



Asan Easy Test[®] Myco Ag (F)

M.pneumoniae Antigens test kit of immunofluorescence assay

IVD

Immunochromatography

EXPLANATION OF THE TEST

Mycoplasma pneumoniae (*M. pneumoniae*), which causes pneumonia, is infected by attaching it to the epithelial cells of the airways due to droplet infection through the respiratory tract. Particularly in children, asthma is exacerbated as well as respiratory diseases such as pneumonia, throat, bronchitis, sinusitis and laryngitis. In addition, it can cause various complications such as nervous system, skin lesion, cardiovascular system, musculoskeletal system, urinary system, digestive system, etc.

The Asan Easy Test[®] Myco Ag (F) kit is a immunofluorescence assay kit for rapid and qualitative detection of *Mycoplasma pneumoniae*(*M. pneumoniae*) antigens from throat swab specimens.

The monoclonal anti-mycoplasma virus antibody is immobilized on the test strip of the nitrocellulose membrane. When a sample dilution buffer is developed on the test device, the antigen of the mycoplasma virus existing in the inside is firstly immune reacted with the anti-mycoplasma virus antibody fluorescent conjugate. This primary complex reacts with the anti-mycoplasma antibody immobilized on the membrane to form a secondary immuno reactivity, which results in the appearance of a fluorescent band on the test line. The result is read out using a fluorescence analyzer.

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. Dropper filter tip.
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 device and all materials should be discarded in a proper biohazard container after testing.

SPECIMEN COLLECTION AND STORAGE

Specimens should be obtained and handled by trained or professional technician, as there are unknown infectibility.

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 refrigerated(2~8 °C), in a clean, dry, closed container for up to 24 hours, or freezer(-20 °C) for up to 48hours prior to testing.

TEST PROCEDURE

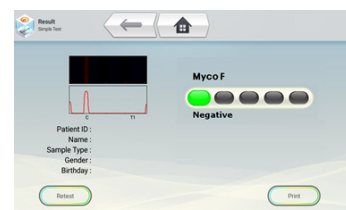
1. All materials should be equilibrated to room temperature (15~25 °C) before performing the test.
2. Place the specimen swab into the tube containing extraction solution and swirl the swab at least 8~10 times while pressing the head against the inside of the tube to release the antigen in the swab.
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. Insert dropper filter into tube and add three drops of the solution (80~100 μl) to the sample well(S).
5. Read the result at 20minutes refer to manual of fluorescence analyzer (ASAN EASY CHECK F-100).
6. As the reaction time increases, the degree of fluorescence emission of the control line and the test line can be narrowed. Therefore, it is more accurate to read the result at a constant time after the reaction starts. If reaction time is long, non-specific reactions may occur, so do not read the results after 20minutes.

INTERPRETATION OF THE TEST

The EASY CHECK F-100 will display positive or negative results on the screen as per test lines which are fluorescent, cannot be seen with the naked eye.

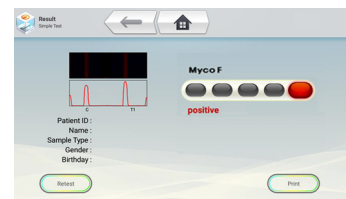
A. Negative result:

The presence of only one fluorescent band (C). The screen show Myco Ag is a negative result.



B. Positive result:

The presence of two fluorescent bands (T and C). The screen show positive result (Strong, Moderate, Weak positive)



C. Invalid result:

If no fluorescent band is visible in the result window or presence of one fluorescent band (T), 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.



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A. Specimen collection B. Test Procedure

