IVD

Asan Easy Test® RSV

Diagnostic kit for respiratory syncytial virus antigen

Immunochromatography

EXPLANATION OF THE TEST

The Asan Easy Test® RSV is a chromatographic immunoassay kit for rapid and qualitative detection of respiratory syncytial virus (RSV) infection from Nasopharyngeal swabs or aspirates. A nitrocellulose membrane is immobilized with a monoclonal antibody against the F protein of the RSV. Another anti-RSV-F-monoclonal antibody is conjugated to colloidal gold particles. This conjugate is placed on a polyester pad as conjugate pad. This test is aimed to the detection of RSV in nasopharyngeal swabs or aspirates after several days in order to reach a better sensitivity.

When the strip is dipped into the extraction solution of sample, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the anti-RSV antibody that it adsorbed onto the nitrocellulose. The result is visible after extraction period within 10~15 minutes in the form of a red line that develops on the strip. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line.

MATERIALS PROVIDED

Asan Easy Test® RSV contains the following items to perform the assay.

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

Specimens should be obtained and handled by standard methods for the collection of nasopharyngeal swab and aspirate

A. Nasopharyngeal swab:

1. Sterile swab is inserted into one or both nostrils to nasopharyngeal area and gently rotated against nasopharyngeal inside wall to collect specimen as much as possible.
2. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8℃ for up to 24 hours.

B. Nasopharyngeal aspirate:

1. Nasopharyngeal aspirate should be collected by a specialist using a mucus trap and a catheter.
2. Specimens must be tested as soon as they are collected. If necessary, they may be stored at 2~8℃ for up to 48hours or at -20℃ for longer periods.

(**NOTE :** It is strongly recommended to avoid the use of sputum)

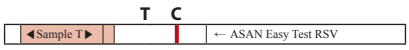
TEST PROCEDURE

1. All materials should be equilibrated to room temperature (4~30℃) before performing the test.
2. Prepare sample collection swabs and sample extraction tubes as you need.
3. a. Nasopharyngeal swabs:
   Add 300㎕ of extraction solution (up to 2nd marked in the dropper) to extraction tube. Swirl the swab at least 10 times in the tube and then discard the swabs squeezing against the wall of the extraction tube .
   b. Nasopharyngeal aspirates:
   Mix 150㎕ of aspirates with 150㎕ of extraction solution in the extraction tube.
4. Remove the test strip from the its protective pouch.
5. 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)
6. Let them react for 15minutes and read the result. Do not interpret test result after 15minutes.

INTERPRETATION OF THE TEST

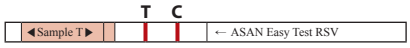
A. Negative result:

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



B. Positive result:

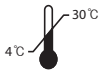
The presence of two red color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result.



C. Invalid result:

If no band is visible within the result 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® RSV should be stored at 4 ~ 30℃ (39.2 ~ 86 ˚F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

This clinical test was performed using a total of 210 specimens. Each specimen was tested with Asan Easy Test® RSV and culture method. The results are summarized in the following tables.

n=210		Culture method		Total
		Positive	Negative	
Asan Easy Test® RSV	Positive	106	0	106
	Negative	2	102	104
Total		108	102	210

※ Relative Sensitivity : 98.1%, Relative Specificity : >99%

LIMITATIONS OF THE RESULTS

Asan Easy Test® RSV 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.

REFERENCES

1. Ahluwalla, G.J Embree, P.McNicol, B. Law, and G.W Hammond. 1987. J. Clin. Microbiol. 257:763-767.
2. Mlinarc-Galinovic G, Falsey AR, Walsh EE. 1996. Eur. J. Clin. Microbiol Infect. Dis. 15:777-781.

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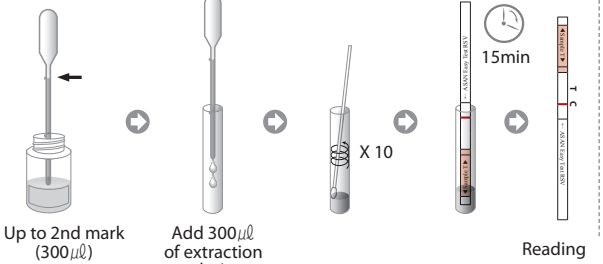
A. Nasopharyngeal swab:



B. Nasopharyngeal aspirate: