, or use it immediately if the humidity is higher.

## Sample Request

1. Serum and plasma samples were collected from the venous blood by conventional method. Plasma sample: add 100ul heparin solution (1%) to 5 ~ 10ml blood; or sodium citrate solution (3.8%) to plasma according to the proportion of 1:9; or EDTA solution (15%) 0.04ml to 5ml plasma.
2. Serum and plasma samples can be stored at 4 °C if tests will be done within 5 days, otherwise stored at -20 °C. No more than 3 times of freeze-thaw.
3. Whole blood samples should be stored at 2-8°C and tested within 3 days, and cannot be frozen.
4. The test result is invalid for hemolysis sample.

## Test Procedure

1. Test preparation: 10µL, 100µL micropipettes and matched tips
2. Test process: The temperature of the kit and the test sample should be the same with room temperature before test. Place the test card on a dry horizontal work surface. Add 10µL serum or plasma sample into the sample well, then add 100 µL of sample dilution immediately. Observe the result in 15-20 minutes after the serum or plasma samples added. The observation is invalid after 20 minutes.

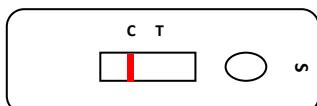
## Interpretation of Results

### Negative result

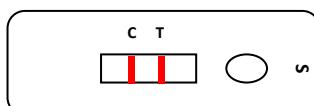
The presence of only one band within the result window indicates a negative result.

### Positive result

The presence of two color bands ("T" and "C") within the result window, no matter which band appears first indicates a positive result.



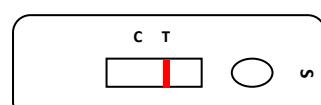
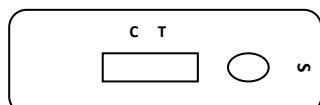
Negative



Positive

### Invalid Result

If the red color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.



## Performance Indicators

Positive coincidence rate: to internal reference (+/+) =10/10; Negative coincidence rate (-/-) =10/10;

Precision (n=10): positive for all tests, and develop color equably;

Minimum detection limit: positive end point is not less than 1:8 dilution of positive reference.

The following positive samples cannot affect results:

Sample	S/C Value	Sample	S/C Value
Toxoplasma IgM antibody	≤ 13.65	Toxoplasma IgG antibody	≤ 13.45
Rubella virus IgM antibody	≤ 11.42	Rubella virus IgG antibody	≤ 10.39
Cytomegalovirus IgM antibody	≤ 13.41	Cytomegalovirus IgG antibody	≤ 13.15
Herpes simplex virus II IgM antibody	≤ 12.53	Herpes simplex virus II IgG antibody	≤ 14.28
Hepatitis B virus surface antigen	≤ 13.57	Hepatitis C virus surface antigen positive	≤ 14.75
Treponema pallidum antibody	≤ 12.35	HIV	≤ 11.37
HEV-IgM	≤ 12.15	RSV-IgM	≤ 5.56
MP-IgM	≤ 9.23	MP-IgG	≤ 9.66
Rheumatoid factor	≤ 54IU/ml	Antinuclear antibody	≤ 1:640
Staphylococcus aureus			

There is impact in test when the lipid content of the sample is higher than 6mmol / L and the bilirubin level is higher than 40 μmol/L.

## Precautions

1. It needs other methods to confirmation when the kit test result is positive.
2. To avoid the test card exposing in the air long time since it can absorb moisture and affect the test results. Use test card within 1 hour once open to atmosphere when the humidity is below 60%, or use it immediately if the humidity is higher.
3. The degree of coloration on the test line do not inherently connected to the antibody titers in test sample.
4. The color of C line is likely to abate when the content of the Cpn-IgM is extremely high in the sample. It is a normal phenomenon.
5. Be attention to the potential biological risks. Wearing necessary protective equipments, and dealing with waste as infectious material.

## Limitations

1. The detection card is one of the assistant diagnostic methods. Its test results are only for reference and should not be the sole basis for clinical diagnosis and treatment. The positive results should be further verified by other methods. Due to the limit of detection sensitivity, the negative results may be observed because the concentration of antibodies is lower than the analysis sensitivity. The clinical diagnosis should combine with the clinical diagnosis, medical history and other detection methods.
2. It was vulnerable to the visual error or subjective judgment factors. Duplicating detection when a stripe color is not obvious.
3. During early stage of infection, IgM may not be generated or in low titer. It might cause negative results. Suggest the patients to review in 7-14 days and do parallel detection to the old samples at the same times to confirm whether serological positive or titer increased significantly.



4. The results are unreliable to the patients with impaired immune function or immunosuppressive treatment.
5. Positive is not only occurs in the primary infection, but also in secondary infection.
6. This kit is a qualitative test and cannot used to determine antibody levels.
7. For the test of serum or plasma samples only, not for saliva, urine or other body fluids testing.

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