Mycoplasma Pneumoniae Antigen Rapid Test Cassette (Throat Swab)

Mycoplasma Pneumoniae Antigen Rapid Test Cassette is a rapid immunochromatographic assay for the qualitative detection of Mycoplasma pneumoniae antigens in human throat swabs. It is intended to aid in the rapid differential diagnosis of Mycoplasma pneumoniae infections.

**SUMMARY**

M. pneumoniae is one of three species of Mycoplasma that frequently cause infection in humans. M. pneumoniae most commonly causes upper respiratory tract infections, but can also cause pneumonia. The identification of M. pneumoniae will help the administration of the disease with appropriate antibiotic treatment. This M. pneumoniae immunoassay is intended to detect M. pneumoniae antigen qualitatively. Because this one-step M. pneumoniae rapid test is easy to carry out, it is widely used as a screening test device and as an aid in the diagnostics of M. pneumoniae disease.

**PRINCIPLE**

The Mycoplasma Pneumoniae Antigen Rapid Test Cassette a qualitative, lateral flow immunochromatographic assay for the detection of M. pneumoniae antigen in throat swab. In this test, antibody specific to M. pneumoniae antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to M. pneumoniae that is coated onto particles. The mixture migrates on the membrane to react with the antibody to M. pneumoniae on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates 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.

**REAGENTS**

The test cassette contains Mycoplasma pneumoniae antibodies coated on the membrane.

**PRECAUTION**

Read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- If the M. pneumoniae antigen rapid test was kept refrigerated, let all the reagents warm up to room temperature (15°C - 30°C) before proceeding with the test.
- Wear gloves when handling the samples, avoid touching the reagent membrane with your fingers.
- Discard gloves, swabs, test tubes, and test devices in accordance with the local regulation.
- Visibly bloody sample should not be used for the testing.

**STORAGE AND STABILITY**

Store the Mycoplasma pneumoniae antigen rapid test kit at room temperature or refrigerated (2-8°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

**SPECIMEN COLLECTION AND PREPARATION**

It is applicable to the diagnosis of the Mycoplasma pneumoniae from the samples of throat swabs. Use freshly collected samples for optimal test performance. 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 mucous. Caution has to be paid to avoid the swab to be contaminated with saliva.
  - Insert the swab into the Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab. Remove the swab. The extracted solution will be used as test sample.

**MATERIALS**

- Test Cassettes
- Sterilized Swabs
- Sample Extraction Buffer
- Tube Tips
- Work Station
- Extraction Tubes

**DIRECTIONS FOR USE**

Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution (Approx. 50μl) to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the Extraction Tube and put the swab into the collection tube. Discard the swab in accordance with your biohazard waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4.
6. Add three drops of the solution (approx.120μl) to the sample well and then start the timer. Read the result at 15 minutes. Do not interpret the result after 20 minutes.

**RESULT INTERPRETATION**

**POSITIVE:** Two colored lines appear. One colored line appears in the control region(C), and one colored line in the test region(T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.

**NEGATIVE:** Only one colored line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no M. pneumoniae in the sample or the number of M. pneumoniae is below the detectable range.

**INVALID:** No line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact the Manufacturer.

**LIMITATION**

1. Mycoplasma pneumoniae antigen rapid test cassette is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with M. pneumoniae.
2. Mycoplasma pneumoniae antigen rapid test cassette detects both viable and non-viable M. pneumoniae antigen. Test performance depends on antigen load in the sample, a positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3. Performance of the test has not been established for monitoring antiviral treatment of M. pneumoniae.

**EXPECTED VALUES**

The Mycoplasma Pneumoniae Antigen Rapid Test Cassette (Throat Swab) has been compared with a leading commercial PCR test. The correlation between these two systems is over 98%.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity, Specificity and Accuracy**

The Mycoplasma Pneumoniae Antigen Rapid Test Cassette (Throat Swab) has been evaluated with specimens obtained from the patients. PCR is used as the reference method for the Mycoplasma Pneumoniae Antigen Rapid Test Cassette (Throat Swab). Specimens were considered positive if PCR indicated a positive result. Specimens were considered negative if PCR indicated a negative result.