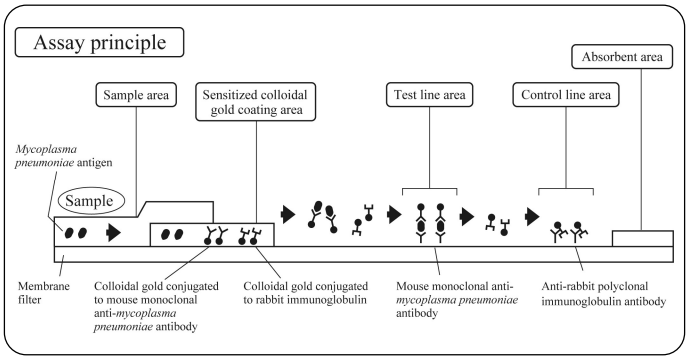
Read this Instructions for Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Mycoplasma pneumoniae antigen kit

Quick Chaser Myco



[Package]

68300: Quick Chaser Myco - 10 tests/kit

[Contents]

1) Test plate - 10 tests
   - Mouse monoclonal anti-*mycoplasma pneumoniae* antibodies
   - Colloidal gold conjugated to mouse monoclonal anti-*mycoplasma pneumoniae* antibodies
2) Extraction reagent solution vial – 0.6 mL×10 vials
   Extraction reagent solution is buffer containing detergent.
3) Swab (for pharyngeal swab specimen) - 10 pieces
4) Rack (for extraction reagent solution vial) - 1 piece
5) Filter (for extraction reagent solution vial) - 10 pieces
6) Blue cap (for temporary storage of extraction reagent solution vial) - 10 pieces
7) Name label for extraction reagent solution vial - 1 sheet

[Intended use]

For qualitative detection of *mycoplasma pneumoniae* antigen in pharyngeal swab specimen
(An aid in the diagnosis of *mycoplasma pneumoniae* infection)

[Principle of the test]

"Quick Chaser Myco" is the in vitro diagnostic reagent for qualitative detection of *mycoplasma pneumoniae* based on the immunochromatographic assay. Colloidal gold conjugated to mouse monoclonal anti-human *mycoplasma pneumoniae* antibodies and colloidal gold conjugated to rabbit immunoglobulins for control line are coated in sensitized colloidal gold coating area on a membrane filter which is set in test plate. Also, mouse monoclonal anti-human *mycoplasma pneumoniae* antibodies are immobilized in test line area, and anti- rabbit immunoglobulin polyclonal antibodies are immobilized in the control line area.

If *mycoplasma pneumoniae* antigens are present in the sample, according to the principle of immunochromatography, they react with colloidal gold conjugated to mouse monoclonal anti-human *mycoplasma pneumoniae* antibodies as they migrate from the sample area. Moreover, they are captured in the test line area by reacting with mouse monoclonal anti-human *mycoplasma pneumoniae* antibodies. As a result, a purple-red line with the colloidal gold appears in the test line area.

At the same time, the colloidal gold conjugated to rabbit immunoglobulins also migrate and will be captured by the anti-rabbit immunoglobulin polyclonal antibodies on the control line area, resulting in the appearance of a purple-red line in the control line area regardless of the presence or absence of *mycoplasma pneumoniae* antigens.

[Warnings and Precautions]

