IVD

Asan Easy Test® Influenza A/B

ASAN

Diagnostic Kit for Influenza Virus Type A/B Antigens

Immunochromatography

EXPLANATION OF THE TEST

The Asan Easy Test® Influenza A/B is a chromatographic immunoassay kit for rapid, qualitative, and differential detection of influenza virus type A and type B (Not type C) infection from nasal or throat swab specimens. Antigens of influenza virus type A and type B in the specimens are allowed to react with the anti-influenza A and anti-influenza B monoclonal antibody-coupled gold conjugate followed by reaction with anti-influenza A or anti-influenza B monoclonal antibodies immobilized in the test lines. When the sample contains influenza virus A and B, a visible line appears in the test region on the membrane. Asan Easy Test® is also very useful to directly and differentially detect influenza Virus (A/B) from nasal swab of human and, avian flu (H5N1) and swine flu (H1N1) with a high accuracy.

MATERIALS PROVIDED

Asan Easy Test® Influenza A/B contains the following items to perform the assay.

1. Test strip in aluminum pouch with a desiccant.
2. Extraction Solution (0.3㎖/tube).
3. Sample collection swabs.
4. Instruction manual for use.
5. Control swab (optional);

Influenza A positive control swab (1): Inactivated Flu A (H_1N_1, H_3N_2).
Influenza B positive control swab (1): Inactivated Flu B (Lee 40).
Influenza negative control swab (1): Inactivated S. pyogenes.

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

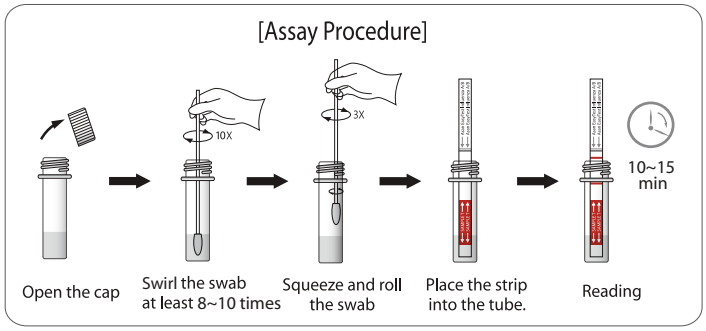
A. Nasal swab specimen:
To collect a nasal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.
B. Throat swab specimen:
To collect a throat swab specimen, vigorously rub the sterile swab on both tonsillar surfaces and the posterior pharynx.

2. Specimen storage

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

TEST PROCEDURE

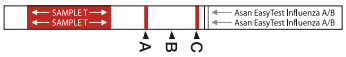
1. All materials should be equilibrated to room temperature (15~25 ℃) before performing the test.
2. Pleace the specimen swab into the tube containing 300㎕ of extraction solution and swirl the swab at least 8~10 times.
3. Discard the swab squeezing against the wall of tube.
4. Immerse the test strip in the tube in the direction indicated by the arrow.
5. Let them react for 10~15minutes and read the result. Do read after 20minutes.



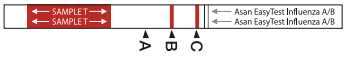
INTERPRETATION OF THE TEST

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

B. Positive result:
-Positive for influenza virus type A: The presence of two red color bands ("A" band and "C" band) within the result window.



-Positive for influenza virus type B: The presence of two red color bands ("B" band and "C" band) within the result window.



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.

QUALITY CONTROL

1. Control procedures: Positive and Negative control swabs should be tested according to the TEST PROCEDURE. (**NOTE**: Put into the extraction solution for 30 seconds before swirling. Because they have been preserved at dry state.)
2. Specification

- Influenza A positive control swab should be interpreted as test line (A) positive.
- Influenza B positive control swab should be interpreted as test line (B) positive.
- Influenza negative control swab should be interpreted as negative.

STORAGE & EXPIRATION

1. Asan Easy Test® Influenza A/B Kit should be stored at 1 to 30℃ (33.8~86 ˚F).
2. Expiration date of this kit is 24 months after its manufacture date.

PERFORMANCE CHARACTERISTICS

Multi-site studies were performed using a total of 271 specimens. Each specimen was tested with Asan Easy Test® Influenza A/B and Real-Time RT-PCR/RT-PCR. The results are summarized in the following tables.

n= 271			Real-Time RT-PCR/RT-PCR			Total
			Positive		Negative	
			Type A	Type B		
Asan Easy Test® Influenza A/B	Positive	Type A	53	0	0	53
		Type B	0	52	0	52
	Negative		4	5	157	166
Total			57	57	157	271

※ Relative Sensitivity : 93.0% (Type A), 91.2% (Type B)
Relative Specificity : 98.1% (Type A), 100% (Type B)

LIMITATIONS OF RESULTS

Asan Easy Test® Influenza A/B 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. Murphy, B.R., and R.G. Webster. 1996. Orthomyxoviruses, pp. 1397-1445. In: Fields' Virology, 3rd deition, B.N. Fields, D.M. Knipe, P.M. Howley, et al. (eds.), Lippincott-Raven, Philadelphia.
2. Comparison of lateral-flow immunoassay and enzyme immunoassay with viral culture for rapid detection of influenza virus in nasal wash specimens from children. 2003. J. Microbiol. 41(5), p2132-2134.

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