SGTi-flex

REF IFNT025E

Influenza A&B

IVD CE

INTENDED USE

SGTi-flex Influenza A&B is an immunoassay for qualitative detection of Influenza virus type A or type B antigens directly from nasopharyngeal swab specimens. The test is used as an aid in the rapid differential diagnosis of influenza A and B viral infections. The test is not intended to detect influenza C viruses.

SUMMARY AND PRINCIPLE

Influenza is an acute respiratory disease caused by influenza virus type A or type B. Influenza is caused by the antigenic drift of the influenza virus, which causes 10 to 20% of the population to be epidemic every winter. The global pandemic of influenza A, which occurs every 10 to 40 years, is a major threat to mankind due to antigenic shifts. As a result of monitoring the national influenza epidemic in Korea, we can confirm that influenza is prevalent every winter (October to April). Influenza is an acute febrile respiratory disease, which is accompanied by respiratory symptoms such as sore throat and cough together with the symptoms of headache, fever, chills and muscle aches. The symptoms of the patient are so diverse. There are cases of respiratory symptoms that do not have fever similar to a cold. Or there are cases typically accompanied by high fever and respiratory symptoms. Differential diagnosis is difficult because it is very similar to common colds caused by various respiratory viruses, especially in winter. However, influenza and cold are other diseases. Unlike colds, they can cause fatal complications. Differential diagnosis is needed because they can use antiviral drugs and effective vaccines. The principle of SGTi-flex Influenza A&B is the qualitative assay to detect influenza virus in the nasopharynx. Influenza virus swabs from nasopharynx are suspended in sample extracts and the suspension is dispensed into the kit. Influenza virus nucleoprotein allows the diagnosis of influenza viruses through visual inspection and analytical device by antigen-antibody immunochromatography combined with nucleoprotein specific antibody and gold in the kit. It is also possible to diagnose influenza A and B simultaneously and separately.

MATERIALS SUPPLIED

- Test Cassette 25
- Sample Diluent Tube..... 25 (0.35 mL/tube)
- Sample Filter Cap 25
- Sample Collecting Swab 25
- Test ID QR Code..... 1
- Instructions for Use 1

MATERIALS REQUIRED BUT NOT SUPPLIED (OPTIONAL)

- INCLIX™ Analyzer

STORAGE AND STABILITY

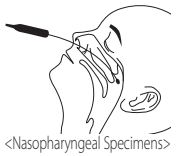
- Store SGTi-flex Influenza A&B Test Cassette and Diluent Buffer at 2-30℃ (36-86℉). It is available to use until the expiration date printed on the package.
- If SGTi-flex Influenza A&B Test Cassette and Diluent Buffer are stored in cold storage, allow them for 30 minutes to return to room temperature before testing.
- Do not open the pouch of Test Cassette until ready to use. After opening aluminum pouch, Test Cassette should be used immediately.
- Keep away from direct sunlight.

WARNING AND PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Clinical diagnosis through this product should be made through a comprehensive review of the specialist based on other test methods and clinical symptoms.
- Please read the instructions carefully before you begin testing and follow the procedure correctly.
- This product can be read with visual inspection or analyzer. If analyzer is used, it should be measured with our own exclusive analyzer. The result of measurement with other instrument is not reliable.
- It is prohibited to reuse Test Cassettes and sample diluent tube because they are single use only.
- Do not mix components or Test ID QR Code from different lots.
- The test result after the expiry date is not reliable.
- Test Cassette should remain in the sealed pouch until use because it is sensitive to moisture. Use Test Cassette immediately after opening the pouch.
- Do not use the Test Cassette if it is broken or the pouch is not stored in sealed.
- This test should be performed by the Nasopharyngeal Swab samples obtained in an appropriate manner. The test using a different kind of body fluid is not possible.
- Samples and Test Cassette must be at room temperature before testing.
- Be cautious that air bubbles do not enter in the sample well of the cassette when dropping the sample, because air bubbles may affect the result of test.
- It is an in-vitro diagnostic product and the risk of infection is low because there is no direct contact with the body. However please be cautious when handling Test Cassettes, analyzer and samples because of the use of clinical samples containing potential infectious sources. Dispose of the used samples, Test Cassettes, sample diluent tube and sample collecting swabs properly in accordance with the relevant regulations.
- The Test Cassette and Analyzer should be used away from vibration. Momentary vibrations during normal use are not affected.
- Smoking and eating are prohibited at test site when handing specimens or kit reagents.

