


Clinical Evaluation Report for GenBody Influenza A/B Ag Rapid Test

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1. Objective

Clinical evaluation of GenBody Influenza A/B Ag Rapid Test for detection of Influenza A and B virus antigen in terms of sensitivity and specificity compared to a commercial kit on the market.

2. Samples

- A) Patient Group: Patients from Korea University Guro Hospital, who showed influenza-like symptoms and agreed to additional clinical tests.
- B) Sampling and Storage Method: Patients' nasopharyngeal swab specimen were tested with RT-PCR for confirmation. The samples were transported and stored in virus transport medium (VTM) and remaining samples were stored in -70°C.

3. Evaluation Method

- A) Product: GenBody Influenza A/B Ag
Manufacturer: GenBody Inc.

To test with GenBody Influenza A/B Ag, mix the specimen in extraction solution and drop 3~4 drops (100ul) into the sample well. Read the results in 5~10 minutes. Testing is conducted according to the instruction manual of use.

- B) Product: Asan Easy Test® Influenza A/B
Manufacturer: Asan Pharm. Co., ltd.

To test with Asan Easy Test Influenza A/B, mix the specimen in extraction solution and place the test strip into the solution. Read the results in 10~15 minutes. Testing is conducted according to the instruction manual of use.

- C) Product: Anyplex TM II RV16 Detection
Manufacturer: Seegene Inc.

To test with Seegene Anyplex II, use the specimen to extract mRNA, convert to cDNA, and amplify the target fragments with specific target primers. Testing is conducted according to the instruction manual of use.

4. Result

Table 1. PCR-Confirmed Specimen Used

		Number of specimen (n)
Influenza positive	A	53
	B	62

Table 2. Comparison of GenBody Influenza A/B Ag and Asan Easy Test Influenza A/B for Influenza Type A

Influenza Type A		Asan Easy Test Influenza A/B		Total
		Positive	Negative	
GenBody Influenza A/B Ag	Positive	53	9	62
	Negative	0	229	229
Total		53	238	291
Sensitivity		100% (95% CI 93.28 ~100%)		
Specificity		96.22% (95% CI 92.94 ~98.26%)		

Table 3. Comparison of GenBody Influenza A/B Ag and Asan Easy Test Influenza A/B for Influenza Type B

Influenza Type B		Asan Easy Test Influenza A/B		Total
		Positive	Negative	
GenBody Influenza A/B Ag	Positive	61	12	73
	Negative	1	217	218
Total		62	229	291
Sensitivity		98.39% (95% CI 91.34 ~99.96%)		
Specificity		94.76% (95% CI 91.03 ~97.26%)		

5. Conclusion & Summary

In this clinical comparison study, GenBody Influenza A/B Ag showed superior performance when compared with Asan Easy Test Influenza A/B. GenBody Influenza A/B Ag showed equal or higher clinical sensitivity and specificity for both influenza type A and type B. The two tests show good agreement, with kappa ratio of 0.903 for type A and 0.875 for type B, where kappa ratio over 0.8 indicates excellent agreement. The study indicates that GenBody Influenza A/B Ag will be a highly effective tool for influenza diagnosis.