1) For in vitro diagnostic use only
2) Procedures not described in the Instructions for Use are not guaranteed.
3) Add fixed volume (3 drops) to the center of sample area from tip of filter about 10mm away from the sample area so as to make droplets. In case of adding other than fixed volume, an accurate reaction may not be performed.
4) Bring test plate and extraction reagent solution to 15 to 30°C prior to testing.
5) Strictly follow interpretation time to avoid false-negative and false-positive.
6) Sample (specimen) may contain infectious materials such as HIV, HBV, and HCV, etc. Handle sample (specimen) with great care as there is a risk of infection during the test.
7) When using, wear protective equipment (glasses, disposable gloves, mask, etc.) and be careful not to let the sample (specimen) or extraction reagent solution directly adhere to the skin or get into your eyes.
8) Do not collect the specimen with a swab soaked in the extraction reagent solution.
9) If a sample (specimen) or extraction reagent solution accidentally gets into your eyes or mouth, take first-aid measures such as rinsing it thoroughly with water and seek medical attention if necessary.
10) Blue cap included in the kit does not provide an airtight seal. Do not use it for purposes of transportation or preservation.
11) Perform the specimen collection under the guidance of a qualified person.
12) The material of the membrane used for the test plate is nitrocellulose. Do not perform tests near a fire as nitrocellulose is extremely flammable.
13) If the sample (specimen) spatters, wipe it off with alcohol for disinfection, etc.
14) Do not freeze this product. Store it in accordance with the description of storage. Do not use frozen reagents as they may change the quality and may not give correct results.
15) Do not use this product beyond the expiration date.
16) Do not store extraction reagent solution vial sideways or upside down.
17) Use extraction reagent solution included in this kit. Do not use extraction reagent solution in other kits.
18) Use the test plate immediately after opening aluminum foil pouch. If test plate is left in a room for a long period of time, it could not react by exposure to moisture.
19) Do not touch sample area, test line area and control line area by hands directly.
20) Do not perform test in the place such as under air conditioner where the dry wind directly blows the surface of the test plate to prevent uneven migration.
21) Do not use the reagent and the accessories etc. of this product for any purpose other than this test.
22) Test plate, swab and extraction reagent solution vial (including filter and caps) are intended for single use only.
23) Use swabs included in this kit.
24) Swabs included in this kit are for pharynges. Do not use it for other specimen collection sites such as eyes, ear, and the nasal cavity.
25) Do not touch spherical tip of swab before use.
26) Use swab immediately after opening the package.
27) Do not use a swab if a break and/or hole are found on the package.
28) Do not use a swab if stained, broken, or bent.
29) Do not bend and curve the rod of swab before collecting specimen.
30) Be careful not to break the rod of the swab or damage the collection site (mucous membrane) by applying too much force or pressing too hard when collecting stool from rectum.
31) After preparing the sample, be careful not to spatter the sample when

removing the swab.

32) If the amount of specimen collected is excessive or the specimen is highly viscose, the filter may become clogged, and adequate sample volume may not be dropped. In that case, collect a new specimen and perform the retest.

33) Handle liquid waste and used utensils by any of the following disinfection and sterilization methods as sample (specimen) may contain infectious material such as HIV, HBV, and HCV, etc.
   a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1,000 ppm) for 1 hour or longer
   b) Immerse in 2% glutaraldehyde solution for 1 hour or longer
   c) Autoclave at 121℃ for 20 minutes or longer

34) Regarding disposal of used reagents and utensils, dispose of them in accordance with the Local Regulation and Law of waste disposal.

[Storage and stability of the device]

Store kit at 1 to 30°C, out of direct sunlight or high humidity. Kit contents are stable until the expiration dates printed on the product box and packaging. Do not store upside down or sideways. Do not freeze.

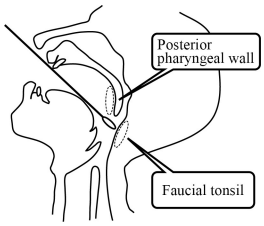
[Preparation of specimen collection]

1. Swab (for pharyngeal swab specimen): Use swab included in kit.
2. Extraction reagent solution: Use it without preparation.

[Specimen collection and handling]

Proper specimen collection and handling are critical to the performance of this kit.

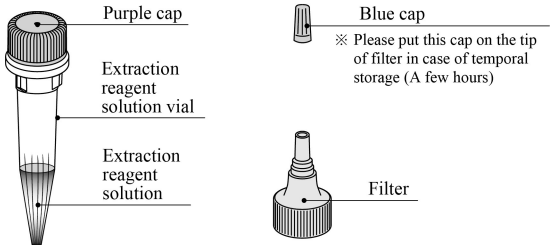
1. Pharyngeal swab specimen:
   Slowly insert swab from oral cavity into pharynx, and collect mucous membrane epidermis by rubbing the posterior pharyngeal wall or faucial tonsil several times.



