SGTi-flex COVID-19 & Flu A/B Ag DUO

REF CAGD025E

IVD CE

▶ INTENDED USE

SGTi-flex COVID-19 & Flu A/B Ag DUO is an immune assay for the simultaneous qualitative detection of SARS-CoV-2 antigens, Influenza virus type A or type B antigens directly from nasopharyngeal swab specimens. The test is used as an aid in the rapid diagnosis of SARS- CoV-2 and influenza A and B viral infections.

▶ SUMMARY AND EXPLANATION

The novel coronavirus (SARS-CoV-2) was identified in December 2019, and in February 2020, the World Health Organization (WHO) officially named the disease caused by SARS-CoV-2 as COVID-19 (Coronavirus Disease 2019). Belonging to the family Coronaviridae, it has a positive-sense single-stranded RNA and can be transmitted between people. The coronaviruses identified for human infection include 229E, NL63 belonging to α-Corona viruses and HKU1, OC43, SARS-CoV, MERS-CoV belonging to β-Coronaviruses. The new coronavirus was published under the name of SARS-CoV-2, with 80% of genetic similarity to SARS-CoV by ICTV (International Committee on Taxonomy of Viruses).

COVID-19 spreads mainly through respiratory droplets, which cause lethargy, fever, dry cough, and dyspnea when infected. It can be even led to death with its severe symptoms like sepsis, MOF (Multiple Organ Failure) and ARDS (Acute Respiratory Distress Syndrome). It is more contagious than SARS which caused more than 800 deaths and 8,000 infected patients. Moreover, it has an incubation period of about 3 days to up to 16 days and becomes a big threat as infectivity appears even during the incubation period. There is currently no specific treatment for COVID-19, and rapid and accurate diagnosis is an important issue for isolation of patients with symptoms of suspected COVID-19.

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.

COVID-19 and Influenza, which are respiratory diseases, have similar infection routes and some of the symptoms, so rapid and accurate differential diagnosis is very important.

▶ PRINCIPLE

SGTi-flex COVID-19 & Flu A/B Ag DUO is an immune assay for qualitative detection of SARS-CoV-2 and influenza A/B antigens directly from nasopharyngeal swab specimens. The SARS-CoV-2 or influenza A/B antigens are extracted from swab in the extraction buffer and the extracted sample solutions are loaded to the sample well of the Test Cassette. When the sample is loaded, the detection antibody binds to SARS-CoV-2 or influenza A/B antigen and flows through the membrane. The detection antibody-gold conjugate and SARS-CoV-2 or influenza A/B antigen move to the test line area and are accumulated by the capture antibody immobilized on the membrane. This leads to the generation of a reddish colored band. The intensity of the band depends on quantity of SARS-CoV-2 or influenza A/B antigen and the test results are interpreted by user‘s eye according to the instructions for use.

▶ MATERIALS SUPPLIED

✓ Test Cassette	25
✓ Extraction Buffer	25 (0.4 mL/tube)
✓ Dropping cap	25
✓ Sample collection swab	25
✓ Instructions for Use	1

▶ STORAGE AND STABILITY

1) SGTi-flex COVID-19 & Flu A/B Ag DUO Test Cassette and Extraction Buffer at 2~30°C (36~86°F).
2) If SGTi-flex COVID-19 & Flu A/B Ag DUO Test Cassette and Extraction Buffer are stored in cold storage, allow them for 30 minutes to return to room temperature before testing.
3) Do not open the pouch of Test Cassette until ready to use.

4) After opening aluminum pouch, Test Cassette should be used immediately.
5) 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 the test and follow the procedure correctly.
- ✓ It is prohibited to reuse Test Cassettes because they are single use only.
- ✓ The test result after the expiry date is not reliable.
- ✓ Test Cassette is sensitive to moisture and should be stored in a sealed pouch until use. 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.
- ✓ Samples and Test Cassette must be at room temperature before testing.
- ✓ It is an in vitro diagnostic product and the risk of infection is low because there is no direct contact with the human body.
- ✓ However please be cautious when handling Test Cassette and samples because of the use of clinical samples containing potential infectious sources. Dispose of the used samples and Test Cassettes properly in accordance with the relevant regulations.
- ✓ Smoking and eating are prohibited at test site when handing specimens or kit reagents.

