

Chlamydia Pneumoniae Antibody IgM Rapid Test Kit

(Immunochromatography)

Product Name

Chlamydia Pneumoniae Antibody IgM Rapid Test Kit (Immunochromatography)

Intended Use

The reagent is used to detect the Chlamydia Pneumoniae IgM antibody in serum / plasma qualitatively. Chlamydia pneumoniae is the causative agent of respiratory tract infectious diseases and spread worldwide through aerosols. Chlamydia pneumonia may cause pneumonia, bronchitis, pharyngitis, sinusitis, stimulate primary pharyngitis. 10~20% of adults and children may get community acquired pneumonia according to chlamydia pneumonia, while 10~20% adults may get acute bronchitis. In fact, most of the chlamydia pneumoniae infection is in the type of subclinical, with no symptoms and rarely cause significant disease, and will be much more serious without treatment. The positive results of infected people showed that the concentration of chlamydia pneumoniae goes with age, which is lower in children but peaking in middle-aged people. It is indicated that chronic infection of Chlamydia pneumoniae is one of the factors that cause the atherosclerosis. The diagnosis of Chlamydia pneumoniae infection by serological methods is still one of the bases for clinical diagnosis so far. Detection of chlamydia pneumoniae antibody is widely used in clinical diagnosis for its simple operation, quickness and low cost.

In normal infection, Cpn-IgM can be detected as early as 3 weeks and disappear in about 2-6 months after infected, while Cpn-IgG can be detected in about 6-8 weeks. The detection of IgM is the basis for early diagnosis.

Test Principle

The test utilizes antibodies including a recombinant antigen Cpn and mouse anti-human monoclonal antibody on the nitrocellulose membrane with colloidal gold marked Cpn antigen as an mark tracer. The reagent is used to detect the Cpn IgM antibody in serum / plasma according to the principle of double antibody sandwich method and gold immunochromatography assay.

The sample mixing up mouse anti-human antibody–marker move along the membrane to the T line, and form the T line when the sample contains Cpn-IgM 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 monoclonal antibody, nitrocellulose membrane coated with Cpn

antigen (expression vector pCPN533T), 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 and 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.
3. Detect immediately after collecting blood. Samples may be stored at 2-8°C for 1 week prior to assay, and at -20 °C 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°C-30°C) 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°C-50°C)

Strip and Cassette:

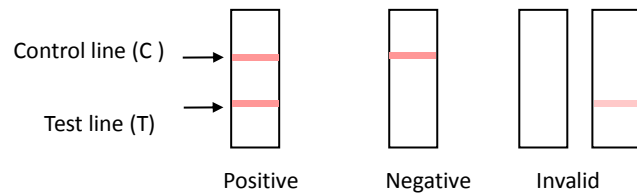
1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ sample hole of the cassette up.
2. Drop 1 drop (15µl) of serum /plasma vertically into the sample adding area of the strip /sample hole of the cassette. Add 2 drops (80-100ul) of sample buffer into the sample adding area of the strip / sample hole of the cassette.
3. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

Result Judgment

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



Limitation

1. This reagent is designed for the qualitative screening test. Concentration of Cpn-IgM cannot be determined by this qualitative test.
2. 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.
3. Negative result may occur when detecting short-term infected samples or window period samples, indicate that the specific antibodies of MP does not exist or the concentration is below detection limit. If chlamydia pneumoniae infection is suspected, the sample should be collected 2-4 weeks later and carry the parallel detection with the first sample.
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 Mycoplasma pneumonia is still suspected, a sample should be collected later and tested again.

Performance Characteristics

1. Negative specificity: The results should all be negative when detecting 10 kits of Cpn-IgM negative quality control samples.

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

Limit of detection: The results should all be positive when detecting diluted Cpn-IgM 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 1000 samples comparing the results obtained using the Anti-Mycoplasma Pneumonia Antibody IgG Rapid Test Kit and other commercially available MP tests. The results demonstrated a 98.20% positive agreement, 99.25% negative agreement, and a 98.90% overall agreement of the Chlamydia Pneumoniae Antibody IgM Rapid Test Kit when compared to the

other Cpn-IgM 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) , TB, MP, RSV, measles virus, varicellazoster virus, rubella virus, EB (VCA) and toxoplasm showed no cross-reactivity.

The retest results are negative when carrying the destruction experiment of Cpn-IgM antibody. The test kit has a strong specificity on Cpn-IgM.

4. Hook effect: the hook effect will not occur even the diluents rate is 1:1024.

Precaution

1. For IN VITRO diagnose only.
2. The test result is invalid over 20 minutes.
3. Do not use after the expiration date.
4. 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.
5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use, although the product itself has no biological safety problems.
6. 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.
7. 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.