Note) Enough antigens cannot be collected from upper respiratory tract because *mycoplasma pneumoniae* grows in lower respiratory tract.
The spherical tip should be placed close to the posterior wall of the pharynx to ensure contact with the area closer to the lower respiratory tract.
In addition, do not use swab for nasopharyngeal specimens as it may cause an insufficient collection of specimens.

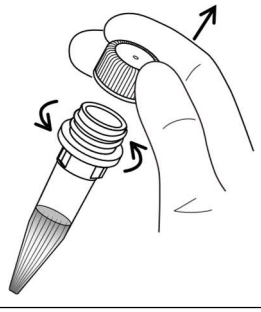
[Sample preparation and Test procedure]

· Details of extraction reagent solution vial

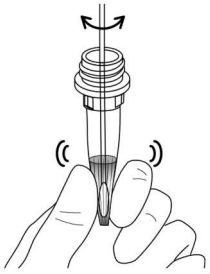


• Sample preparation

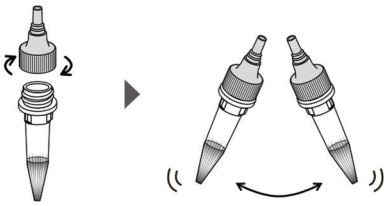
1. Loosen the purple cap by turning it counterclockwise.



2. Insert the spherical tip with the specimen into the bottom of the extraction reagent solution vial and press the spherical tip from the outside of the vial for extracting the specimen. Turn the swab clockwise and counterclockwise about five times and rub the spherical tip on the inside wall and the bottom of the vial. Squeeze out liquid from the spherical tip and take the swab out of the vial.

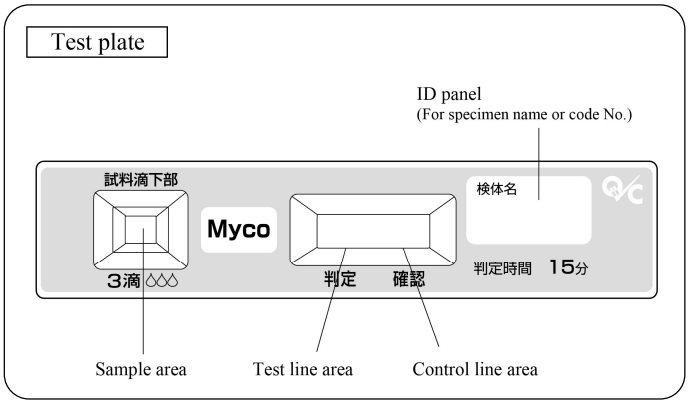


3. Install filter and shake the vial gently to mix specimen thoroughly. The sample is ready for use.



Samples should be tested as soon as possible. However, if specimens cannot be tested immediately, specimens extracted in the extraction reagent solution can be held at 2 to 8℃ for up to 24 hours. Do not use the filter and filter cap for the purposes of transportation or preservation as they do not provide an airtight seal. Bring samples to room temperature before testing.

· Details of test plate



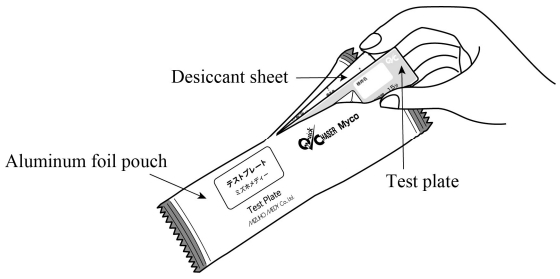
· Test procedure

1) Preparation of reagent

Test plate: No prior preparation required.

