Please read this package insert carefully before use.

Capilia™ Mycoplasma

INTENDED USE

To detect *Mycoplasma pneumoniae* antigens in pharyngeal swabs (to assist in the diagnosis of mycoplasma infection).

SUMMARY AND EXPLANATION OF THE TEST

Mycoplasma pneumonia is a type of pneumonia caused by a bacterium called *Mycoplasma pneumoniae*.

Mycoplasma pneumonia is different from that caused by *pneumococcus*, and is therefore called atypical pneumonia. It is said that mycoplasma pneumonia accounts for 30% to 40% of atypical pneumonias.

Mycoplasma pneumoniae is the smallest, self-replicating microorganism biologically classified as a bacterium. However, unlike other bacteria, it does not have cell walls.

Mycoplasma pneumonia generally presents with symptoms of cough, fever, headache and malaise, and is indistinguishable from the common cold, a factor that often delays diagnosis and treatment. Mycoplasma pneumonia affects predominantly preschool and school-age children and young adults.

The incubation period from infection to onset is generally 1 to 3 weeks, but may extend to 4 weeks. Therefore, the infection can spread in communities such as schools and companies. To prevent the spread of the infection, a reliable diagnosis at an early stage is required.

Testing methods include bacterial isolation, antibody testing, and bacterial DNA detection. However, these methods present problems, such as complicated procedures, requiring special equipment or instruments, and taking time to obtain test results.

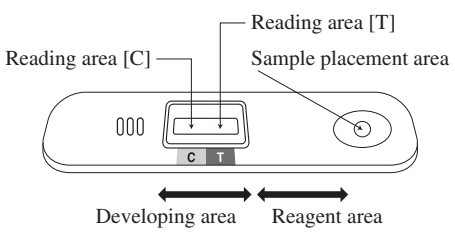
Compared with these methods, Capilia Mycoplasma allows rapid detection of *Mycoplasma pneumoniae*, without requiring special skills or instruments.

PRINCIPLE OF THE TEST

Measurement using this product is based on an immunochromatography assay using a monoclonal antibody that recognizes *Mycoplasma pneumoniae* antigens.

This product comprises a test plate with a carrier strip containing a sample placing area, a reagent area including a colloidal platinum-gold labeled anti-*Mycoplasma pneumoniae* monoclonal antibody (mouse) (hereinafter referred to as "colloidal platinum-gold labeled anti-*Mycoplasma pneumoniae* antibody"), a reading area [T] that fixes the anti-*Mycoplasma pneumoniae* monoclonal antibody (mouse) (hereinafter referred to as "anti-*Mycoplasma pneumoniae* antibody"), and a reading area [C] that fixes an anti-mouse immunoglobulin polyclonal antibody (rabbit) (hereinafter referred to as "anti-mouse immunoglobulin antibody").

Names of each area of the test plate



When a sample is placed on the sample placement area of the test plate, the colloidal platinum-gold labeled anti-*Mycoplasma pneumoniae* antibody dissolves and forms an immune complex with *Mycoplasma pneumoniae* antigens in the sample. This immune complex migrates through the developing area by capillary action, is captured by the anti-*Mycoplasma pneumoniae* antibody fixed in the developing area, and forms a black line of colloidal platinum-gold in the reading area [T]. The black line visually displays the existence of *Mycoplasma pneumoniae* antigens in the sample.

Regardless of the existence of *Mycoplasma pneumoniae* antigens in the sample, excess colloidal platinum-gold labeled anti-*Mycoplasma pneumoniae* antibodies further migrate through the developing area, are captured by anti-mouse immunoglobulin antibodies fixed in the developing area, and form a black line of colloidal platinum-gold in the reading area [C]. This means the colloidal platinum-gold labeled anti-*Mycoplasma pneumoniae* antibodies have migrated normally.

REAGENTS AND MATERIALS PROVIDED

REF CAMP1570 Capilia Mycoplasma (20 Tests)

Test plates

・Components

Colloidal platinum-gold labeled anti-*Mycoplasma pneumoniae* monoclonal antibody (mouse)

Anti-Mycoplasma pneumoniae monoclonal antibody (mouse)

Extraction Buffer

・Buffer, detergent, sodium azide (0.09%)

Nozzles

MATERIALS REQUIRED BUT NOT PROVIDED

Timer, micropipette, pipette tips, FLOQSwabs (shown below)

Use FLOQSwabs™ (Cat No. 502CS01, Copan Italia S.p.A., Italy).

