Mycoplasma pneumoniae IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF IMP-425	English

A rapid test for the qualitative detection of IgG and IgM antibodies to Mycoplasma pneumoniae (M. pneumonia) in human whole blood, serum or plasma.

For professional in vitro diagnostic use only.

INTENTED USE

The *Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Mycoplasma pneumoniae* in whole blood, serum, or plasma to aid in the diagnosis of *Mycoplasma pneumoniae* infection.

SUMMARY

Mycoplasma pneumoniae 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-IgG 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/IgG antibody can diagnose MP infection in early stage.

PRINCIPLE

The *Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of *Mycoplasma pneumoniae* IgG and IgM antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG or IgM is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with *Mycoplasma pneumoniae* antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG or IgM. If the specimen contains *Mycoplasma pneumoniae* IgG and/or IgM antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain *Mycoplasma pneumoniae* antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains *Mycoplasma pneumoniae* antigen coated particles and anti-human IgG and IgM coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The *Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette can be performed using whole blood (from venipuncture or fingerstick) serum or plasma.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- 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 for more than three times.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

- Test cassettes
- Droppers
- Buffer
- Package insert

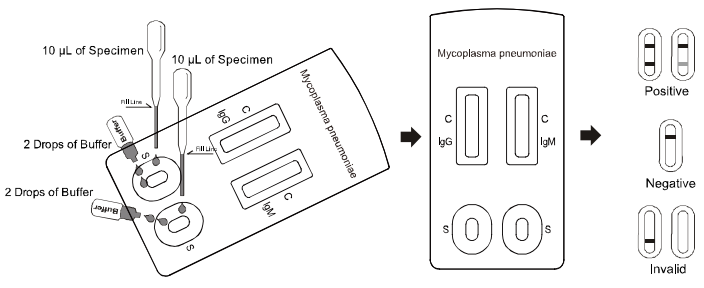
Materials required but not provided

- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen and buffer to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically, draw the specimen (whole blood/serum/plasma) up to the **Fill Line** as shown in illustration below (approximately 10 µL). Transfer the specimen to the sample well (S) each, then hold the buffer bottle vertically and add **2 drops of buffer (approximately 80µL)** to the sample well (S) each, and start the timer. See the illustration below.
3. Wait for the colored line(s) to appear. **The result should be read at 10 minutes.** Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of Mycoplasma Penumonia antibody present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).

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

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of MP-IgG and/or MP-IgM cannot be determined by this qualitative test.
2. Negative result may occur when detecting short-term infected specimens or window period specimens, 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 AIDS is still suspected, a specimen should be collected later and tested again.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The *Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with commercial M.pneumonia rapid test cassette; the results show that *Mycoplasma pneumoniae* IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high sensitivity and specificity.

For IgG

Method		Other Rapid Test		Total Results
***Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette**	**Results**	Positive	Negative	
	Positive	110	22	132
	Negative	9	351	360
Total Results		119	373	492

Relative Sensitivity: 92.4% (95%CI*: 86.1%-96.5%) *Confidence Interval
Relatively Specificity: 94.1% (95%CI*: 91.2%-96.3%)
Accuracy: 93.7% (95%CI*: 91.2%-95.7%)

For IgM

Method		Other Rapid Test		Total Results
***Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette**	**Results**	Positive	Negative	
	Positive	115	15	130
	Negative	6	359	365
Total Results		121	374	495

Relative Sensitivity: 95.0% (95%CI*: 89.5%-98.2%) *Confidence Interval
Relatively Specificity: 96.0% (95%CI*: 93.5%-97.7%)
Accuracy: 95.8% (95%CI*: 93.6%-97.4%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of five specimens: a negative, a IgG low positive, a IgM low positive, a IgG medium positive and a IgM medium positive. The negative, low positive and medium positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the *Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, low positive and medium positive specimens. The specimens were correctly identified >99% of the time

Cross-reactivity

Sera containing known amounts of antibodies to *Mycoplasma pneumoniae* have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the *Mycoplasma pneumoniae* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high degree of specificity for antibodies to *Mycoplasma pneumoniae.*

Interfering Substances

The *Mycoplasma pneumoniae* IgG/IgM Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

Index of Symbols

⚠	Caution	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by	②	Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Consult instructions for use		Manufacturer

ACRO BIOTECH, Inc.
4650 Arrow Highway,
Suite D-6 Montclair, CA 91763, U.S.A.
Tel: +1 (909) 541-5085 www.acrobiotech.com

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

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