ACCUCARE®
ONE STEP INFLUENZA Flu A+B STRIP TEST
(Nasopharyngeal Secretion)

INTENDED USE
Influenza virus type A or type B antigens directly from nasopharyngeal swab specimens. The test is used as an aid in the rapid diagnosis of influenza A and B viral infections.

For *In Vitro* Diagnostic Use Only
ORDER INFORMATION

Pack Size	REF
1 Tests	FLUC 1
10 Tests	FLUC 10
25 Tests	FLUC 25
50 Tests	FLUC 50

SUMMARY AND EXPLATION
Influenza is an acute respiratory disease caused by influenza virus type A or type B. Influenza is caused by the antigenic drift of the influenza virus, which causes 10 to 20% of the population to be epidemic every winter. The global pandemic of influenza A, which occurs every 10 to 40 years, is a major threat to mankind due to antigenic shifts. As a result of monitoring the national influenza epidemic in Korea, we can confirm that influenza is prevalent every winter (October to April). Influenza is an acute febrile respiratory disease, which is accompanied by respiratory symptoms such as sore throat and cough together with the symptoms of headache, fever, chills and muscle aches. The symptoms of the patient are so diverse. There are cases of respiratory symptoms that do not have fever similar to a cold. Or there are cases typically accompanied by high fever and respiratory symptoms. Differential diagnosis is difficult because it is very similar to common colds caused by various respiratory viruses, especially in winter. However, influenza and cold are other diseases. Unlike colds, they can cause fatal complications. Differential diagnosis is needed because they can use antiviral drugs and effective vaccines.

PRINCIPLE
Influenza A/B Antigen is a chromatographic immunoassay kit for rapid, qualitative, and differential determination 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&B, a visible line appears in the test region on the membrane. Influenza A/B Antigen is also very useful to directly and differentially detect influenza virus (A/B) from nasal swab with a high accuracy.

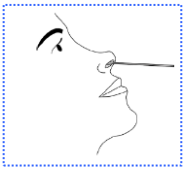
MATERIALS PROVIDED
Influenza A/B Antigen kit contains the following items:
1. Test Cassettes individually foil-pouched with a desiccant
2. Assay Buffer Solution
3. Instruction manual
4. Sample Dropper
5. Nasal Swab

MATERIAL REQUIRED BUT NOT PROVIDED
1. Stopwatch

SPECIMEN COLLECTION AND STORAGE
1. Nasopharyngeal swabs: sterile swab is inserted into one or both nostrils to the nasopharyngeal area. The swab is allowed to remain in the nostrils for a few seconds to absorb secretions, rotated gently, and then withdrawn.
2. Liquid nasopharyngeal aspirates/or washing: Aspirate (150$\mu\ell$) should be collected by a specialist using disposable sample transfer pipette.

Specimen Collection

<u>Nasopharyngeal swab method</u>:



1. Bend shaft to follow curve of nasopharynx.
2. Insert swab through nostril to posterior nasopharynx.
3. Rotate swab a few times to obtain infected cells.
4. For an optimal sample, repeat procedure using other nostril.
5. Process the swab as soon as possible after collecting the specimen.

<u>Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):</u>

1. Instill several drops of solution saline into each nostril.
2. Place catheter through nostril to posterior nasopharynx.
3. Apply gentle suction. Using rotating motion, slowly withdraw catheter.
4. For an optimal sample, repeat procedure using other nostril.

TEST PROCEDURE

Place test strip and Extraction Solution and allow them to room temperature prior to testing.
Prepare the disposable dropper and the disposable test tubes as you need.
Hold the disposable dropper vertically, draw up approximately 300µl of bottom) as shown in the following drawings. And then, dispense the solution into Disposable test tubes.
Insert the patient swab sample into the test tube, then, swirl the swab at least 6 times while pressing the head against the bottom and side of the test tube. [In the case of Control swabs, we recommend that, before swirling the swabs, the swab should be put into the Extraction Solution for ~30 seconds because they have preserved at dried state. Then, swirling and pressing steps are followed to get better results]

Roll the swab head against the inside of the tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol. Remove the test strip from the foil pouch.
Place the test strip into the Extraction tube with the arrows on the test strip pointing down. Do not handle or move the test strip until the test is completed and ready for reading.
Read the result after 10 minutes. Some positive results may appear sooner.