WARNING AND PRECAUTIONS

1. Precautions when handling (including hazard control)

1) Handle all the specimens as if they contain infectious agents.
2) In consideration of the risk of infection, wear protective clothes such as a mask and gloves and handle the specimens and samples carefully during the test.
3) If the extraction buffer gets into your eyes, immediately flush with a large quantity of water for 15 minutes or more. If you still feel some abnormality, see a doctor for treatment.
4) If the extraction buffer comes into contact with your hands or clothes, wash your hands and/or clothes with soap and a large quantity of water.

2. Precautions when using

1)This product is a rapid test for detecting mycoplasma antigens. A definite diagnosis should be made by an attending physician, in combination with clinical symptoms, results of bacterial isolation and other test results.
2) This product should be used in accordance with the procedure stated in the package insert.
3) Avoid touching saliva when collecting pharyngeal swab. If the specimen is mixed with saliva, the lines on the test plate may become fainter.
4) In order to prevent deterioration, this product should be stored between 2°C and 30°C, avoiding high temperatures, high humidity and direct sunlight.
5) If this product has been refrigerated, it must be removed from the refrigerator at least 30 minutes before use to be acclimatized to room temperature.
6) The aluminum pouch containing a test plate should not be opened until the test plate is about to be used.
7) The sample placement area and the reading area of the test plate should not be touched with the hands.
8) Do not use a swab if it is broken, bent or stained.
9) Be sure to use a nozzle (with a filter) provided in the kit.
10) Do not use any products beyond the expiration date.

3. Precautions for disposal

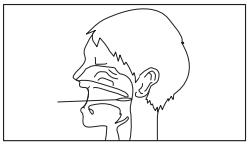
1) Because used test plates, swabs, tubes and nozzles after use, remaining samples, etc. may cause infections, they should be autoclaved (121°C, 20 min) or soaked in 0.1% sodium hypochlorite for more than one hour. When reagents, remaining reagents or their accessories are disposed of, they should be treated in accordance with the laws and regulations concerning medical waste disposal and water pollution control.
2) In the extraction buffer, 0.09% of sodium azide is included as a preservative. When solutions containing sodium azide continue to be discarded over a long period of time, explosive metallic azide may be produced if a drain is made of metal. Therefore, they should be discarded with a large quantity of water.

STORAGE CONDITIONS

Storage : Store at 2°C to 30°C. **DO NOT FREEZE.**
Keep away from direct sunlight.
Do not use test plate or extraction buffer after expiration date.

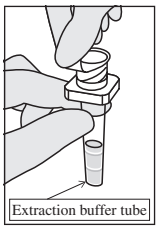
SPECIMEN COLLECTION AND PREPARATION

1. Methods of specimen collection

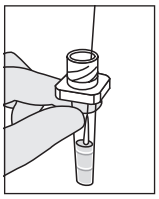


Sampling of pharyngeal swab
Firmly insert the pharyngeal swab into the pharynx through the oral cavity, and collect the mucosal epithelium by swabbing the areas centering around the posterior wall of the pharynx and the palatine tonsil several times. **Avoid touching saliva. If the specimen is mixed with saliva, the lines on the test plate may become fainter.**

2. Sample preparation

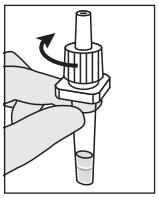


Remove the aluminum sealing cap from the extraction buffer tube, while taking care not to spill the liquid.



Soak the swab that collected the specimen in the extraction buffer, and stir.
Then, pinch the tip of the swab firmly with the soft wall of the extraction buffer tube with your fingers and squeeze out the swab. Use this squeezed-out liquid as the sample.

TEST PROCEDURE

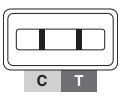


1) Firmly attach the nozzle (with a filter) provided in the kit to the top of the extraction buffer tube.
2) Hold the middle of the extraction buffer tube with the fingers and dispense **3 drops (80 to 120 µL)** of the sample onto the sample placement area of the test plate. Hold the tube perpendicularly and take care not to let the tip of the nozzle touch the sample placement area.
3) Observe the reading area of the test plate after **5 to 15 minutes** and interpret the result according to the "READING TEST RESULTS."