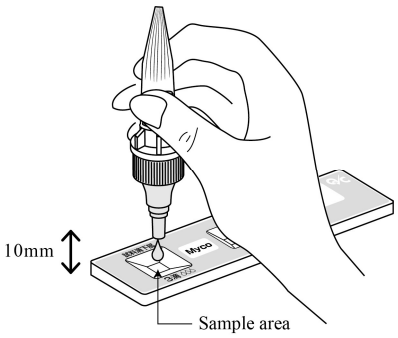
2) Test procedure

1.Remove the test plate from the aluminum foil pouch. Discard the desiccant sheet included in the aluminum foil pouch.



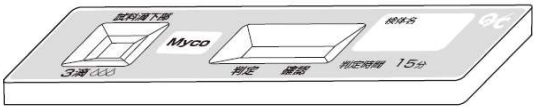
2. Add 3 drops (about 100 µL) of sample to the sample area of the test plate from the extraction reagent solution vial containing the prepared sample. Hold the vial vertically so that the tip of the extraction filter does not come into contact with the sample area of the test plate.

*Add the predetermined amount of sample from about 10 mm away from sample area



3. Leave to react at 15 to 30°C.

Interpret test results visually by reading lines in the test line area and control line area after 5 to 15 minutes.



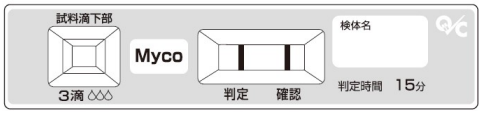
[Interpretation]

Interpretation by the existence of red-purple lines in the test line area and control line area.

<Positive>

Both test line and control line appear.

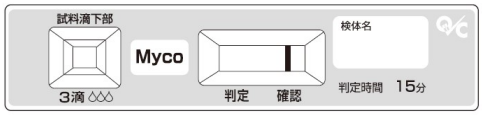
Positive



<Negative>

Only a control line appears.

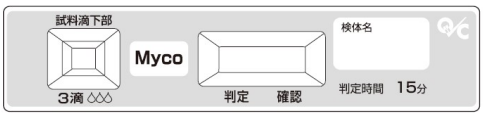
Negative



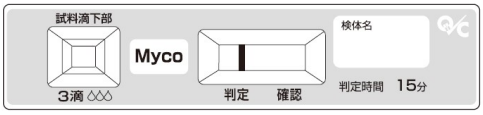
<Retest>

If both test line and control line do not appear or no control line appears, an operational error such as insufficient sample volume may be considered. Recheck test procedure and retest with the new test plate. If the same result comes out in the retest again, confirm it with other methods.

Retest



Retest



[Limitations]

1) The diagnosis of *mycoplasma pneumoniae* infection should not be based solely on the test results of this product but should be comprehensively made in consideration of other test results and clinical symptoms.

2) Do not use saliva and sputum as a specimen.

3) In case test line and control line appear at 5 to 15 minutes after dropping sample, it can be interpreted as positive. Negative should be interpreted at 15 minutes after dropping sample. The streak line might temporarily appear due to the flow of colloidal gold. Do not interpret the temporal streak line as appearance of test line. After 15 minutes, colloidal gold can appear like line due to drying of test plate with time. Therefore, interpret test results within 15 minutes.

4) This product is used as an aid in the diagnosis for infection of *mycoplasma pneumoniae*. In case that *mycoplasma pneumoniae* antigen amount in specimen is below the detection limit of the test or inadequate specimen collection, test result could be interpreted as negative, even though patients are infected by *mycoplasma pneumoniae*. In addition, a non-specific reaction may occur depending on the factors in the sample, and a negative specimen may be interpreted as positive. The final definitive diagnosis should be made comprehensively from clinical symptoms and other test results.

[Performance characteristics]

1) Performance

1. Sensitivity

When in-house positive control [note 1)] was tested, a positive result was obtained.

2. Accuracy

- When in-house positive control was tested, a positive result was obtained.
- When in-house negative control [note 2)] was tested, a negative result was obtained.

3. Reproducibility

- When in-house positive control was tested three times simultaneously, positive result was shown in all cases.
- When in-house negative control was tested three times simultaneously, negative result was shown in all cases.

