INFUENZA A+B

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC16

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for detection of various Flu A+B serotypes in human nasopharyngeal secretions.

CLINICAL SIGNIFICANCE

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 5 ml/vial
3. Instruction manual
4. Sample tube

MATERIALS REQUIRED BUT NOT PROVIDED

Sterile swab

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

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 The swab is allowed to remain in the nostrils for a few seconds to absorb secretions, rotated gently, and then withdrawn.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 µl) should be collected by a specialist using disposable sample transfer pipette.

Specimen Collection:

Nasopharyngeal swab method:

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.

Nasopharyngeal aspirate method (suction apparatus, sterile suction catheter):

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.

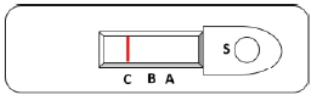
TEST PROCEDURE

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 µl) Assay Solution in the sample well of Influ A/B test device.
7. After 15~20 minutes, interpret the results.

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

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:
One band appears in the control region (C). No apparent bands appears in the test regions (A or B).

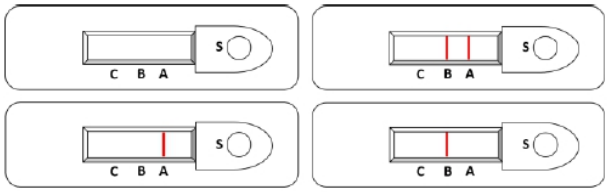


POSITIVE RESULT:

Influenza virus type A Positive:
The presence of a band at 'C' and at 'A' within the Result Window, indicates a positive result for Influenza virus type A.

Influenza virus type B Positive:
The presence of a band at 'C' and at 'B' within the Result Window, indicates a positive result for Influenza virus type B.

INVALID TEST:
No visible band at the control region. Repeat with a new test device.



Note: If, at 15 minutes, the red colour 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.

PERFORMANCE CHARACTERISTICS

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).

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).

QUALITY CONTROL

Although the testing device contains an internal quality control (coloured band in the control region), good laboratory practice recommends to run a known positive and negative control sample to ensure proper performance. All controls should be handled in the same manner as patient

LIMITATIONS

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.

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