SAMPLE COLLECTION AND PREPARATION

1. SGTi-flex Influenza A&B uses the sample of nasopharyngeal swab.
   (1) Please use single use sample collecting swab.
   (2) Insert a nasopharyngeal swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. Swab should reach depth equal to distance from nostrils to outer opening of the ear.
   (3) Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions. And slowly remove swab while rotating it.


<Nasopharyngeal Specimens>

2. Test should be done **immediately** after sample collecting.
   (1) If samples are not used immediately after sample collection, store the swap specimens in a VTM (Viral Transport Media) container with a lid.
   (2) The specimen in a VTM container is recommended to be stored in deep freezer at -70˚C(or in dry ice or liquid nitrogen). A freezer at -20˚C is NOT recommended. If the specimen is stored in a fridge (cooler), it can be stored up to 7 days.
   (3) Repetitive freezing-thawing should be avoided as it may affect to the test results. It is recommended to make small aliquots before freezing.

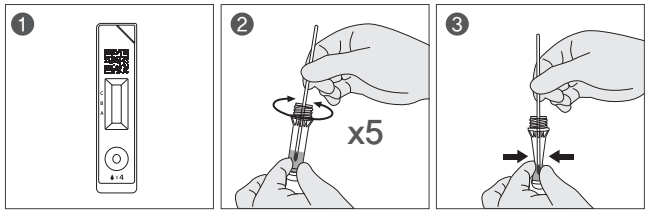
TEST PROCEDURE

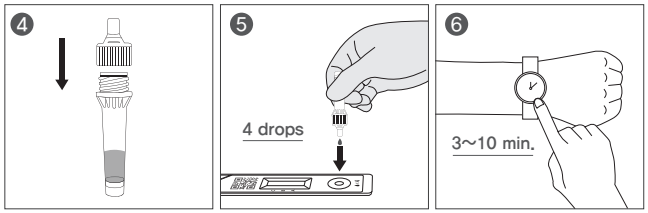
Preparation before Test

1. All specimens and reagents must be brought to room temperature for **15~30 minutes** before use so that homogeneous state should be maintained.
2. Test Cassette is sensitive to humidity. Perform the test immediately after opening the pouch.
3. In case of using analyzer, allow the analyzer to warm up for **15 minutes** before performing the test. Please refer to the analyzer user manual.

[TEST PROCEDURE – Visual Inspection]

1. Open the pouch and take out the Test Cassette. Place it on a flat, dry and clean surface.
2. Put the sample collecting swab into the tube containing the sample diluent and turn it more than **5 times** so that the extraction can take place.
3. Take the sample collecting swab out by pressing and squeezing the remaining extract in the tube. Used swab is classified as infectious waste and dispose of used swab properly in accordance with the relevant regulations.
4. After attaching the sample filter cap to the sample diluent tube, dispense **4 drops** of extracted sample vertically onto the sample well of the cassette.
5. Read the results in **3~10 minutes** after dispensing the sample. Some positive results may appear faster right after the reaction. Please do NOT consider the test result appeared after 15 minutes.





INTERPRETATION OF TEST RESULTS

(1) Positive

Control line (C) and test line (A) are appeared in the result window: Positive for Influenza virus A.

Control line (C) and the test line (B) are appeared in the result window: Positive for Influenza virus B.

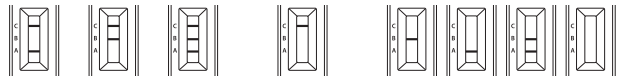
Control (C) and two test lines [test line (A) & (B)] are appeared together in the result window: Positive for both influenza virus A and B.

(2) Negative

If only control line (C) appears in the result window: it means negative for both influenza viruses A and B.

(3) Invalid / Retest

If control line (C) is not appeared in the result window, it is determined to be invalid test. Perform test again using new Test Cassette.



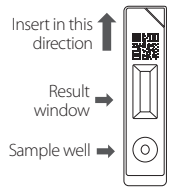
[TEST PROCEDURE – Analyzer Reading]

(1) TEST ID QR Code Registration

1. In case of testing using analyzer, TEST ID QR Code must be registered prior to use when using new lot of Test Cassette.
2. Test ID QR Code needs to be registered only once for a new lot.
3. Click the 'TEST' icon from the main menu of the analyzer. Open the cassette tray and insert Test ID QR Code and close it.
4. Test ID QR Code is automatically recognized and registered and the messages ("A new lot information was entered. Test Name: Influenza, Lot Num: xxxxx") will be shown on the screen.
5. After clicking 'OK', remove it from the cassette tray.

