



Asan Easy Test[®] Strep A (F)

Group A Streptococcal antigen detection kit of immunofluorescence assay

IVD

Immunochromatography

EXPLANATION OF TEST

Group A streptococcus causes tonsillitis, sore throat, and scarlet fever. The Asan Easy Test Streptococcus (F) Kit is a diagnostic reagent that can detect Group A streptococcus from the nasopharyngeal secretions of patients using fluorescence immunochromatography.

On the test line of the nitrocellulose membrane, goat anti-Strep A antibodies that react specifically with Group A streptococcal antigens are dispensed, and anti-Strep A antibodies of rabbits are conjugated to fluorescence, and therefore, group A streptococcal antigens may be present in the specimen. In this case, the immune reaction is first performed with the antibody conjugated to the fluorescence, and the group A streptococcal-fluorescent conjugate proceeds along the membrane and secondly with the antibody distributed on the membrane. That result is then read as positive using a fluorescence analyzer.

MATERIALS PROVIDED

Asan Easy Test[®] Strep A (F) contains the following items to perform the assay.

1. Test device in aluminum pouch with a desiccant.
2. Extraction solution A (10ml/vial).
3. Extraction solution B (10ml/vial).
4. Sample collection swabs.
5. Sample extraction tubes.
6. Disposable droppers.
7. 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) The sample uses throat secretions collected by a skilled or professional technician.
- 2) Using a specimen collect swab included in the kit, insert a specimen collect swab on the tonsil surface of the throat inner wall or the inside of the throat and spin it slowly to extract enough secretion to see.
- 3) Samples should be used at fresh status, if possible, immediately after they are collected. If the specimens cannot be inspected immediately, they should be placed in a container with a lid within 24 hours of refrigerated storage (2 ~ 8 °C) and in the frozen storage (-20 °C), it must be used within 48 hours.

PREPARATION BEFORE TEST

- 1) Preparation for analyzer
Please refer to our Easy Check F-100 manual to prepare analyzer.

- 2) Preparation for specimen and solution
Keep unused test devices, specimen extract buffers and specimen at room temperature and shake lightly before use. The test temperature is most suitable at room temperature (15 ~ 25 °C). If the reagents are stored at room temperature, they can be used immediately.

TEST PROCEDURE

- 1) Add 3 drops (90µl) of Extraction Solution A and Extraction Solution B each to a specimen extraction tube.
- 2) Place the specimen swab from patient nasal or throat into the tube and swirl the swab enough to be extracted at least 10 times.
- 3) The extracted swap is removed by rotating it along the wall of the test tube. In this process, the loss of the extraction solution on the swap is minimized.
- 4) Used swaps are classified as infectious waste and disposed of safely.
- 5) The device is removed from the aluminum pouch, and 3 drops (90-100 µl) are added to the test specimen dropping whole by a dropper for reaction.
- 6) After 5mins Read the test result referring to fluorescent analyzer manual.
- 7) As the reaction time increases, the degree of fluorescence emission from the control line and the inspection line can be amplification, so it is more accurate to judge the judgment at a certain time after the start of the reaction. Long-term reactions may cause non-specific reactions, so results after 20 minutes are not used for judgment.

INTERPRETATION OF THE TEST

Either this product may have a fluorescent band on the test line or not, and it is depending on the presence or absence of Group A streptococcus antigens in the specimen. Depending on the presence or absence of a fluorescence band on this test line, positive and negative are displayed on the monitor of the fluorescence analyzer.

A. Negative result:

The presence of only one fluorescent band (C). The screen shows Strep A(F) is a negative result.



B. Positive result:

The presence of two fluorescent bands (T and C). The screen shows Strep A(F) is a positive result.



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[®] Strep A(F) 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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Code No.: 22496
Document Code: STPAFG0-STE00

A. Specimen collection

B. Test Procedure

