



Asan Easy Test[®] Strep A

Diagnostic Kit for Strep A Antigen Detection

IVD

Immunochromatography

INTRODUCTION

Beta-haemolytic group A Streptococcus is a major cause of upper respiratory infections in humans. The most commonly occurring group A Streptococcal disease is pharyngitis. Early diagnosis and treatment of group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications such as rheumatic fever and glomerulo-nephritis. Conventional methods used for the identification of group A Streptococci depend on the isolation and subsequent identification of the organisms. These methods of identification require 18-24 hours to complete. Historically physicians experienced delay in obtaining a laboratory diagnosis of streptococcal group A infections, often administering therapy to acute throat infections without knowing the etiological agent. Immunological techniques which can detect group A Streptococcal antigen directly from throat swabs have now been developed. By the elimination of the lengthy culture procedure, rapid test results may be achieved.

EXPLANATION OF THE TEST

The Asan Easy Test[®] Strep A is a chromatographic immunoassay kit for rapid and qualitative detection of group A Streptococcal antigen from throat swabs. The test detects bacterial antigen and may therefore detect from swab organisms which may fail to grow on culture. The extracted antigen is transferred to sample pad, it moves through the conjugate pad and mobilizes gold anti-Strep A polyclonal antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-Strep A polyclonal antibody that is coated on the test region. If Strep A antigen is present, the result is the formation of a colored band in the test region. If Strep A antigen is lower than detection level in the sample, the area will remain colorless. The sample continues to move to the control area where Goat anti-rabbit IgG antibody will capture gold antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.

MATERIALS PROVIDED

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

1. Test strip in aluminum pouch with a desiccant.
2. Extraction Solution A (15ml/vial).
3. Extraction Solution B (15ml/vial).
4. Sample collection swabs.
5. Sample extraction tubes.
6. 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

Specimens should be obtained and handled by standard throat swab collection methods. It is preferable to use dacron-tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate or wooden shafted swabs.

2. Specimen storage

Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8 °C for up to 24hours.

NOTE: To use Asan Easy Test[®] Strep A as a culture confirmation test, remove an isolated beta-haemolytic colony from the culture plate with a clean swab. Then, proceed as described in below.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature (2~30 °C) before performing the test.
2. Add 3 drops (150 μ l) of Extraction Solution A and Extraction Solution B each to a sample extraction tube.
3. Place the specimen swab into the tube and swirl the swab at least 10times.
4. Keep the swab in the tube for 2~10 minutes, but no longer than 10 minutes.
5. Discard the swab squeezing against the wall of tube.
6. Immerse the test strip in the tube in the direction indicated by the arrow. (**NOTE:** Care should be taken not to contact solution or specimen with test line on the strip)
7. Let them react for 15minutes and read the result.

EXPECTED RESULTS

It is believed that approximately 19% of all upper respiratory tract infections are caused by group A streptococci. Streptococcal pharyngitis is most prevalent in winter and early spring and the highest incidence of disease occurs in crowded populations such as school children. Males and females are equally affected by group A Streptococcal infection.

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.



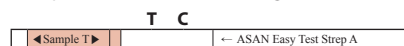
B. Positive result:

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[®] Strep A Kit should be stored at 2 to 30 °C (35.6~86 °F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

The performance of Asan Easy Test[®] Strep A has been determined in a multi-centre clinical evaluation. It was performed using a total of 195 specimens. Each specimen was tested with Asan Easy Test[®] Strep A and throat culture. The results are summarized in the following tables.

n= 195		Throat culture		Total
		Positive	Negative	
Asan Easy Test [®] Strep A	Positive	89	0	89
	Negative	3	103	106
Total		92	103	195

※ Relative Sensitivity : 96.7 %, Relative Specificity : >99%

※ Detection limit : 3.9 x 10⁵CFU/ml

LIMITATIONS OF RESULTS

Asan Easy Test[®] Strep A is for use only with throat swabs or colonies taken from culture plates. The performance of the test with swabs taken from other sources or with other samples such as saliva or urine has not been established. The test does not differentiate between carriers and infected individuals. Pharyngitis may be caused by other organisms beside group A streptococci. Negative results may be obtained when the amount of extracted antigen is below the sensitivity of the test. False negatives may result from improperly taken samples.

Additional follow-up testing using the culture method is required if the Asan Easy Test[®] Strep A result is negative and clinical symptoms persist.

Do not use Test Units which have become wet or which have been left out of the foil pouch more than 24 hours.



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