

EZER™ Mycoplasma pneumoniae Antigen Rapid Test

This kit is designed for testing freshly collected throat swab samples.

INTENDED USE

The EZER™ Mycoplasma pneumoniae Antigen Rapid Test is an *in vitro* diagnostic test based on the principle of immuno-chromatography for the qualitative detection of *Mycoplasma Pneumoniae* (*M. pneumoniae*) antigens in human throat swab samples. It is intended to aid in the rapid differential diagnosis of *M. pneumoniae* infections.

BACKGROUND

Mycoplasma pneumoniae is a common respiratory pathogen that produces diseases of varied severity ranging from mild upper respiratory tract infection to severe atypical pneumonia. Although rarely fatal, *M. pneumoniae* is an important cause of acute respiratory tract infection, especially as a potential etiology of the clinical entity termed “atypical pneumonia”. Of the many species of *Mycoplasma* known to infect man, *M. pneumoniae* is an important cause of respiratory tract infections.

M. pneumoniae is the smallest, self-replicating microorganism biologically classified as a bacterium. However, it is distinguished from bacterium by the lack of cell wall structure.

The clinical presentation of *M. pneumoniae* respiratory disease is often similar to what is seen with other atypical pathogens, particularly *Chlamydia pneumoniae*, various respiratory viruses and bacteria. Typical clinical features include an initial pharyngitis, sore throat, hoarseness, and fever. It is indistinguishable from the common cold, a factor that often delays diagnosis and treatment. *Mycoplasma pneumoniae* affects pre-dominantly preschool and school-age children and young adults.

The test kit is to qualitatively detect *M. pneumoniae* antigen from the specimen without requiring special skills or instruments.

PRINCIPLE

The EZER™ Mycoplasma Pneumoniae Antigen Rapid Test is an immunochromatographic assay for the qualitative detection of *M. pneumoniae* antigens.

The Mycoplasma Pneumoniae Antigen Rapid Test has two letters on the surface of the test device indicating test line (T) and control line (C). Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line must appear every time when the test is performed. If *M. pneumoniae* is present in the sample, the test line would appear. The highly selective antibodies to *M. pneumoniae* are used as capture and detector in the

assay. These antibodies can detect *M. pneumoniae* antigens directly, with a high accuracy.

CONTENTS

Mycoplasma Pneumoniae Antigen test devices	20
Sterilized swabs	20
Extraction tubes	20
Nozzles	20
Tube Stand	1
Package Insert	1

STORAGE CONDITIONS

Test devices must be stored at 2~30°C. DO NOT FREEZE. Devices must be brought back to room temperature at time of testing.

WARNINGS AND PRECAUTIONS

1. For *in vitro* Diagnostic Use only.
2. Pathogenic microorganisms may be present in clinical specimens. All specimen and the related contaminated items need to be handled, stored and disposed following “Standard Precautions” and institutional guidelines.
3. Use the Sterilized swab supplied in the kit for collecting throat sample.
4. The aluminum pouch containing a test device should not be opened until the test device is about to be used.
5. Wear gloves when handling the samples, avoid touching the sample placement area and reading area of the test plate with your fingers.
6. Do not use kit components beyond the expiration date.
7. Apply universal precaution when performing the test.
8. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
9. Do not reuse the device.
10. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device ensuring that the test procedure has been followed accurately.
11. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present.
12. Visibly Bloody samples should not be used for the testing.

SAMPLE COLLECTION AND PREPARATION

Use freshly collected samples of throat swabs for optimum test performance. Prepare test samples with sample extraction buffer for immediate testing after collection. If immediate testing is not possible, collected samples need to be held refrigerated (2-8°C) for up to 48 hours prior to testing and follow sample extraction procedures for swabs prior to refrigerating. Inadequate sample collection or improper sample handling may yield a false-negative result.



Throat Swabbing

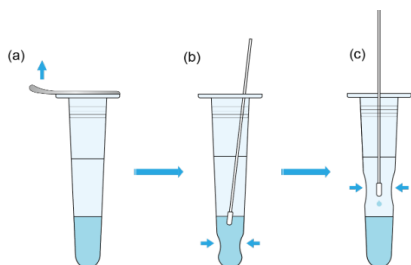
Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid touching saliva.

PROCEDURE

Reagents, specimens and devices must be at room temperature (15–30 °C) for testing. Please read the instruction completely before beginning to test specimens.

1. Sample Extraction

Insert swab with collected sample into extraction tube containing 0.5ml extraction buffer. Squeeze the swab several times by compressing the outside walls of the tube end against the swab to mix well. Finally squeeze the swab to make most of the solution stays in the extraction tube and remove the swab. Use extraction solution as test sample. (step a~c)

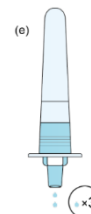


2. Test Reaction

- 1) Remove test device from sealed foil pouch prior to testing and lay flat on work bench.
- 2) Insert nozzle into the extraction tube with test sample. (step d)



- 3) Invert the extraction tube and add 3 drops of test sample into sample well by gently squeezing the extraction tube. (step e)

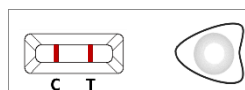


- 4) Read results at 15 minutes. Do not read test result after 30 minutes. A positive result may be visible at 3 minutes. However, the complete reaction time of 15 minutes is required to confirm a negative result.

