IVD

Asan Easy Test® Influenza A/B(D)

Diagnostic Kit for Influenza Virus Type A and Type B Antigens

Immunochromatography

EXPLANATION OF THE TEST

The Asan Easy Test® Influenza A/B is a chromatographic immunoassay kit for rapid, qualitative, and differential detection of influenza virus type A and type B (Not type C) infection from nasopharyngeal secretion 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 and B, a visible line appears in the test region on the membrane. Asan Easy Test® is also very useful to directly and differentially detect influenza Virus (A/B) from nasopharyngeal secretion of human with a high accuracy.

MATERIALS PROVIDED

Asan Easy Test® Influenza A/B(D) contains the following items to perform the assay.

1. Test device in aluminum pouch with a desiccant.
2. Extraction solution tubes (0.3㎖/tube).
3. Sample collection swabs.
4. Dropper filter tips.
5. Control swab (optional);
   Influenza A positive control swab (1): Inactivated Flu A (H1N1, H3N2).
   Influenza B positive control swab (1): Inactivated Flu B (Lee40).
   Influenza negative control swab (1): Inactivated S.pyogenes.
6. Instruction manual for use.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
3. Do not eat or smoke while handling specimens.
4. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
5. Avoid splashing or aerosol formation.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Decontaminate and dispose of all specimens and reaction waste after test, according to GLP or other applicable national standards and / or laws.
8. Do not mix and interchange different specimen.
9. The presence of humidity may decrease the stability of the reagents. Thus, carry out the test immediately after removing the device from the foil pouch.
10. Do not use it beyond the expiration date.
11. Do not change the usage of the product or components.
12. Do not re-use the product becuse it is disposable.

SPECIMEN COLLECTION AND STORAGE

Specimens should be obtained and handled by standard methods for the collection of nasopharyngeal swab and aspirate

A. Nasopharyngeal swab:

1. Use provided sample collection swab to collect nasopharyngeal swab.
2. Sterile swab is inserted into nostrils where the most secretions are discharged to the point of nasal turbinal and gently rotate as much as possible.
3. Specimens must be tested as soon as they are collected.

B. Nasopharyngeal aspirate:

1. Nasopharyngeal aspirate should be collected by a specialist using a mucus trap and a catheter.
2. Slightly put a few drops of sterile saline into the nostrils, and place a flexible plastic tube along with the nostril wall and make it parallel to the palate.
3. After push the tube down to the nasopharyngeal, aspirate the secretion removing the tube and collect it in the collection cup.
4. Specimens must be tested as soon as they are collected.

C. Storage of collected specimen:

If the specimen is not immediately used, it could be stored in storage container with lid containing the transportation medium (Viral Transport Media) in refrigerator (2 ~ 8 ℃), frozen storage (- 20℃) for up to 3 days.

TEST PROCEDURE

1. All materials should be equilibrated to room temperature (15~25℃) before performing the test.
2. **a. Nasopharynegeal swab:**
   Place the specimen swab into the tube containing extraction solution and swirl the swab at least 8~10 times while pressing the head against the inside of the tube to release the antigen in the swab.
   b. Nasopharyngeal aspirates:
   Mix 300㎕ of aspirates with 300㎕ of extraction solution in tube at 1:1 ratio.
3. Discard the swab squeezing against the wall of tube, as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
4. Insert dropper filter into tube and add 4drops of the solution (100~120μl) into the sample well(S).
5. Read the result at 10~15minutes. Do not read after 15minutes.

INTERPRETATION OF THE TEST

A. Negative result:

The presence of only one red color band ("C" band) within the result window indicates a negative result.

B. Positive result:

The presence of two red color bands ("1" or "2" band and "C" band) within the result window regardless of which band appears first indicates a positive result.

-Positive for Influenza type A virus: Two bands appears. ("1" and "C")

-Positive for Influenza type B virus: Two bands appears. ("2" and "C")

C. Invalid result:

If no band is visible within the window after performing the test, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.

STORAGE & EXPIRATION

1. Asan Easy Test® Influenza A/B(D) Kit should be stored between 1 to 30℃(33.8~86°F).
2. Expiration date of this kit is 24 months after its manufacture date.

LIMITATIONS OF RESULTS

Asan Easy Test® Influenza A/B(D) is designed for primary screening test. 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.

ASAN
ISO13485:2003

Manufactured & Sold by
ASAN PHARMACEUTICAL CO., LTD
Factory1: 163, Yeongcheon-ro, Hwaseong-si, Gyeonggi-do 18462, Korea
Factory2: 122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, 17551, Korea

Tel: +82-31-376-5990~2
Fax: +82-31-376-5993
http://www.asanpharm.com

REF Code No.: 022851
Document Code: INFLUD-STE00

A. Specimen collection

B. Test Procedure