▶ TEST PREPARATION

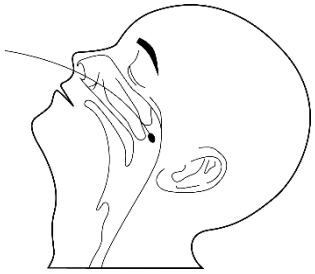
1. Test should be done immediately after sample collecting.
   1) If sample swabs are not used immediately after sample collection, specimen is recommended to be stored in deep freezer at -70˚C (or in dry ice or liquid nitrogen). A freezer at -20˚C is NOT recommended.
   2) If the specimen is stored at 2-8˚C, it can be stored up to 72 hours.
2. Preparation before Test
   1) All samples and reagents should be stored at room temperature and stayed homogenous 15~30 minutes prior to testing.
   2) Test cassette is moisture sensitive so should be used immediately after opening.

▶ SAMPLE COLLECTION

SGTi-flex COVID-19 & Flu A/B Ag DUO can be performed with nasopharyngeal swab.

1. Remove the sealing foil from the Extraction Buffer Tube and place it in the tube rack.
2. SGTi-flex COVID-19 & Flu A/B Ag DUO uses the sample of nasopharyngeal swab.

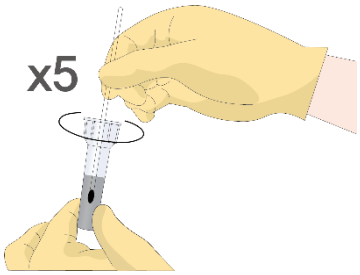
1) Please use single use sample collecting swab.
2) Insert a nasopharyngeal swab into the nostril of the patient, swab over the surface of the posterior nasopharynx.
   Swab should reach depth equal to distance from nostrils to outer opening of the ear.



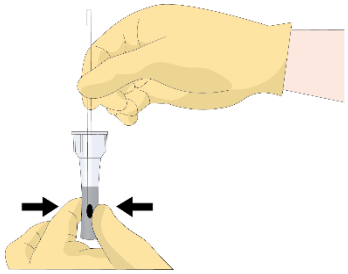
< nasopharyngeal swab >

※ The sample collection swab provided by SGTi-flex COVID-19 & Flu A/B Ag DUO is used for nasopharyngeal swab.

3) Gently rub and roll the swab. Leave swab in place for several seconds to absorb secretions.
   And slowly remove swab while rotating it.
4) Place the sample collecting swab into the Extraction Buffer tube containing 300 µL extraction buffer and rotate it more than 5 times to allow extraction.



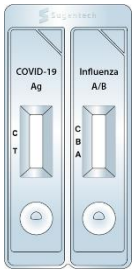
5) Take the sample collecting swab out by pressing and squeezing the sides of the tube to extract the remaining liquid from the swab. Used swab is classified as infectious waste and dispose of used swab properly in accordance with the relevant regulations.



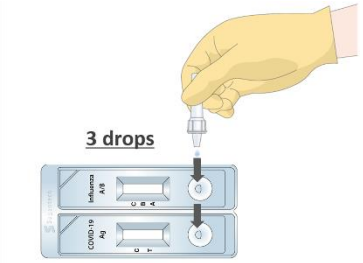
6) Press the Dropping Cap onto the Extraction Buffer tube containing the processed sample.

▶ TEST PROCEDURE

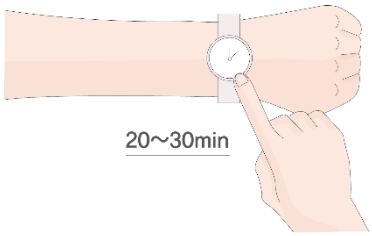
1. Open the pouch and take out the Test Cassette. Place it on a flat, dry and clean surface.



2. Invert the Extraction Buffer tube and add 3 drops of processed sample into the sample well on the each Test Cassette.



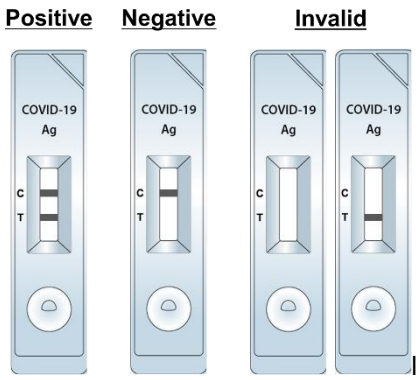
3. Read the results in 20~30 minutes after dispensing the sample. Some positive results may appear faster right after the reaction. The result after 30 minutes is invalid.



