Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD F

Influenza A/B FIA

REF FINF01G

STANDARD™ F Influenza A/B FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

EXPLANATION AND SUMMARY

[Introduction]

Influenza, commonly known as the flu, is a highly contagious and acute viral infection of the respiratory tract caused by an influenza virus. Three types of influenza viruses affect people, called Type A, Type B, and Type C. Type A viruses are the most prevalent and are associated with most serious epidemics. The clinical symptoms by the infection of Type A viruses are more severe than symptoms caused by Type B viruses. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season. Type C viruses have never been connected with a large epidemic of human disease. Influenza can take on a variety of appearances, ranging from isolated respiratory findings that resemble the common cold, to severe pneumonia requiring hospitalization and death. STANDARD F Influenza A/B FIA, containing a highly specific and sensitive antibody, provides significantly fast, easy and accurate system to identify the target antigen in a nasopharyngeal extraction specimen.

[Intended use]

The STANDARD F Influenza A/B FIA is the fluorescence immunoassay to detect influenza infection in human nasal swab and nasopharyngeal swab, wash, or aspirate specimens, identifying existence of influenza virus type A (H1N1) and type B (Taiwan). STANDARD F Influenza A/B FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. This is intended for professional use, only for an initial screening test.

[Test principle]

STANDARD F Influenza A/B FIA is based on immunofluorescence technology with STANDARD F Analyzer to detect influenza antigen. STANDARD F Influenza A/B FIA has two test lines ("A" and "B") and a control line which is coated with monoclonal anti-influenza A, monoclonal anti-influenza B and polyclonal mouse IgG each. The patient's sample is applied into the sample well of the test device and the sample migrates through the membrane. If influenza A/B viral antigen is present in patient sample, it will react with europium conjugated monoclonal anti-influenza A/monoclonal anti-influenza B in the conjugation pad and form antibody-antigen fluorescence particle complexes. These complexes move along to the membrane to be captured by the anti-influenza A/anti-influenza B on the test line and make fluorescence signal. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer manufactured by SD BIOSENSOR. STANDARD F Analyzer can analyze the presence of the influenza A/B virus in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

[Kit contents]

① Test device ② Extraction buffer tube ③ Sterile swab ④ Filter cap ⑤ Positive control ⑥ Negative control
⑦ Fixed volume dropper (100µl) ⑧ Fixed volume dropper (200µl) ⑨ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer
- Timer

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the extraction buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Use the STANDARD F Influenza A/B FIA at 15-32°C / 59-90°F and 10-90%RH.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly when afterwards.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all specimens as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
12. Immediately use the test device after taking out of aluminum foil pouch.
13. If the test result with positive/negative control swab is abnormal, do not use the kit.
14. As the detection reagent is a fluorescent compound, no visible results will form on the test device.
15. The bar code of the test device is used by analyzer to identify the type of test being run and to identify the individual test device so as to prevent to a second read of the test device by the same analyzer.
16. Once a test device has been successfully scanned by analyzer, do not attempt to scan the test device again in the same analyzer.
17. Improper specimen collection, handling or transport may yield inaccurate results.
18. Do not write on the bar code or damage the bar code of the test device.

SPECIMEN PREPARATION, STORAGE AND TRANSPORT

[Methods of sample collection]

Nasal Swab | Nasopharyngeal Swab | Nasopharyngeal Aspirate | Nasopharyngeal Wash (Syringe method) | Nasopharyngeal Wash (Bulb method)

[Specimen preparation]

- **Nasal swab**

1. To collect a nasal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril).
3. Rotate the swab a few times against the nasal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. If not use of transport media, specimens may be stored at refrigerated (2-8°C/36-46°F) or at room temperature (15- 30°C/59-86°F), in a clean, dry, closed container for up to 48 hours at refrigerated (2-8°C / 36-46°F) or 24 hours at room temperature (15-30°C / 59-86°F) prior to testing.

- **Nasopharyngeal swab**

1. To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinate.
3. Rotate the swab a few times against the nasopharyngeal wall.
4. Remove the swab from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. If not use of transport media, specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48hours in a clean, dry, closed container prior to testing.

- **Nasal/nasopharyngeal swab in transport media**

1. Transport fresh specimens to the laboratory as rapidly as possible in a suitable liquid transport system.
2. The BD Universal Viral Transport and Copan Universal Transport Medium have been tested and found to be compatible with STANDARD F Influenza A/B Test.
3. For nasal/nasopharyngeal swabs in transport media, use the 1-3 ml of transport media.

CAUTION

- Minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.

- **Nasopharyngeal wash**

1. Fill the syringe or aspiration bulb with the minimal volume of nonbacteriostatic saline (pH 7.0) required per the subject's size and age.
2. Instill the saline into one nostril while the head is tilted back.
3. Aspirate the wash specimen back into the syringe or bulb.
4. Repeating procedure for the second nostril will deliver optimal combined specimens.
5. Specimen should be tested as soon as possible after collection. If not use the specimen immediately, specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48hours after collection.