READING TEST RESULTS

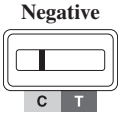
Allow the samples to react according to the procedure and read the black lines that appear in the reading area.

Positive



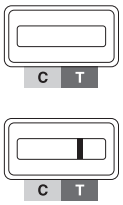
When black lines are seen at both [T] and [C] in the reading area (two lines), the result is read as positive. When a very faint black line is seen in the reading area [T], the result is also interpreted as positive.

Negative



When no black line is seen at [T] in the reading area but a black line is seen only at [C] in the reading area (one line), the result is read as negative.
When a black line at [C] in the reading area is faint but visually recognizable, chromatographic development has occurred normally.

Retesting



When no black line is seen at [C] in the reading area, there may be some problem with the test procedure or the reagent quality. The test should be performed again, using another test plate. If the amount of antigens is very high, a very thick line may be observed at [T] in the reading area and no line may be absorbed at [C] in the reading area. In that case, dilute the sample with the extraction buffer and perform the test again.

A line that appears anywhere within the sections of the reading area, which are separated by color, is considered valid.

(Note)

1. Black lines seen at both [T] and [C] in the reading area 5 to 15 minutes after dispensing the sample are read as positive. When no black line is seen at [T] in the reading area even 15 minutes after dispensing the sample, the result is read as negative. Do not use the test plate for reading beyond the judgment time as the result may change because of drying, etc.
2. A black line may not appear at [C] in the reading area due to problems with the test procedure or the reagent quality. In this case, the test should be performed again, using another test plate. If the same result is obtained in the re-test, try the test once more using the sample diluted twofold with saline as the black line may not appear at [C] in the reading area due to a factor in the specimen or the effect of saliva.
3. If the amount of antigen is very high, a very thick line may be seen at [T] in the reading area and no black line may be seen at [C] in the reading area. In that case, dilute the sample with more extraction buffer and perform the test again.
   Example) Method for dilution of sample: Dispense 3 drops of the sample to a new extraction buffer tube, mix thoroughly and use the solution as the test sample.
4. The line is valid even if there is unevenness in depth and there are breaks in the line.

LIMITATIONS

1. This product is a rapid test for detecting mycoplasma antigens. A definite diagnosis should be made by an attending physician, in combination with clinical symptoms, results of bacterial isolation and other test results.
2. 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.
3. This product should be used for *in vitro* diagnosis only and should not be used for any other purposes.
4. Please use this product following the operational method described in this package insert. We cannot guarantee results obtained from any other operations and for any other purposes that are not described in the package insert.
5. The extraction buffer contains sodium azide. If the solution comes into contact with eye or mouth or adheres to the skin by mistake, take emergency measures such as thorough washing with water and seek medical treatment, if necessary.

PERFORMANCE CHARACTERISTICS

1. Clinical data

1) The result of the clinical performance evaluation in Japan (Comparison with approved product)

		Approved product		
		Positive	Negative	Total
This product	Positive	23	7[Note1)]	30
	Negative	14[Note2)]	59	73
	Total	37	66	103

Sensitivity: 62.2% (23/37)
Specificity: 89.4% (59/66)
Accuracy: 79.6% (89/103)

Note 1) By the PCR method, all 7 patients tested positive.
Note 2) By the PCR method, 1 patient tested positive and 13 patients tested negative.

2) The result of the clinical performance evaluation in Japan (Comparison with PCR)

		PCR method		
		Positive	Negative	Total
This product	Positive	30	0	30
	Negative	7	66	73
	Total	37	66	103

Sensitivity: 81.1% (30/37)
Specificity: 100% (66/66)
Accuracy: 93.2% (96/103)

2. Information on the reference material for calibration

After determination of the bacterial count from the number of colonies formed in the culture fluid of *Mycoplasma pneumoniae*, a dilution series of the standard culture fluid was prepared using the extraction buffer to establish the standard concentrations.

3. Sensitivity (Detection limit)

The minimum detection limit is 7.4×10^3 CFU/Test

4. Cross reactivity

1) Reactivity with other Mycoplasma species

No cross-reactivity was found in the following Mycoplasma species.