(2) Test Procedure

1. Click the 'TEST' icon from the main menu of the analyzer. In the Patient ID box, scan or type the patient's ID or click 'SEARCH' icon to select the patient's ID from registered patient's information. Then, select the specimen type from drop-down list.
2. Open the pouch and take out the Test Cassette. Place it on a flat, dry and clean surface.
3. Put the sample collecting swab into the tube containing the sample diluent and turn it more than 5 times so that the extraction can take place.
4. Take the sample collecting swab out by pressing and squeezing the remaining extract in the tube. Used swab is classified as infectious waste and dispose of used swab properly in accordance with the relevant regulations.
5. Tightly screw the Sample Filter Cap onto the Sample Diluent Tube.



6. Measurement

Caution: Make sure the correct direction of Test Cassette when it is inserted into the Cassette Tray of the Analyzer.

6-1. Analyzer's Standard Mode :

Before dispensing sample extract on the sample well of the cassette, open the cassette tray and insert the Test Cassette. Using a sample diluent tube with the disposable sample

filter cap, apply **4 drops** of extracted sample vertically to the sample well of the cassette. After dispensing the sample, close the cassette tray immediately but gently to prevent sample overflow. After confirming the barcode on the cassette, it is automatically recognized as Influenza. Click "STANDARD" icon on the screen and then the analyzer is reacted automatically for **10 minutes**. After 10 minutes, it will be switched to 'Test Result' screen.

6-2. Analyzer 'Quick mode'

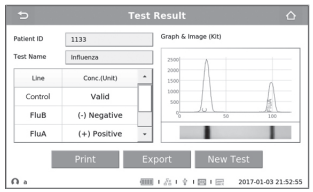
Using a sample diluent tube with the disposable sample filter cap, apply 4 drops of extracted sample vertically to the sample well of the cassette. Leave the test cassette for 3~10 minutes at room temperature. If the Test Line and Control Line are appeared visually, **immediately** open the cassette tray and insert the Test Cassette and close it. Some positive results may appear faster right after the reaction. Please do NOT consider the test result appeared after 15 minutes.

7. After the barcode is recognized as 'Influenza' correctly, click the 'QUICK' icon. The 'Test Result' is displayed on the screen in a few seconds.

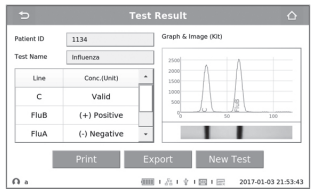
INTERPRETATION OF TEST RESULTS

(1) Positive

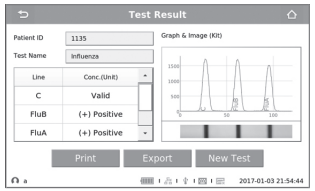
- Positive for Influenza virus A



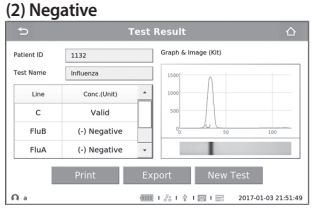
- Positive for Influenza virus B



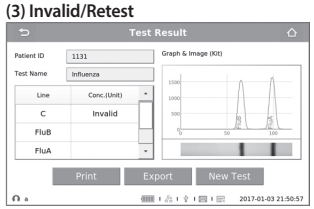
- Positive for both influenza virus A and B.



(2) Negative



(3) Invalid/Retest



QUALITY CONTROL

1. The test results should show a red line on the control line (C).
2. When tested according to the test procedure, Influenza A Positive Control Swab should be judged to be positive for influenza A.
3. When tested according to the test procedure, Influenza B Positive Control Swab should be judged to be positive for influenza B.
4. When tested according to the test procedure, Influenza Negative Control Swab should be judged to be negative.
5. Quality Control materials (Influenza A positive control swab, Influenza B positive control swab, influenza negative control swab) can be purchased separately.

