QuickStripe™ M. pneumoniae IgM
(Whole Blood/Serum/Plasma)

A rapid test for the qualitative detection of IgM antibody to *Mycoplasma pneumoniae (M. pneumoniae)* in whole blood, serum or plasma. For professional in vitro diagnostic use only.

INSTRUCTION MANUAL

Test kit for 20 determinations
(Catalog No.41208)

For professional in vitro diagnostic use only
Store at 2-30°C. **Do Not Freeze**

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INTENDED USE

The QuickStripe™ M. pneumoniae IgM is a rapid chromatographic immunoassay for the qualitative detection of IgM antibody to Mycoplasma pneumoniae in whole blood, serum, or plasma to aid in the diagnosis of Mycoplasma pneumoniae infection.

SUMMARY AND EXPLANATION:

Mycoplasma pneumoniae is a common respiratory tract pathogen causing pharyngitis, tracheobronchitis, or pneumonia (1), Characterized by symptoms of 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, Mycoplasma pneumoniae IgM can be detected as early as 1 week after infected, continue to rise very rapidly for a long term, peaking in about 4~5 weeks. Simultaneous detection of Mycoplasma pneumoniae IgM infection can improve the detection rate of Mycoplasma pneumoniae infection.

PRINCIPLE OF THE PROCEDURE

The QuickStripe™ M. pneumoniae IgM is a rapid qualitative membrane immunoassay test for the detection of Mycoplasma pneumoniae IgM antibody in whole blood, serum, or plasma. In this test procedure, anti-human 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 IgM. If the specimen contains Mycoplasma pneumoniae IgM antibody, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain Mycoplasma pneumoniae antibody, 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 IgM coated on the membrane.

WARNING AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- 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 either at refrigerated or room temperature (2-30ºC). 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 QuickStripe™ M. pneumoniae IgM Rapid Test 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 federal regulations covering the transportation of etiologic agents.

MATERIALS

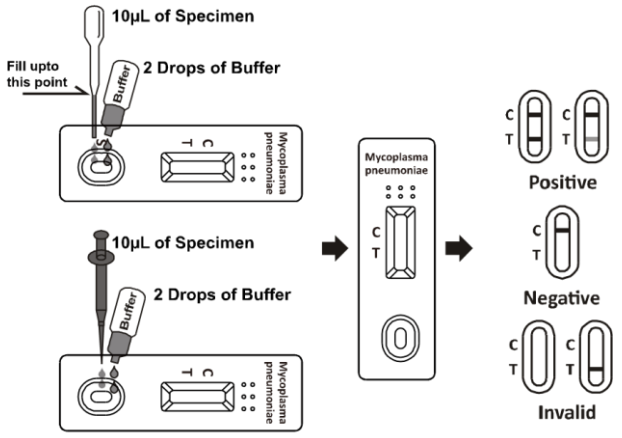
Materials provided:
- 20 Test Cassettes
- 20 Droppers
- 1 Buffer bottle (3ml)
- Package Insert (upon request)

Materials required but not provided:
- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)

PROCEDURE

Test Procedure (see illustration below)
Allow the tests samples and buffer to reach room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

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 point as shown in illustration below (approximately 10µl). 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), 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 distinct 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 pneumoniae IgM 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 apparent 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 OF THE PROCEDURE

1. This reagent is designed for the qualitative screening test. Concentration of *M. pneumoniae* 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 IgM antibody of *M. pneumoniae* 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.

EXPECTED VALUES

The QuickStripe™ M. pneumoniae IgM has been compared with other CE commercially *M. pneumoniae* rapid test, the overall accuracy could reach to 98.9%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

In clinical study performed, the QuickStripe™ M. pneumoniae IgM was compared with a commercial *M. pneumoniae* rapid test cassette; the results show that QuickStripe™ M. pneumoniae IgM has a high sensitivity and specificity.

Method		Other Rapid Test		Total Results
QuickStripe™ M. pneumoniae IgM	Results	Positive	Negative	
	Positive	111	3	114
	Negative	2	355	357
Total Results		113	358	471

Relative Sensitivity: 98.2% (95%CI*: 93.8%-99.8%) *Confidence Interval
Relatively Specificity: 99.2% (95%CI*: 97.6%-99.8%)
Accuracy: 98.9% (95%CI*: 97.5%-99.7%)

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high 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 QuickStripe™ M. pneumoniae IgM have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time

Cross-Reactivity

The QuickStripe™ M. pneumoniae IgM has been tested with

- Hepatitis A, B, C, E,
- HIV and
- Syphilis.

No cross-reactivity was observed

Interfering Substances

The QuickStripe™ M. pneumoniae IgM 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.

BIBLIOGRAPHY

Clyde, W. A. 1993. Clinical overview of typical Mycoplasma pneumoniae infections. Clin. Infect. Dis. 17(Suppl. 1):S32–S37.

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Symbols for IVD components and Reagents			
	Manufacturer	IVD	For *in vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		