ISO 13485:2016

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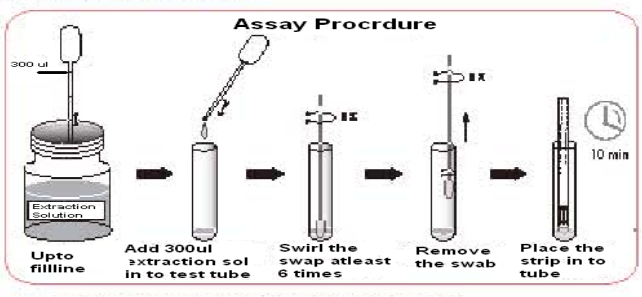
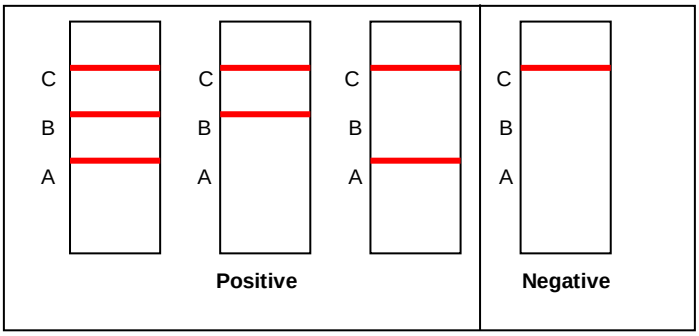


INTERPRETATION OF THE RESULTS

1. Negative result: ONLY one band in the control line (C).
   Positive result:
   A. Positive for influenza virus type A: two bands are appeared in the test line A and control line (C).
   B. Positive for influenza virus type B: two bands are appeared in the test line B and control line (C).
2. Invalid result:
   If, at 15 minutes, the red color band does not appear in the control line, even if any shade of a pink-to-red test line appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new test strip.

INTERPRETATION OF RESULTS



STORAGE & EXPIRATION

1. Flu A+B kit should be stored between 2 to 30℃ (36-86℉).
2. Expiration date of this kit is 24 months after its manufacture date.

Total Clinical Sensitivity and Specificity

Influenza Specimen		Accucare Influenza A/B	
		Positive	Negative
Positive	145	128	17
Negative	136	0	136

- Clinical Sensitivity: 88.27% (95% CI: 83.03%- 93.51%)
- Clinical Specificity: 100%

Influenza A/B Type Clinical Sensitivity

Influenza Specimen		Accucare Influenza A/B	
		Positive	Negative
A Positive	76	65	11
B Positive	69	63	6

- A Type Clinical Sensitivity: 85.53% (95% CI: 77.63%-93.43%)
- B Type Clinical Sensitivity: 91.30% (95% CI: 84.65%-97.95%)

LIMITATIONS OF THE TEST

Flu A+B is designed for primary screening test of Flu A+B. 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.

PERFORMANCE CHARACTERISTICS

1. Precision and Accuracy

According to the report of its evaluation for FDA (Food and Drug Administration), Flu was determined to 100% of identity by using 3 different replicates of 3 lots of the kit with 12 kinds of standard samples (9 positives and 3 negatives).

2. Sensitivity and Specificity

According to the clinic report of its evaluation for FDA Adeno/RSV/Flu A+B gave 96.0% of sensitivity with 204 positive samples and 98.0% of specificity with 200 negative samples, and 98.5% of correlation with RT-PCR (reverse transcription-PCR).

REFERANCE

WHO Guide for field operations; Collecting, preserving and shipping specimens for the diagnosis of avian influenza A (H5N1) virus infection. (October 2006)

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
IVD	For *in vitro* Diagnostic use only		Keep Dry
Σ	Tests per Kit		Do Not Use if Damaged

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