▶ INTERPRETATION OF TEST RESULTS

1. COVID-19

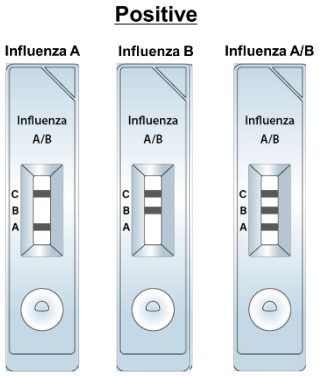
1) Positive: Test line (T) and Control line (C) are appeared in the result window: Positive for SARSCoV-2 antigen
2) Negative: If only Control line (C) appears in the result window: Negative for SARS-CoV-2 antigen
3) Invalid: If control line fails to appear, the result is invalid and retest with a new Test Cassette.



2. Influenza A/B

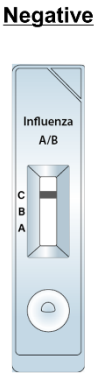
1) Positive

- 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.



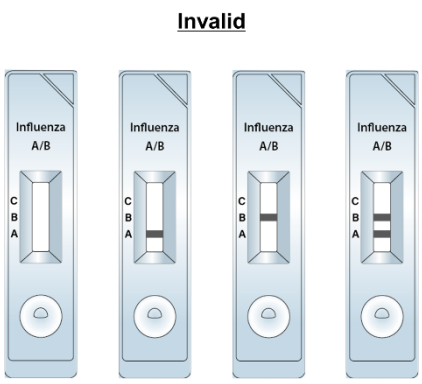
2) Negative

- 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.



▶ Quality Control

1. A procedural control is included in the test. A colored line appearing in the control line region(C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
2. Quality Control materials (positive control swab and negative control swab) can be purchased separately.

▶ LIMITATIONS OF THE SYSTEM

1. The test is for qualitative detection of SARS-CoV-2 and influenza A/B antigen in human nasopharyngeal and it does not indicate the quantification of the virus.
2. The test is for in vitro diagnostic use only.
3. Negative results do not rule out SARS-CoV-2 or influenza A/B infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
4. Test result may vary due to storage and stability of specimen and Extraction Buffer.
5. SARS-CoV may cause positive results. SARS-CoV can be detected as a cross reaction.
6. Specimen with rarely high reactivity for a particular antibody such as anti-mouse antibody can affect the performance of the test results.
7. False positive results might be happened due to the non-specific cross-reaction of some components in the specimen to the antibody.
8. 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.

▶ PERFORMANCE CHARACTERISTICS

1. COVID-19

(1) Limit of Detection (LOD) :

The study used heat inactivated viral culture fluid of SARS-CoV-2 isolated USA-WA1/2020.

The LOD is 5.3 x10^2 $TCID_{50}$/mL.

(2) Cross-Reactivity

SGTi-flex COVID-19 Ag was evaluated with 23 other virus and 19 bacteria. The results show that the SGTi-flex COVID-19 Ag has no cross-reactivity with samples containing tested viruses and bacteria except on SARS -CoV.

Virus

No	Strain	Results
1	Alpha Coronavirus (229E)	Negative
2	Beta Coronavirus OC43	Negative
3	Human Coronavirus NL63	Negative
4	Beta Coronavirus (MERS) NP protein	Negative
5	Beta Coronavirus (SARS-CoV) NP protein	Positive
6	Influenza A/H1N1 A/Brisbane/02/2018 (H1N1)pdm09-like virus (13/234)	Negative
7	Influenza A/H3N2 Influenza Antigen A/New Caledonia/71/2014 (H3N2, 15/238)	Negative
8	Influenza A/H5N1 Influenza Antigen A/Anhui/1/05 (H5N1, 07/290)	Negative
9	Influenza B Influenza Antigen B/Guangdong/120/2000 (01/546)	Negative
10	Epstein-Barr Virus	Negative
11	Rhinovirus group A	Negative
12	Respiratory Syncytial virus type A	Negative
13	Respiratory Syncytial virus type B	Negative
14	Mumps Virus	Negative
15	Adenovirus type 5	Negative
16	Human Coxsackie B4	Negative
17	Human Meta pneumovirus	Negative
18	Human Measles Mvi/Moscow Rus/1988 Genotype A	Negative
19	Parainfluenza Virus serotype 1	Negative
20	Parainfluenza Virus serotype 2	Negative
21	Parainfluenza Virus serotype 3	Negative
22	Parainfluenza Virus serotype 4	Negative
23	Human Coronavirus HKU1	*In silico*

