SCREEN *Mycoplasma pneumoniae* Antigen Rapid Test Cassette (Throat Swab) Package Insert

REF IMP-502	English

A rapid test for the qualitative detection of Mycoplasma pneumoniae Antigen in throat swab. For professional in vitro diagnostic use only.

【INTENDED USE】

Mycoplasma pneumoniae Antigen Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of *Mycoplasma pneumoniae*(*M. pneumoniae*) antigens in human throat swabs. It is intended to aid in the rapid differential diagnosis of *Mycoplasma pneumoniae* infections.

【SUMMARY】

M. pneumoniae is one of three species of Mycoplasma that frequently cause infection in humans.[1] *M. pneumoniae* most commonly causes upper respiratory tract infections, but can also cause pneumonia. The identification of the *M. pneumoniae* will help the administration of the disease with appropriate antibiotic treatment. This *M. pneumoniae* immunoassay is intended to detect *M. pneumoniae* antigen qualitatively. Because this one-step *M. pneumoniae* rapid test is easy to carry out, it is widely used as a screening test device and as an aid in the diagnostics of *M. pneumoniae* disease.

【PRINCIPLE】

The *Mycoplasma pneumoniae* Antigen Rapid Test Cassette a qualitative, lateral flow immunoassay for the detection of *M. pneumoniae* antigen in a throat swab. In this test, antibody specific to *M. pneumoniae* antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to *M. pneumoniae* that is coated onto particles. The mixture migrates up the membrane to react with the antibody to *M. pneumoniae* on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates 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 cassette contains *Mycoplasma pneumoniae* particles coated on the membrane.

【PRECAUTION】

Please read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- If the *M. pneumoniae* antigen rapid test was kept refrigerated, let all the reagents warm up to room temperature (15°C -30°C) before proceeding with the test.
- Wear gloves when handling the samples, avoid touching the reagent membrane with your fingers.
- Discard gloves, swabs, test tubes, and test devices in accordance with the local regulation.
- Visibly Bloody samples should not be used for the testing.

【STORAGE AND STABILITY】

Store the *Mycoplasma pneumoniae* antigen rapid test kit at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

【SPECIMEN COLLECTION AND PREPARATION】

It is applicable to the diagnosis of the *Mycoplasma pneumoniae* from the samples of throat swabs. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

- **Throat Swabbing**

Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.

Insert the swab into the Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab. Remove the swab. The extracted solution will be used as test sample.

【MATERIALS】

Materials provided

Test Cassettes	Sterilized Swabs	Sample Extraction Buffer
Tube Tips	Workstation	Package Insert
Extraction Tubes		

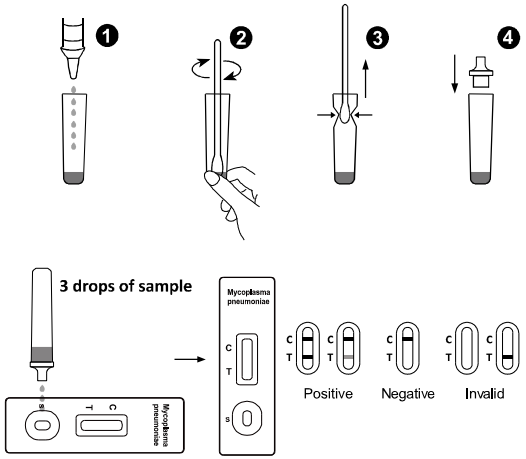
Materials Required But Not Provided

Timer

【DIRECTIONS FOR USE】

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution (Approx. 500µl) to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4.
6. Add three drops of the solution (approx.120µl) to the sample well and then start the timer. Read the result at 15 minutes. Do not interpret the result after 20 minutes.



【RESULT INTERPRETATION】

POSITIVE: Two colored lines appear. One colored line appears in the control region(C), and one colored line in the test region(T). The shade of color may vary，but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one colored line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no M. pneumoniae in the sample or the number of M. pneumoniae is below the detectable range.

INVALID: No line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive 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.

【LIMITATION】

1. *Mycoplasma pneumoniae* antigen rapid test cassette is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with M. pneumoniae.
2. *Mycoplasma pneumoniae* antigen rapid test cassette detects both viable and non-viable M. pneumoniae antigen. Test performance depends on antigen load in the sample,A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3. Performance of the test has not been established for monitoring antiviral treatment of M. pneumoniae.

【EXPECTED VALUES】

The *Mycoplasma pneumoniae* Antigen Rapid Test Cassette (Throat Swab) has been compared with a leading commercial PCR test. The correlation between these two systems is over 98%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity, Specificity and Accuracy

The *Mycoplasma pneumoniae* Antigen Rapid Test Cassette (Throat Swab) has been evaluated with specimens obtained from the patients. PCR is used as the reference method for the *Mycoplasma pneumoniae* Antigen Rapid Test Cassette (Throat Swab). Specimens were considered positive if PCR indicated a positive result. Specimens were considered negative if PCR indicated a negative result.

Method		PCR		Total Result
Mycoplasma pneumoniae Antigen Rapid Test Cassette(Throat Swab)	Results	Positive	Negative	
	Positive	33	3	36
	Negative	2	233	235
Total Result		35	236	271

Relative sensitivity: 94.3% (95%CI*: 80.8%~99.3%);
Relative specificity: 98.7% (95%CI*: 99.6%~100.0%);
Accuracy: 98.2% (95%CI*: 95.7%~99.4%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates off our specimens: a negative, a low positive, a middle positive and a high positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a middle positive and a high positive. Three different lots of the *Mycoplasma pneumoniae* Antigen Rapid Test Cassette(Throat Swab)have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

①Virus

No cross reaction with following pathogens:

Influenza virus A(H1N1,H3N2), Influenza virus B;Adenovirus Type 1～8,11,19,37, Coxsackie virus Type A16,B1～5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, HSV-1, Mumps virus, Parainfluenza virus Type 1～3, Poliovirus Type 1～3, Respiratory syncytial virus, Rhinovirus Type 1A,13,14.

②Mycoplasma etc.

No cross reaction with Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis.

③Bacteria

No cross reaction with following bacteria:

Acinetobacter baumannii,Bacteroides fragilis, Bordetella pertussis, Candida albicans, Candida glabrata, Cardiobacterium hominis ,EikeneUa corrodens, Enterococcus gallinarum. Escherichia coil，Haemophilus phrophlus, aemophilus infiuenzae, Haemophilus parainfluenzae, Haemophilus paraphrophilus, Kingella kingae, Klebsiella pneumoniae, Listeria monocytogenes, Moraxella catarrhalis, Neisseria gonorrhoeae Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus, pyogenes, Streptococcus agalactiae, Streptococcus sp. group C, G, F, Streptococcus mutans

【BIBLIOGRAPHY】

1. Al-Moyed KA,Al-Shamahy HA．*Mycoplasma pneumoniae* infection in Yemen：incidence, presentation and antibiotic susceptibility．East Mediterr Health J．2003 May；9(3)：279-90

Index of Symbols

	Do not use if package is damaged	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 #

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