FRENOVO

Mycoplasma pneumoniae IgM Rapid Test Kit

Instructions For Use

PRODUCT NAME

Mycoplasma pneumoniae IgM Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

Mycoplasma pneumoniae IgM Rapid Test Kit is an in vitro qualitative immunochromatographic assay for the rapid detection of mycoplasma pneumoniae (MP) IgM antibodies in human serum, plasma or whole blood samples.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Mycoplasma pneumoniae is the causative agent of respiratory tract infectious 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.

The Mycoplasma pneumoniae IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a colored conjugate pad containing recombinant MP antigen conjugated with colloidal gold and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing a T line and a control line (C line). The T line is pre-coated with monoclonal anti-human IgM for the detection of IgM to MP, and the C line is pre-coated with a control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-MP IgM antibodies if present in the specimen will bind to the MP antigen conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody forming a colored T line, indicating a MP IgM positive test result. Absence of T line suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies regardless of the color development on the test line. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS

Each kit contains:

1. Test devices: 25 pieces test devices individually pouched.
2. Wash Buffer Solution: 3.0 ml in dropper bottle.
3. Droppers: 25 pieces droppers of 10 ul.
4. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micro-pipette

WARNINGS

1. Read the Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The Instructions For Use instructions must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of sample collection tubes, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix sample collection tubes/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of collected specimen. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the extraction Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

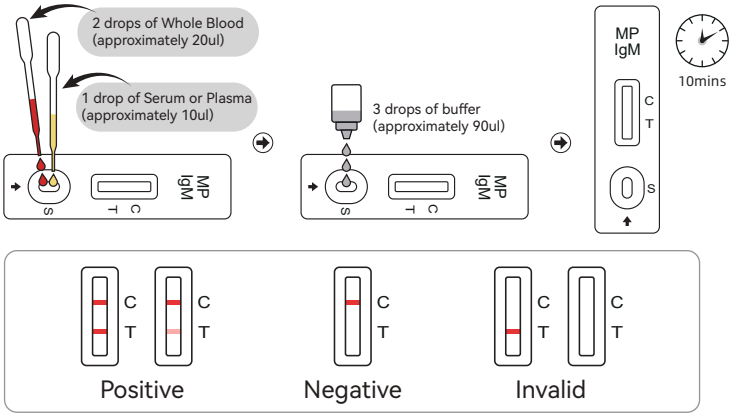
SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood/Serum/Plasma.
2. Separate serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected as soon as possible. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
8. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

TEST PROCEDURE

Allow the test cassette, specimen, buffer solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. For Serum or Plasma Specimens
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (one drop/approximately 10ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
   To use a micro-pipette: Pipette and dispense 10ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.
   For Whole Blood Specimens
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 20ul), then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
   To use a micro-pipette: Pipette and dispense 20ul of specimen to the sample well of the test cassette, then squeeze the wash buffer solution bottle, add three drops wash buffer solution inside (approximately 90ul) to the sample well and start the timer.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Test line and quality control line develop color. It is suggested that the IgM antibody of Mycoplasma pneumoniae is positive.

NEGATIVE: Only the quality control line is colored in the test window. It is suggested that the concentration of Mycoplasma pneumoniae IgM antibody does not reach the detection level.

INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and a commercially available Mycoplasma pneumoniae IgM Rapid Test as reference. The results indicated that The kit has a high sensitivity and specificity as summarized below:

MP IgM clinical study		Other Rapid Test		Total Results
Mycoplasma pneumoniae IgM Rapid Test Kit	Results	Positive	Negative	
	Positive	121	7	128
	Negative	5	342	347
Total Results		126	349	475

Clinical sensitivity=96.03% (90.98% ~ 98.70%)
Clinical specificity=97.99% (95.91% ~ 99.19%)
Accuracy=97.47% (95.63% ~ 98.69%)

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.

Interfering Substances

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.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C 30°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

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