Bacteria

No	Strain	Results
1	*Group A streptococcus antigen*	Negative
2	*Group B streptococcus antigen*	Negative
3	*Streptococcus Pneumoniae antigen*	Negative
4	*Escherichia coli culture*	Negative
5	*Corynebacterium glutamicum culture*	Negative
6	*Lactobacillus plantarum culture*	Negative
7	*Legionella spp culture*	Negative
8	*Pseudomonas aeruginosa culture*	Negative
9	*Staphylococcus epidermidis culture*	Negative
10	*Mycobacterium tuberculosis*	Negative
11	*Hemophilus influenzae*	Negative
12	*Streptococcus spp*	Negative
13	*Candida albicans*	Negative
14	Pooled human nasal fluid	Negative
15	*Bordetella pertussis*	Negative
16	*Mycoplasma pneumoniae*	Negative
17	*Chlamydophila pneumoniae*	Negative
18	*Legionella pneumophila*	Negative
19	*Pneumocystis jirovecii(PJP)*	*In silico*

(3) Analytical Specificity – Interference test

Various concentrations of potential interfering substances were prepared in negative and positive sample. The results show that the SGTi-flex COVID-19 Ag has no interference by the potential interfering substances below which may exist in specimen, such as prescription/OTC drugs, and elevated levels of chemical and biological analytes.

Interfering substances

No	Substance	Concentration	No	Substance	Concentration
1	Albumin	50mg/mL	10	Menthol	40mg/mL
2	Glucose	1.2mg/mL	11	Zanamivir	10mg/mL
3	Hemoglobin	4mg/mL	12	Tobramycin	20mg/mL
4	Bilirubin	5mg/mL	13	Tamiflu (Oseltamivir)	6mg/mL
5	Phenylephrine	10mg/mL	14	mucin	1.0 %
6	Dexamethasone	0.6mg/mL	15	Whole blood	1.0 %
7	Flunisolide	2.5mg/mL	16	Acetaminophen	10 mg/mL
8	Budesonide	1mg/mL	17	Ibuprofen	5 mg/mL
9	Benzocaine	5mg/mL	18	Aspirin	2 mg/mL

(4) Precision test

Within-run, Between-run, Batch-to-batch performance results meet 100% of the acceptance criteria.

(5) Clinical Agreement Study

Comparison studies between the test device (SGTi-flex COVID-19 Ag) and the predicate device (Reference method, real time RT-PCR) were conducted by lab professionals, using total 243 specimens.

The results showed the accuracy (overall percent agreement) was 96.71%. The sensitivity and specificity (positive and negative agreements) were 95.10% and 99.00%, respectively.

		Reference method		
		Positive	Negative	Total
Test device (SGTi-flex COVID-19 Ag)	Positive	136	1	137
	Negative	7	99	106
	Total	143	100	243

- Accuracy (Overall percent agreement): 96.71% (235/243, 95% CI: 93.64%~98.32%)
- Sensitivity (Positive percent agreement): 95.10% (136/143, 95% CI: 90.24%~97.61%)
- Specificity (Negative percent agreement): 99.00% (99/100, 95% CI: 94.55%~99.82%)

2. <u>Influenza A/B</u>

(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

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 108 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/Mos cow 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

Total Clinical Sensitivity and Specificity

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

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

Influenza A/B Type Clinical Sensitivity

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

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

▶ REFERENCES

1. WHO, Coronavirus disease 2019 (COVID-19) Situation report
2. J.virol. Methods. 2008, 152(1-2): 77-84, A rapid point of care immunoswab assay for SARS-CoV detection
3. 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
	Do not reuse
	Consult instructions for use.
30℃ 2℃	Store between 2°C and 30°C
	Caution, consult accompanying documents
LOT	Batch code
	Use by
REF	Catalogue number
	Manufacturer
EC REP	Authorized representative in the European community
CE	The device conforms to EU-regulations.

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