LIMITATIONS OF THE SYSTEM

- SGTi-flex Influenza A&B can be used with INCLIX™ Analyzer only.
- Test result may vary due to storage and stability of specimen and Diluent Buffer.
- Specimen with rarely high reactivity for a particular antibody such as anti-mouse antibody can affect the performance of the test results.
- False positive results might be happened due to the non-specific cross-reaction of some components in the specimen to the antibody.
- Interfering materials above the limited concentrations, untested interfering substance to be administered to the specimen and other substances that may affect the results may affect the results.
- The results of SGTi-flex Influenza A&B should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed. In order to make a medical diagnosis, other clinical symptoms together with this test results must be considered.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

1) Influenza Antigen A (H1N1): 2.5 ng/mL
2) Influenza Antigen A (H3N2): 5 ng/mL
3) Influenza Antigen B : 5 ng/mL

2. Analytical Specificity

(1) Cross Reactivity

SGTi-flex Influenza A&B was evaluated with a total of 23 microorganisms. The 14 viruses were evaluated at concentrations for Ct values. The 9 bacteria were tested at a target concentration of approximately 10^8 cells/mL. The results show that the SGTi-flex Influenza A&B has no cross-reactivity with added substances such as viruses, bacteria and human influenza viruses.

Virus

1	Rota virus Antigen	8	Human Coxsackie B4
2	Norovirus GII	9	Epstein-Barr Virus
3	Parainfluenza Virus serotype 1	10	Human Norovirus GI
4	Parainfluenza Virus serotype 2	11	Human Meta pneumovirus
5	Parainfluenza Virus serotype 3	12	Human Rhinovirus Genogroup A
6	Parainfluenza Virus serotype 4	13	Human Coronavirus 229E
7	Human Respiratory syncytial virus A2	14	Human Measles Mvi/Moscow Rus/1988 Genotype A

Bacteria

15	Group A streptococcus antigen	20	Lactobacillus plantarum culture
16	Group B streptococcus antigen	21	Legionella spp culture
17	Streptococcus Pneumoniae antigen	22	Pseudomonas aeruginosa culture
18	Escherichia coli culture	23	Staphylococcus epidermidis culture
19	Corynebacterium glutamicum culture		

(2) Interfering Substances

Various concentrations of potential interfering substances were prepared in negative and positive sample. The results show that the SGTi-flex Influenza A&B has no interferences by the potential interfering substances below which may exist in specimen, such as drugs, chemical and biological analytes.

No.	Substance	Concentration	No.	Substance	Concentration
1	Albumin	50mg/mL	8	Budesonide	1mg/mL
2	Glucose	1.2mg/mL	9	Benzocaine	200mg/mL
3	Hemoglobin	200mg/mL	10	Menthol	40mg/mL
4	Bilirubin	15mg/mL	11	Zanamivir	10mg/mL
5	Phenylephrine	10mg/mL	12	Tobramycin	40mg/mL
6	Dexamethasone	0.6mg/mL	13	Tamiflu (Oseltamivir)	6mg/mL
7	Flunisolide	2.5mg/mL			

3. Clinical evaluation of SGTi-flex Influenza A&B vs RT-PCR, commercial influenza test

(1) Total Clinical Sensitivity and Specificity

Influenza Specimen		SGTi-flex Influenza A&B	
		Positive	Negative
Positive	145	128	17
Negative	136	0	136

1) Clinical Sensitivity: 88.27% (95% CI: 83.03% - 93.51%)
2) Clinical Specificity: 100%

(2) A&B Type Clinical Sensitivity

Influenza Positive Specimen		SGTi-flex Influenza A&B	
		Positive	Negative
A type Positive	76	65	11
B type Positive	69	63	6

1) A Type Clinical Sensitivity: 85.53% (95% CI: 77.63% - 93.43%)
2) B Type Clinical Sensitivity: 91.30% (95% CI: 84.65% - 97.95%)

REFERENCES

WHO Guide for field operations ; Collecting, preserving and shipping specimens for the diagnosis of avian influenza A(H5N1) virus infection.(October 2006)

EXPLANATION OF SYMBOLS USED ON PACKAGE

IVD	*In-vitro* diagnostic medical device	Σ 25	Contains sufficient for 25 tests
	Consult instructions for use.	30°C 2°C	Store between 2°C and 30°C
LOT	Batch code		Use by
	Manufacturer	EC REP	Authorized representative in the European community
	Do not reuse	REF	Catalogue number
	Caution, consult accompanying documents	CE	The device conforms to EU-regulations.

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Rev.No. IS201E-02/2020.11.19