ACCUCARE
INFLUENZA Flu A+B TEST

Rapid detection kit for various Flu A+B serotypes in nasopharyngeal secretion

EXPLANATION OF THE TEST

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 Soution 5 ml/vial
3. Instruction manual for usdropper

MATERIAL REQUIRED BUT NOT PROVIDED

1. Sterile swab
2. Test tube or Vail

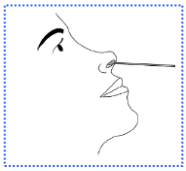
SPECIMEN COLLECTION AND STORAGE

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 The swab is allowed to remain in the nostrils for a few seconds to absorb secretions, rotated gently, and then withdrawn.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

1. Place all specimens, test devices, and sample collection device containing assay solution and allow them to room temperature prior to testing (15~30 min).
2. Prepare the test device as you need, and then mark the patient's ID onto the device. Please perform the test immediately after removing the device from foil pouch.
3. Place 8-10 drops of Assay Buffer in a disposable test tube and insert the swab into the device containing assay solution.
4. Mix the swab with vigorous rotation until the sample has been dissolved into the assay solution. And then, discard the swab.
5. Mix well again with shaking the test tube.
6. Hold the sample dropper vertically, and add 2-3 drops (60-80 $\mu\ell$) Assay Solution in the sample well of Influ A/B test device.
7. After 15~20 minutes, interpret the results.

* Please do not read the results after 30 minutes of the test.

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 B (T1) and control line (C).
B. Positive for influenza virus type B: two bands are appeared in the test line A (T2) 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.

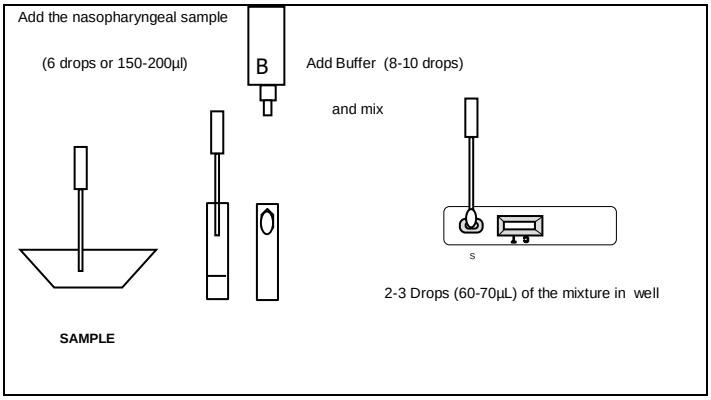
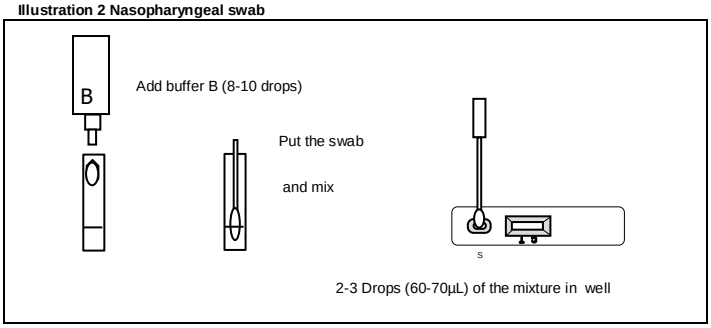
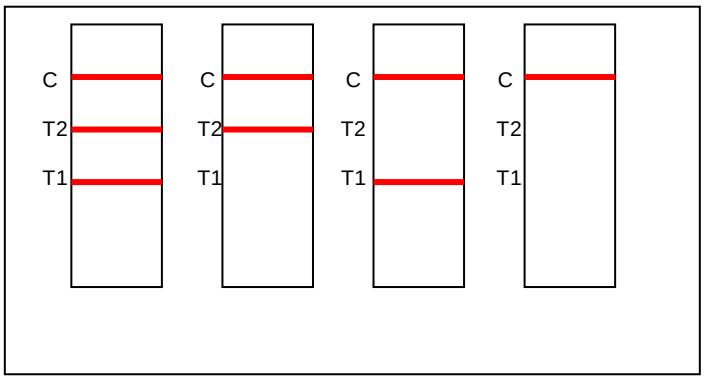


Illustration 2 Nasopharyngeal swab



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.

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.

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 • Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com

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).

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 • Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com