INTERPRETATION OF RESULTS

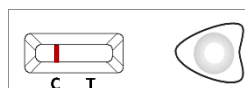
Allow the samples to run according to the instruction and read the test result in the reading area.

Positive Result



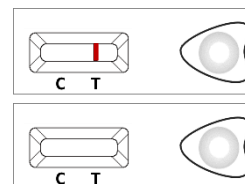
Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T). This indicates that the specimen contains detectable amount of *M. pneumoniae* antigen. The shade of color may vary, but it should be considered positive whenever there is even a faint line.

Negative Result



Only one reddish line appears in the control region of the device. No reddish line is visible next to the Test "T". This indicates that there is no detectable *M. pneumoniae* antigen in the sample.

Invalid Result



No red line appears in the control region (C). The test is invalid even if there is a line in the region (T). Review testing procedures and repeat the test using a new rapid test device.

QUALITY CONTROL

Internal control

Each *EZER*TM Mycoplasma pneumoniae antigen rapid test contains internal/procedural controls. The appearance of a control line at the Control "C" position validates the proper reagent function and assures that the correct test procedure was followed.

PERFORMANCE CHARACTERISTICS

Minimum detection limit

The minimum detection limit for *EZER*TM Mycoplasma pneumoniae Antigen Rapid Test is 7.81x10³ CFU/mL.

Clinical study (throat swabbing)

The clinical performance for *EZER*TM Mycoplasma pneumoniae Antigen Rapid Test were compared with

PCR method.

		PCR		
		+	-	Total
Mycoplasma pneumoniae Antigen Rapid Test	+	509	14	523
	-	18	589	607
	Total	527	603	1130

Sensitivity : 96.6%

Specificity : 97.7%

Overall Percent Agreement : 97.2%

Cross-reactivity evaluation

1. Bacteria

No cross reactivity with the following bacteria:

Escherichia coli, *Pseudomonas aeruginosa*, *Branhamella catarrhalis*, *Enterococcus faecalis*, *Citrobacter spp*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Yersinia enterocolitica*, *Vibrio Parahaemolyticus*, *Shigella flexneri*, *Bacteroides fragilis*, *Mycobacterium bovis*, *Mycobacterium tuberculosis*, *Mycobacterium avium complex*, *Salmonella enteritidis*, *M. simiae*, *Actinobacteria*, *Campylobacter jejuni*.

2. Viruses

No cross reactivity with the following viruses:

Influenza virus A (H1N1, H3N2), Influenza virus B, Adenovirus Type3, Adenovirus Type 6, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Mumps, Rotavirus, Measles, Respiratory syncytial virus(long).

3. Mycoplasma species

No cross reaction with *Chlamydia pneumoniae* and *Chlamydia trachomatis*

Interference substances

(1) No interference with following drug concentration up to 1 µg/mL: Dexamethasone acetate, cefradine, gentamycin sulfate, oseltamivir phosphate

(2) No interference with mucin and asthma samples.

(3) When the blood concentration in the sample is not higher than 1%, there is no interference reaction, but above this concentration, the result may be difficult to judge due to membrane staining. And even a small blood sample may cause an abnormal non-specific reaction due to the influence of plasma or blood cell components. Therefore, try to avoid getting blood when sampling.

(4) When the saliva concentration in the sample is not higher than 5%, there is no interference reaction, but above this concentration, the sensitivity may be lowered or the C line may disappear. Therefore, try to avoid saliva when sampling.

LIMITATIONS OF THE PROCEDURE

1. This kit is a qualitative test and cannot determine the amount of antigen in the sample.
2. The Mycoplasma Pneumoniae Antigen Rapid Test detects both viable and non-viable *M. Pneumoniae* antigens. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3. A false-negative result may occur if the antigen amount in the specimen was below the LoD of the reagent, or if the specimen was collected or transported improperly. A negative result does not eliminate the possibility of *M. Pneumoniae* infection.
4. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.

REFERENCES

1. Surender K, Malay S, Mycoplasma pneumonia: Clinical features and management. Lung India, 2010 Apr-Jun, 27: 75-85
2. Atkinson TP, Waites KB, Mycoplasma pneumoniae Infections in Childhood. Pediatr, Infect Dis, J.33, 92-94(2014).

AVAILABILITY

Product	Cat. No.	Contents
EZER™ Mycoplasma pneumoniae Antigen Rapid Test	P211006	20 Tests

Index of Symbols			
	Attention, see instructions for use		Tests per kit
	For in vitro diagnostic use only		Use by
	Store between 2~30°C		Lot Number
	Authorized Representative		Do not reuse
	Catalog #		



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