AG MYCOPLASMA PNEUMONIAE Ag RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene – *Mycoplasma Pneumoniae* Ag Rapid Test Kit is a rapid and convenient immunochromatographic assay for the qualitative detection of *M. Pneumoniae* antigens from throat swab obtained from patient with signs and symptoms of respiratory infection. The device is designed to aid in the rapid diagnosis of *M. Pneumoniae* infection.

PRINCIPLE

AstraGene – *Mycoplasma Pneumoniae* Ag Rapid Test Kit is an antigen-capture immunochromatographic assay, detecting presence of *M.pneumoniae* antigen in throat swab samples. This assay utilizes the chemical extraction of viral antigens followed by solid-phase immunoassay technology for the detection of extracted antigen *M.pneumoniae*. Monoclonal antibodies specifically against *M.pneumoniae* antigen are conjugated with colloidal gold and deposited on the conjugate pad, and immobilized on the Test Zone on the nitrocellulose membrane. When a sample is added, the gold-antibody conjugate is rehydrated and the *M.pneumoniae* antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone where they will be captured by immobilized antibodies, forming a visible pink line (Test band) indicative of positive results. If *M.pneumoniae* antigen are absent in the sample, no pink line will appear in the Test Zone (T).

To serve as an internal process control, a control band was designed to indicate that the test is performed properly. By utilizing the different antigen/antibody reaction, this control line should always be seen after test is completed. Absence of a pink control line in the control region is an indication of an invalid result.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassettes with desiccant	10	1
Extraction tubes with buffer and tips	10	1
Sterile Swab	10	1
IFU	1	1

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/MPAg/24/01	AG/RTK/MPAg/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Disposable Gloves
- Pipette

STORAGE &STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date.
- Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

- Throat Swab Sample (for optimal test performance with a Swab specimen, use the Swabs supplied in the kit)
- **Throat Swabbing**: Insert the sterilized swab deeply into the throat and swab several times to collect tthe epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.

PROCEDURE

Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

A) Add 400 ul reagent solution (approximately12 drops) into the reagent tube.	
B) Add throat swab to the tube with reagent solution.	
C) Vigorously rotate and twist the swab against the side of the tube at least 10 times.	

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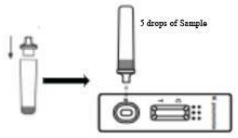
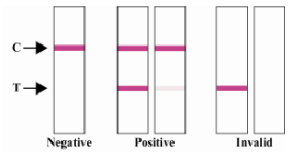
D) Squeeze the sides of the tube to obtain as much liquid as possible. Dispose of swab properly.	
E) Apply the cap to the tubes with specimen, and hold the tube vertically, add 5 drops (about120 µl) of the specimen without air bubbles into the sample well. *Note: For condensed samples, if the sample does not migrate to the membrane within 20 seconds, to apply one to two more drops of reagent solution to help the sample migrate onthe membrane. Read results at 15 minutes.	 Note: DO NOT INTERPRET RESULTS AFTER 30 MINUTES 

RESULT INTERPRETATIONS



Negative A pink colored band appears only at the control region (C), indicating a negative result.
Positive A clear pink control band (C) and a detectable test band T appears, indicating a positive result.
Invalid No visible band appears at the control region. Repeat with a new test kit. If the test still fails, please contact the distributor with the lot number.

LIMITATION OF THE PROCEDURE

- The contents of this kit are to be used for the qualitative detection of *M.pneumoniae* antigen from throat swab specimens.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.
- Test Results must be evaluated in conjunction with other clinical data available to the physician.
- Negative test results do not rule-out possible other non-*M.pneumoniae* infections.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not identify specific *M.pneumoniae* subtypes.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials or performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.

- Keep out of children's reach.

SYMBOLS

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

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