Anti-Mycoplasma Pneumonia Antibody IgM Rapid Test Kit
（Immunochromatography）

Product Name

Anti-Mycoplasma Pneumonia Antibody IgM Rapid Test Kit （Immunochromatography）

Intended Use

The reagent is used to detect the mycoplasma pneumonia IgM antibody in serum / plasma qualitatively.

Mycoplasma pneumonia is the causative agent of respiratory tract nfectious diseases and complication of other systems. There will be a symptom with headache, fever, dry cough, and muscle pain. People of all age groups can be infected while youth, middle-aged and children under 4 years old have a higher infection rate. 30% of the infected population may have a whole lung infection.

In normal infection, MP-IgM can be detected as early as 1 week after infected, continue to rise very rapidly, peaking in about 2-4 weeks, decreasing gradually in 6 weeks, disappear in 2-3 months. Detection of MP-IgM antibody can diagnose MP infection in early stage.

Test Principle

The test utilizes antibodies including a recombinant protein MP-P1 and mouse anti-human monoclonal antibody on the nitrocellulose membrane with colloidal gold marked MP antigen as an mark tracer. The reagent is used to detect the MP IgM antibody in serum / plasma according to the principle of double antibody sandwich method and gold immunochromatography assay.

The sample mixing up MP antibody –marker move along the membrane to the T line, and form the T line when the sample contains MP-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 MP-P1，control line coated with goat anti rabbit IgM 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 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 device onto the desk with sample adding area of the strip/ the sample window of the cassette up.

2. Drop 1 drop (30μl) of serum/plasma vertically into the sample adding area of the strip/sample hole of the cassette. Add about 2 drops of (80μl-100μl) sample buffer into sample adding area of the strip /the sample hole of the cassette.

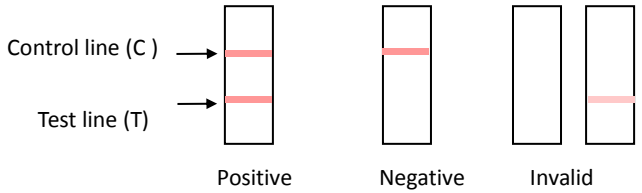
3. Observe the test results immediately within 10-20 minutes, the result is invalid over 20 minutes.

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 MP-IgM 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 MP 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 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 MP-IgM negative quality control samples.

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

Limit of detection: The results should all be positive when detecting diluted MP-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 1033 samples comparing the results obtained using the Anti-Mycoplasma Pneumonia Antibody IgM Rapid Test Kit and other commercially available MP tests. The results demonstrated a 98.94% positive agreement, 99.20% negative agreement, and a 99.13% overall agreement of the Anti-Mycoplasma Pneumonia Antibody IgM Rapid Test Kit when compared to the other MP-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, Cpn, adenovirus, RSV, streptococcus pneumonia, influenza virus type A, influenza virus type B, cytomegalovirus, measles virus, mumps virus, toxoplasm, varicella zoster, rubella virus, herpes simplex virus (mixed), and EB showed no cross-reactivity.

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

4. Hook effect: the hook effect will not occur even the diluents rate is 1:512.

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.