Mycoplasma buccale	*Mycoplasma faucium*
Mycoplasma fermentans	*Mycoplasma genitalium*
Mycoplasma hominis	*Mycoplasma lipophilum*
Mycoplasma orale	*Mycoplasma penetrans*
Mycoplasma primatum	*Mycoplasma pulmonis*
Mycoplasma salivarium	

2) No cross-reactivity was found in the following viruses, bacteria and fungi.

(1) Viruses

Adenovirus Type 1	Adenovirus Type 4
Adenovirus Type 5	Adenovirus Type 6
Adenovirus Type 7	Adenovirus Type 10
Adenovirus Type 22	Adenovirus Type 37
Influenza virus A (H1N1)	Influenza virus A (H1N1) pdm09
Influenza virus A (H3N2)	Influenza virus B
Influenza virus C	Respiratory syncytial virus A
Respiratory syncytial virus B	

(2) Bacteria and fungi

Acinetobacter baumannii	*Acholeplasma laidlawii*
Aspergillus niger	*Bordetella pertussis*
Burkholderia cepacia	*Candida albicans*
Chlamydophila pneumoniae	*Chlamydophila psittaci*
Chlamydia trachomatis D	*Chlamydia trachomatis* G
Chlamydia trachomatis F	*Enterococcus faecalis*
Enterococcus gallinarum	*Escherichia coli*
Haemophilus aphrophilus	*Kingella kingae*
Legionella anisa	*Legionella bozemanii*
Legionella dumoffii	*Legionella gormanii*
Legionella jordanis	*Legionella longbeachae*
Legionella micdadei	*Legionella pneumophila* SG 1
Legionella pneumophila SG 2	*Legionella pneumophila* SG 3
Legionella pneumophila SG 4	*Legionella pneumophila* SG 5
Legionella pneumophila SG 6	*Legionella pneumophila* SG 7
Legionella pneumophila SG 8	*Legionella pneumophila* SG 9
Legionella pneumophila SG 10	*Legionella pneumophila* SG 11
Legionella pneumophila SG 12	*Legionella pneumophila* SG 13
Legionella pneumophila SG 14	*Legionella pneumophila* SG 15
Listeria monocytogenes	*Moraxella catarrhalis*
Mycobacterium avium	*Mycobacterium fortuitum*
Mycobacterium kansasii	*Mycobacterium marinum*
Proteus mirabilis	*Proteus vulgaris*
Pseudomonas aeruginosa	*Serratia marcescens*
Staphylococcus aureus	*Staphylococcus epidermidis*
Streptococcus sp. Group A	*Streptococcus sp.* Group B
Streptococcus sp. Group C	*Streptococcus sp.* Group F
Streptococcus sp. Group G	*Streptococcus mutans*
Streptococcus mitis	*Streptococcus pneumoniae*
Streptococcus pneumoniae Type 1	*Streptococcus pneumoniae* Type 19F
Streptococcus pneumoniae Type 5A	*Streptococcus pyogenes*

INTERFERING SUBSTANCES OR DRUGS

The following over-the-counter drugs and prescription drugs were found to have no effect on the results at the concentrations indicated.

commercially available cold remedy (7.5 mg/mL); commercially available cough drop (40 mg/mL); 2 types of commercially available eye drops (0.25 mL/mL); 2 types of commercially available nose drops (0.025 mL/mL); commercially available gargle (0.025 mL/mL); commercially available mouthwash (0.25 mL/mL); zanamivir (500 ng/mL); amantadine hydrochloride (5 mg/mL); powdered Platycodon root (36 mg/mL); diphenhydramine hydrochloride (1 mg/mL); (R)-(-)-phenylephrine hydrochloride (1 mg/mL); erythromycin (5 mg/mL); minocycline hydrochloride (2 mg/mL); clarithromycin (20 mg/mL); acetylsalicylic acid (20 mg/mL); oxymetazoline hydrochloride (100 ng/mL).

INQUIRES

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GLOSSARY OF SYMBOLS

CE	CE Marking (European directive 98/79/EC on *in vitro* diagnostic medical devices)	EC REP	Authorized representative in the European Community
IVD	*In vitro* diagnostic medical device		Do not reuse
2℃ 30℃	Temperature limitation		Manufacturer/Manufactured by
	Use by YYYY-MM		Consult instructions for use
LOT	Batch code		Caution, consult accompanying documents.
REF	Catalog number		Keep away from sunlight
Σ n	Contents sufficient for <n> tests		Fragile, handle with care
	Open here		