Note 1) *Mycoplasma pneumoniae* purified antigen diluted with extraction reagent solution to be equivalent to 1.1×10^7 copies/mL of calibration reference material

Note 2) Extraction reagent solution

4. Detection limit

2.8×10^6 copies/mL

2) Correlations

Comparison with existing approved product (immunochromatographic assay)

Quick Chaser Myco

Other product		Positive	Negative	Total
	Positive	49	5[*1]	54
	Negative	2[*2]	117	119
	Total	51	122	173

Positive agreement rate: 90.7%(49/54)
Negative agreement rate : 98.3%(117/119)
Total agreement rate : 96.0%(166/173)

[*1] All five discrepant cases were negative with Real-time PCR method
[*2] Both discrepant cases were positive with Real-time PCR method

Comparison with Real time PCR method

Quick Chaser Myco

Real time PCR method		Positive	Negative	Total
	Positive	46	10	56
	Negative	0	67	67
	Total	46	77	123

Positive agreement rate : 82.1%(46/56)
Negative agreement rate : 100.0%(67/67)
Total agreement rate : 91.9%(113/123)

3) Calibration reference material (Standard material)

Mycoplasma pneumoniae antigen solution (in-house standard)

4) Interfering substances and medications

Following substances and blood did not interfere with the performance of this product at the concentration listed below.

Acetyl salicylate (5 mg/mL)	
Diphenhydramine hydrochloride (0.63mg/mL)	
Dextromethorphan hydrogen bromide (0.63 mg/mL)	
Cold medicine 1	Acetaminophen concentration (5 mg/mL)
Cold medicine 2	Ibuprofen concentration (2.5 mg/mL)
Nasal drop 1	containing Sodium cromoglicate, Chlorpheniramine maleate, Naphazoline hydrochloride (10%)
Nasal drop 2	containing Ketotifen fumarate (10%)
Gargle 1	containing Tincture of Myrrh (1 %)
Gargle 2	containing Povidone iodine (3 %)
Intraoral antiphlogistic	containing Sodium Azulene Sulfonate (10 %)
Cough drop 1	containing Di-potassium Glycyrrhizinate (20 mg/mL)
Cough drop 2	containing Nandina Fruit Extract (Dry) (10 mg/ml)
Cough drop 3	containing Cetylpyridinium chloride (20 mg/mL)
Blood (1%)	

5) Cross reactivity

Cross reactivity was not observed with the following viruses and bacteria.

・Other Mycoplasma

Mycoplasma fermentans	*Mycoplasma genitarium*
Mycoplasma orale	*Mycoplasma salivarium*
Mycoplasma buccale	*Mycoplasma hominis*
Mycoplasma faucium	*Mycoplasma penetrans*
Mycoplasma laidlawii	*Ureaplasma urealyticum*

・Bactria

Candia albicans	*Chlamydophila pneumoniae*
Chlamydia trachomatis	*Citrobacter freundii*
Enterobacter aerogenes	*Enterobacter cloacae*
Escherichia coli	*Haemophilus influenzae*
Klebsiella pneumoniae	*Listeria monocytogenes*
Legionella pneumophila	*Moraxella catarrhalis*
Proteus mirabilis	*Pseudomonas aeruginosa*
Serratia marcescens	*Staphylococcus aureus*
Staphylococcus epidermidis	*Streptococcus anginosus*
Streptococcus mutans	*Streptococcus pneumoniae*
Streptococcus pyogenes (group A)	*Streptococcus agalactiae* (group B)
Streptococcus (group C)	

・Viruses

Influenza A virus	Influenza B virus
Adenovirus Type 1	Adenovirus Type 2
Adenovirus Type 3	Adenovirus Type 4
Adenovirus Type 5	Adenovirus Type 7
Human Coronavirus	Coxsackie virus A9
Coxsackie virus B5	Human Echovirus 9
Herpes simplexvirus Type1	Human Metapneumovirus
Mumps virus	Parainfluenza virus 1
Rhinovirus 8	Respiratory Syncytial virus A
Respiratory Syncytial virus B	

[Shelf life]

24 months from the date of manufacture
(As indicated on the product box and packaging)

Technical information
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