AG Mycoplasma IgG& IgM RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene – Mycoplasma IgG & IgM Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to *Mycoplasma pneumoniae* in whole blood, serum, or plasma to aid in the diagnosis of *Mycoplasma pneumoniae* infection.

PRINCIPLE

AstraGene – Mycoplasma IgG & IgM Rapid Test Kit is a qualitative membrane-based immunoassay for the detection of Mycoplasma pneumoniae IgG and IgM antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG or IgM is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with Mycoplasma pneumoniae antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG or IgM. If the specimen contains Mycoplasma pneumoniae IgG and/or IgM antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain Mycoplasma pneumoniae antibodies, a colored line will not appear in this region indicating 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.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassettes with desiccant	10	1
Dropper	10	1
Buffer	1×2.0mL	1×0.20mL
IFU	1	1

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

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Disposable Gloves
- Specimen collection containers
- Lancets
- Centrifuge

STORAGE &STABILITY

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

SPECIMEN COLLECTION & PREPARATION

- AstraGene – Mycoplasma IgG & IgM Rapid Test Kit can be performed using whole blood (from venipuncture or fingerstick) serum or plasma.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect Fingerstick Whole Blood specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20 °C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically, draw the specimen (Whole blood/Serum/Plasma) up to the Fill Line as shown in illustration below (approximately 10 µL). Transfer the specimen to the sample well (S) each, then hold the buffer bottle vertically and add 2 drops of buffer (approximately 80 µL) to the sample well (S) each, and start the timer. See the illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret results after 20 minutes.

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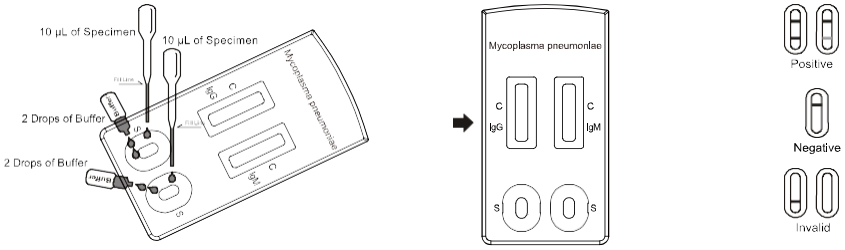

RESULT INTERPRETATIONS

- **POSITIVE:*** Two colored lines appear. One line should be in the control region (C) and another line should be in the test region (T).
  *NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of anti-TB antibodies present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.
- **NEGATIVE**: One colored line appears in the control region (C). No colored line appears in the test region (T).
- **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATION OF THE PROCEDURE

- This reagent is designed for the qualitative screening test. Concentration of MP-IgG and/or MP-IgM cannot be determined by this qualitative test.
- Negative result may occur when detecting short-term infected specimens or window period specimens, indicate that the specific antibodies of MP does not exist or the concentration is below detection limit.
- The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
- Abnormal results may occur according to operator error or drug use. If AIDS is still suspected, a specimen should be collected later and tested again.

SENSITIVITY & SPECIFICITY

AstraGene – Mycoplasma IgG & IgM Rapid Test Kit was compared with commercial M.pneumonia rapid test cassette; the results show :

For IgG:

Relative Sensitivity: 92.4% (95%CI*: 86.1%-96.5%) ; Relatively Specificity: 94.1% (95%CI*: 91.2%-96.3%) ; Accuracy: 93.7% (95%CI*: 91.2%-95.7%) *Confidence Interval

For IgM:

Relative Sensitivity: 95.0% (95%CI*: 89.5%-98.2%) ; Relatively Specificity: 96.0% (95%CI*: 93.5%-97.7%) ; Accuracy: 95.8% (95%CI*: 93.6%-97.4%) *Confidence Interval

WARNING AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if the package is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.

SYMBOLS

Do not use if package is damaged Manufacturer LOT Batch Code

CE mark of Conformity Refer to the instructions ISO 13485:2016 ISO GMP

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