

### EXPLANATION OF THE TEST

The Asan Easy Test<sup>®</sup> Influenza A/B(F) is immunofluorescence assay kit to detect influenza virus type A and type B (Not type C) infection from nasopharyngeal secretion specimens. Monoclonal anti-influenza virus antibodies (T1-A, T2-B) are immobilized on the test line(T1, T2) of the nitrocellulose membrane. First, when a specimen containing influenza virus is pretreated with a specimen extract solution, the antigen on the virus surface is exposed. At this time, if the extract is developed into the test device, the antigen of the influenza virus present in the genome is firstly immunoreactive with the anti-influenza virus A antibody fluorescent conjugate or B antibody fluorescent conjugate. This primary complex reacts with the anti-influenza A or B antibody immobilized on the membrane to form a secondary immunoreactivity that fluoresces on the test line. The results are read as positive using a fluorescence analyzer.

### MATERIALS PROVIDED

Asan Easy Test<sup>®</sup> Influenza A/B(F) contains the following items to perform the assay.

1. Test device in aluminum pouch with a desiccant.
2. Extraction solution tubes (0.3ml/tube).
3. Sample collection swabs.
4. Dropper filter tip.
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 because it is disposable.

### SPECIMEN COLLECTION AND STORAGE

Specimens should be obtained and handled by trained or professional technician, as there are unknown infectibility.

#### 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 °C ), frozen storage (- 20 °C ) for up to 3 days.

### TEST PROCEDURE

1. All materials should be equilibrated to room temperature (15~25 °C ) before performing the test.
2. a. Nasopharyngeal 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  $\mu$ l of aspirates with 300  $\mu$ l 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 (100~120 $\mu$ l) into the sample well(S).
5. Read the result at 20minutes refer to manual of fluorescence analyzer (ASAN EASY CHECK F-100).
6. As the reaction time increases, the degree of fluorescence emission of the control line and the test line can be narrowed. Therefore, it is more accurate to read the result at a constant time after the reaction starts. If reaction time is long, non-specific reactions may occur, so do not read the results after 20 minutes.

### INTERPRETATION OF THE TEST

The EASY CHECK F-100 will display positive or negative results on the screen as per test lines which are fluorescent, cannot be seen with the naked eye.

#### A. Negative result:

The presence of only one fluorescent band (C). The screen show INF A and INF B are negative result.

#### B. Positive result:

- Positive for Influenza type A virus: The presence of two fluorescent bands("1" and "C"). The screen show INF A is positive as a reading of 'Strong', 'Moderate' or 'Weak' positive and INF B is negative.

- Positive for Influenza type B virus: The presence of two fluorescent bands("2" and "C"). The screen show INF A is negative and INF B is positive as a reading of 'Strong', 'Moderate' or 'Weak' positive.

#### C. Invalid result:

If no fluorescent band ("C", "1" and "2") is in the result window or presence of two fluorescent bands("1" and "2"), 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

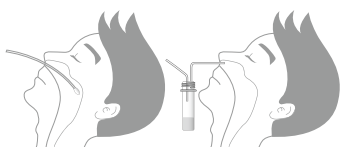
1. Asan Easy Test<sup>®</sup> Influenza A/B(F) Kit should be stored between 1 to 30 °C (33.8~86 °F ).
2. Expiration date of this kit is 24 months after its manufacture date.



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### A. Specimen collection



### B. Test Procedure