- **Nasopharyngeal aspirate**

1. Have the patient sit with head tilted slightly backward.
2. Instill 1-1.5 ml of nonbacteriostatic saline (pH 7.0) into one nostril.
3. Flush a plastic catheter or tubing with 2-3 ml of saline.
4. Insert the tubing into the nostril parallel to the palate (not upwards).
5. Aspirate nasopharyngeal secretions. Collect the specimens in sterile vials. If permitted, repeat this procedure for the other nostril.
6. Specimen should be tested as soon as possible after collection. If not use the specimen immediately, specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48hours after collection.

TEST PROCEDURE

[Preparation]

1. Allow test device and collected sample to room temperature (15-30°C/59-86°F) prior to testing.
2. Carefully read the instructions for using the STANDARD F Influenza A/B FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

4. Open the foil pouch, and check the test device and the silica gel pack in the foil pouch.

CAUTION

- If a violet colored band (check band) does not appear in the result window of the test device, do not use it.

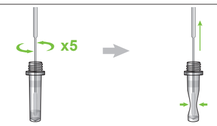
CAUTION

- Do not write on the bar code or damage the bar code of the test device.

[Collection of sample]

- **Nasal/nasopharyngeal swab**

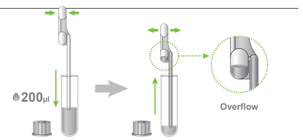
1. Allow test device to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Insert the nasopharyngeal swab sample of patient into an extraction buffer tube. Swirl the swab at least five times.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.



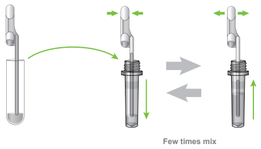
4. Tightly screw the filter cap onto the tube.

- **Nasal/nasopharyngeal swab in transport media**

1. Allow test device and collected sample to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Compress the top bulb of a fixed volume dropper (200µl) and place the tip of the dropper into the collected sample.
3. Slowly release the top bulb of the dropper dipping the tip of the dropper into the sample.



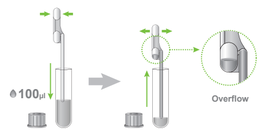
4. Completely squeeze the sample into an extraction buffer tube pressing hard the top bulb of the dropper.
5. Repeat carefully pressing and releasing the top bulb of the dropper a few times to mix the sample and the extraction buffer.



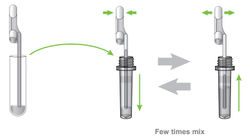
6. Remove the dropper and tightly screw the filter cap onto the tube.

- **Nasopharyngeal wash/aspirate**

1. Allow test device and collected sample to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Compress the top bulb of a fixed volume dropper (100µl) and place the tip of the dropper into the collected sample.
3. Slowly release the top bulb of the dropper dipping the tip of the dropper into the sample.



4. Completely squeeze the sample into an extraction buffer tube pressing hard the top bulb of the dropper.
5. Repeat carefully pressing and releasing the top bulb of the dropper a few times to mix the sample and the extraction buffer.



6. Remove the dropper and tightly screw the filter cap onto the tube.

NOTE

- Fixed volume dropper is designed to aspirate the correct amount of solution by collecting overflowed liquid in the bottom bulb of dropper.

- **Positive/Negative control**

1. Insert the positive/negative control swab in the kit into an extraction buffer tube. Swirl the swab at least five times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose of the used swab in accordance with your biohazard waste disposal protocol.

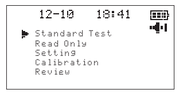
3. Tightly screw the filter cap onto the tube.

[Analysis of sample]

- **Using a STANDARD F100 Analyzer**

- **'Standard Test' mode**

1. Prepare a STANDARD F100 Analyzer and set the `Standard Test' mode according to the analyzer's manual.



2. Take the test device out of the foil pouch.
3. Insert the test device to the Test Slot of the analyzer. The analyzer automatically reads the information of the bar code on the test device and releases the test device for adding sample.

4. Apply 4 drops of mixed sample to the sample well in the test device holding the prepared extraction buffer tube upside down.

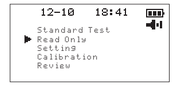
5. **After applying the sample, immediately press the center button to start the test.**

- **'Read only' mode**

1. Take the test device out of the foil pouch and place it on a flat and dry surface.
2. Apply 4 drops of mixed sample to the sample well in the test device holding the prepared extraction buffer tube upside down.

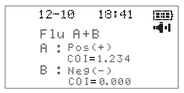
3. Leave the test device for 10 minutes. Notice that the test device should not leave for 20 more minutes.

