

Singclean Flu A&B Test 05

Advantages

- a. Easy to operate: All components include in kit, no additional equipment or laboratory resources required;
- b. Fast detection: 15 minutes to interpret the result after collecting specimen;
- c. Joint testing: Influenza A and B can both be tested in one reagent;
- e. Accurate, Rapid, Sensitive

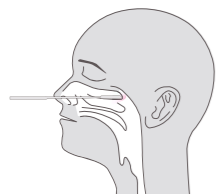
High quality CE marked and approved for sale in Europe

Performance Characteristics

A total of 406 samples were tested in this study. The results of test reagent and control reagent both were 215 negative specimens, 92 Flu A positive specimens and 99 Flu B positive specimens.

Method		Reference Reagent Results			Total
		FLU A Positive	FLU B Positive	Negative	
Test Reagent Results	Positive	89	97	2	188
	Negative	3	2	213	218
Total		92	99	215	406
FLU A Sensitivity		96.74%	95% confidence interval	90.85%~98.88%	
FLU B Sensitivity		97.98%		92.93%~99.44%	
Specificity		99.07%		96.67%~99.74%	
Accuracy		98.28%		96.48%~99.16%	

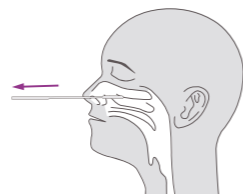
Test Procedure



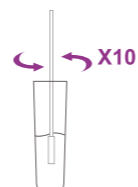
1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



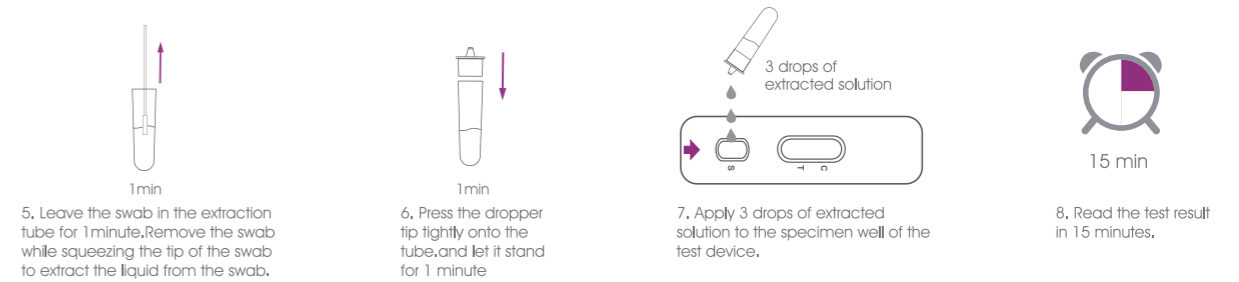
2. Swab over the surface of the posterior nasopharynx.



3. Withdraw the sterile swab from the nasal cavity.



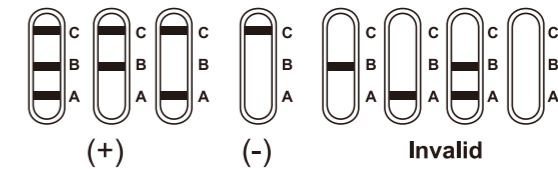
4. Insert the swab into an extraction buffer tube pre-added with 6 drops of extraction buffer, rotate the swab about 10 times, while pressing the swab head against the tube wall to release the antigen in the swab.



Interpretation of Results

Positive:

Positive influenza A and B:
Line C, Line A and Line B all appeared. A positive result in the influenza A region and influenza B region indicates that both Influenza A and B antigens were detected in the sample.



Influenza A Positive:

Line C and Line A both appeared. A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

Influenza B Positive:

Line C and line B both appeared. A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

Negative:

Only Line C appeared, the absence of any burgundy color in the T band, the result indicates that no Flu A/B antigens are detected in the specimen.

Invalid:

Control line fails to appear.

Limitations

1. Use fresh samples whenever possible.
2. Optimal assay performance requires strictly adherence to the assay procedure described in Instruction for use. Deviations may lead to aberrant results.
3. A negative result for an individual subject indicates absence of detectable Flu A/B antigen. However, a negative test result does not preclude the possibility of exposure to or infection with Flu A/B
4. A negative result can occur if the quantity of the Flu A/B antigen present in the specimen is below the detection limits of the assay, or failed to collect the Flu A/B antigen in the nasal cavity of the patient.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.