



Asan Easy Test[®] Myco Ag

Diagnostic Kit for *M.pneumoniae* Antigens from human throat swab

IVD

Immunochromatography

EXPLANATION OF THE TEST

The Asan Easy Test[®] Myco Ag is a chromatographic immunoassay kit for rapid and qualitative detection of *Mycoplasma pneumoniae*(*M. pneumoniae*) antigens from throat swab specimens. *M. pneumoniae* specific antibody with gold conjugate is placed in the conjugate pad, and coated on the test line region of the test. During the test, the extracted throat swab specimen reacts with an antibody to *M. pneumoniae* that is coated onto particles. The mixture migrates up 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 coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

Asan Easy Test[®] Myco Ag contains the following items to perform the assay.

1. Test device in aluminum pouch with a desiccant.
2. Extraction solution tubes (0.4ml/tube).
3. Sample collection swabs.
4. Disposable droppers.
5. Instruction manual for use.

PRECAUTIONS

1. For *in-vitro* diagnostic use only.
2. The test kit should remain in the sealed pouch until ready for use.
3. The test kit is sensitive to humidity and to heat.
4. Do not smoke, eat or drink in areas where specimens or kit component are handled.
5. All specimens and reagents should be considered potentially hazardous and handled in the same manner as an infection agent.
6. Wear protective gloves while handling samples and wash hands thoroughly after the assay is complete.
7. Avoid any contact with the eyes, broken skin or mucous membranes.
8. The test strip and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

1. Specimen collection

Throat swab specimen:
To collect a throat swab specimen, deeply insert the sterilized swab and vigorously rub it on both tonsillar surfaces and the posterior pharynx. Caution had to be paid to avoid the swab to be contaminated with saliva.

2. Specimen storage

Specimens must be tested as soon as they are collected. If necessary, they may be stored at room temperature(1~30 °C), in a clean, dry, closed container for up to 8 hours, or refrigerated(2~8 °C) for up to 24hours prior to testing.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature (15~25 °C) before performing the test.
2. Place the specimen swab into the tube containing extraction solution and swirl the swab at least 8~10 times while pressing the head against the inside of the tube to release the antigen in the swab.
3. Discard the swab squeezing against the wall of tube, as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
4. Add three drops of the solution (80~100 µl) to the sample well(S) and read the result at 15minutes. Do not read after 20minutes.

INTERPRETATION OF THE TEST

A. Negative result:

The presence of only one red color band ("C" band) within the result window indicates a negative result.



B. Positive result:

The presence of two red color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.



C. Invalid result:

If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.



STORAGE & EXPIRATION

1. Asan Easy Test[®] Myco Ag Kit should be stored at 1 to 30 °C (33.8~86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

LIMITATIONS OF RESULTS

Asan Easy Test[®] Myco Ag is designed for primary screening test. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.



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A. Specimen collection B. Test Procedure