4. Prepare a STANDARD F100 Analyzer and set the 'Read Only' mode according to analyzer's manual.



5. Insert the test device to the Test Slot of the analyzer.

6. The analyzer will automatically display the test result.



- **Using a STANDARD F200 Analyzer**

- **'Standard Test' mode**

1. Prepare a STANDARD F200 Analyzer and select the `Standard Test' on the analyzer's screen.

2. Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer by touching the 'Direct' item, the analyzer will regard the test as that of the guest.
3. Take the test device out of the foil pouch.

4. Once the 'Insert Device' is displayed in the screen, insert the test device into the Test Slot of the analyzer.

5. When inserting the test device to the analyzer, the analyzer automatically reads the information of the bar code on the test device and releases the test device for adding sample.

6. Apply 4 drops of mixed sample to the sample well in the test device holding the prepared extraction buffer tube upside down.
7. **After applying the sample, immediately press the start button.**

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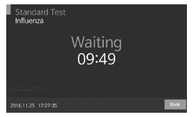
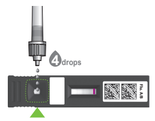
8. The analyzer will automatically display the test result within 10 minutes. Strong positive results may be observed earlier, in 90 seconds, 3 minutes, or 5 minutes after starting the test.



- **'Read only' mode**

1. Take the test device out of the foil pouch and place it on a flat and dry surface.
2. Apply 4 drops of mixed sample to the sample well in the test device holding the prepared extraction buffer tube upside down.



3. Leave the test device for 10 minutes. Notice that the test device should not leave for 20 more minutes.

4. Prepare a STANDARD F200 Analyzer and select the `Read Only' on the analyzer's screen.

5. Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer by touching the 'Direct' item, the analyzer will regard the test as that of the guest.

6. Once the 'Insert Device' is displayed in the screen, insert the test device to the Test Slot of the analyzer.

7. When inserting the test device to the analyzer, the analyzer automatically reads the information of bar code on the device to check whether the device is valid.

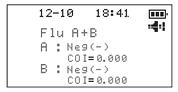
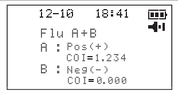
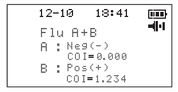
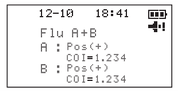
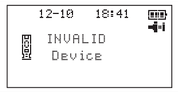
8. The analyzer will automatically display the test result.

NOTE

- The mark on the label between sample well and result window is scanned by the STANDARD F200 Analyzer and displayed on the screen.
- The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. COI is calculated that a measured signal is divided by an appropriate cutoff value.
  - Test results of a COI ≥ 1.00 are considered positive for Influenza A and/or B.
  - Test results of a COI < 1.00 are considered negative for Influenza A and/or B.

INTERPRETATION OF TEST RESULTS

[Displays of STANDARD F100 Analyzer]

Test result		Window example
Negative		
Positive	Influenza A positive	
	Influenza B positive	
	Influenza A/B positive	
Invalid		

[Displays of STANDARD F200 Analyzer]

Test result		Window example
Negative		
Positive	Influenza A positive	
	Influenza B positive	
	Influenza A/B positive	
Invalid		

QUALITY CONTROL

[STANDARD F Analyzers calibration check]

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzer's manual.

When to use calibration set

1. Before using the analyzer for the first time
2. When you drop the analyzer
3. Whenever you do not agree with your result
4. When you want to check the performance of an analyzer and test device

How to use calibration set

Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

CAUTION

- The STANDARD F100 Analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with CAL devices. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

[Internal procedural control]

1. The internal procedural control zone is in the end of the membrane of the test device. STANDARD F Analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.
2. The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F analyzers shows 'Invalid Device', turn off and turn on the analyzer again and re-test with a new test device.

[External quality control]

1. Positive and negative controls are supplied with each kit and these controls are provided as a means of additional quality control to demonstrate a positive or negative reaction.
2. It is recommended that positive and negative controls be run:
   - once for each new lot.
   - once for each untrained operator.
   - as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of influenza A/B viruses in the specimen and should not be used as the sole criteria for the diagnosis of influenza A/B virus infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate of influenza A/B viruses concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

BIBLIOGRAPHY

1. Montalto NJ. An office-based approach to Influenza: clinical diagnosis and laboratory testing. Am Fam Physician. 2003; 67(1):111-118.
2. Rodriguez WJ, Schwartz RH, Thorne MM. Evaluation of diagnostic tests for Influenza in a pediatric practice. Pediatr Infect Dis J. 2002; 21(3):193-196.
3. Ali T, Scott N, Kallas W, Halliwell ME, Savino C, Rosenberg E, Ferraro M, Hohmann E. Detection of Influenza antigen with rapid antibody-based tests after intranasal.

Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE IVD

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Issue date : 2018.02

REF Reference number

IVD *In vitro* Diagnostics

Consult Instructions for Use

Contains Sufficient for <n> Tests

Caution

Do not re-use.

Use by

To indicate the temperature limitations in which the transport package has to be kept and handled.

LOT Batch code

Manufacturer

Date of manufacture

Note

Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices