EN | REF Q-CVFL-01C

Cat No.: 09COV102D

STANDARD Q

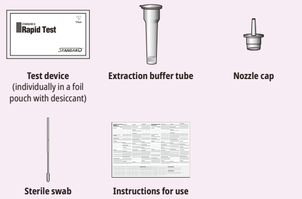
COVID/Flu Ag Combo

STANDARD™ Q COVID/Flu Ag Combo Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS



Test device (individually in a foil pouch with desiccant)

Extraction buffer tube

Nozzle cap

Sterile swab

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

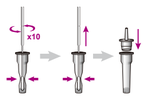
SPECIMEN COLLECTION

■ Specimen preparation

(Nasopharyngeal swab)

1. Remove the swab from the packaging by pulling on both flaps of the plastic film. Only touch the swab at the handle, not at the tip.
2. Tilt the patient's head slightly back (approximately 70 degree angle).
3. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. Do not apply pressure.
4. Rotate the swab 3-4 times against the nasopharyngeal surface. Remove the swab from the nasal cavity carefully.

5. Carefully open the extraction buffer tube avoiding spillage. If buffer is spilled, do not use the tube.
6. Insert the swab from patient into an extraction buffer tube. While squeezing the buffer tube, stir the swab at least 10 times.
7. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
8. Press the nozzle cap tightly on to the tube.



⚠ Failure to squeeze the tube can lead to incorrect results due to insufficient elution of the material into the buffer or excess buffer in the swab.

PREPARATION AND TEST PROCEDURE

■ Preparation

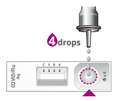
Foil pouch | Test device | Desiccant

1. Carefully read the instructions for using the STANDARD Q COVID/Flu Ag Combo Test.
2. Look at the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.
3. Open the foil pouch, and check the test device and the desiccant inside the foil pouch.

⚠ Prior to starting the procedure, test devices and reagents must be equilibrated to operating temperature (15-30 °C / 59-86 °F).

■ Test Procedure

1. Place the test device on a flat surface and apply **4 drops** of extracted specimen to the specimen well of the test device.



2. Read the test result at 15-30 minutes. Do not touch or move the test device until the result can be read.

⚠
- Place the test device on a flat surface to allow optimal capillary action.
- Dispense the specimen at 90 degree angle to allow for free falling drops and avoid bubbles.
- Test results that are read before 15 minutes or after 30 minutes may be incorrect.

INTERPRETATION OF TEST RESULTS

■ Visual inspection

Test result		Example	Description
Negative		C S B A	Only band ("C" Control line) within the result window indicates a negative result.
Positive	Influenza A positive	C S B A	Two colored bands ("C" Control line and "A" Test line) within the result window indicate influenza A positive.
	Influenza B positive	C S B A	Two colored bands ("C" Control line and "B" Test line) within the result window indicate influenza B positive.
	SARS-CoV-2 positive	C S B A	Two colored bands ("C" Control line and "S" Test line) within the result window indicate SARS-CoV-2 positive.
	Influenza A/B positive	C S B A	Three colored bands ("C" Control line, "A" Test line and "B" Test line) within the result window indicate influenza A/B positive.
	Influenza A & SARS-CoV-2 positive	C S B A	Three colored bands ("C" Control line, "S" Test line and "A" Test line) within the result window indicate SARS-CoV-2 and influenza A positive.
	Influenza B & SARS-CoV-2 positive	C S B A	Three colored bands ("C" Control line, "S" Test line and "B" Test line) within the result window indicate SARS-CoV-2 and influenza B positive.
	Influenza A/B & SARS-CoV-2 positive	C S B A	Four colored bands ("C" Control line, "S", "A" and "B" Test line) within the result window indicate SARS-CoV-2 and influenza A/B positive.
Invalid		C S B A	If the control band ("C" Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new test device.
		C S B A	

⚠
- Positive results should be considered in conjunction with the clinical history and other data available.
- The presence of any line no matter how faint it is, should be considered as a line formed.
- This test is for screening purposes. Confirmatory testing according to national guidelines is recommended to confirm the infection status.

INTERNAL QUALITY CONTROL

A control line is used in the test as a procedural control. A visible control line confirms that the lateral flow of the test is successful but is not the confirmation that the specimen and buffer have been applied properly.

EXTERNAL QUALITY CONTROL

- Positive/Negative control

Test should be run following the instructions for use provided by the test kit for unknown specimens. Please follow the procedure from step 5 of Specimen preparation with the control swabs. Positive and negative controls are available separately from the test kit.
It is recommended that positive and negative controls be run:

- Once for each new lot,
- Once for each untrained operator,
- Once for each new shipment of test kits,
- As required by test procedures in these instructions and in accordance with local, state and federal regulations or accreditation requirements.

EXPLANATION AND SUMMARY

■ Introduction

Influenza virus and SARS-CoV-2 both have a similar disease presentation. They both cause respiratory disease, which presents as a wide range of illness from asymptomatic or mild through to severe disease and death. Both viruses are transmitted by contact, droplets and fomites. STANDARD Q COVID/Flu Ag Combo Test, containing a highly specific and sensitive antibody to SARS-CoV-2, Influenza A and Influenza B, provides significantly fast, easy and accurate system to identify the target antigen in an extraction from nasopharyngeal swab specimens. The test is the reliable clinical diagnosis of SARS-CoV-2 or influenza and enables supportive clinical decisions.

■ Intended use

The STANDARD Q COVID/Flu Ag Combo Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 and Influenza A and Influenza B present in human nasopharyngeal specimens. The STANDARD Q COVID/Flu Ag Combo Test for rapid detection of SARS-CoV-2, Influenza A and Influenza B is a differentiated test, such that SARS-CoV-2 viral antigens can be distinguished from Influenza A or Influenza B viral antigens from a single specimen using a single device. This test is for administration by healthcare workers and labs only, as an aid to early diagnosis of SARS-CoV-2, Influenza A or Influenza B infection in patient with clinical symptoms with viral infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2, Influenza A or Influenza B infection.

■ Test principle

The STANDARD Q COVID/Flu Ag Combo Test has four pre-coated lines, "C" Control line, "A", "B", "S" test lines on the surface of the nitrocellulose membrane. The control line and test lines in the result window are not visible before applying any specimens. Mouse monoclonal anti-SARS-CoV-2 antibody, monoclonal anti-influenza A and monoclonal anti-influenza B are coated on the each "S", "A" and "B" test line region and mouse monoclonal anti-Chicken IgY antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 antibody, monoclonal anti-influenza A and monoclonal anti-influenza B conjugated with color particles are used as detectors for each target antigens. During the test, antigens in the specimen and the gold conjugated antibodies make complexes and the complexes move along membrane to the test and control line via capillary action to react with the antibodies coated on the surface of membrane. A colored test line would be visible in the result window if SARS-CoV-2, Influenza A or Influenza B antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of antigens present in the specimen. If antigens are not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

KIT STORAGE AND STABILITY

Store the kit at 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.

WARNINGS AND PRECAUTIONS

1. Bring the kit contents and the specimens to room temperature before testing.
2. Do not re-use the test kit.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Do not use the extraction buffer tube of another lot.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
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 biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. The test should be used for the detection of SARS-CoV-2, Influenza A or Influenza B antigen in human nasopharyngeal swab specimens only, other specimen types have not been validated.
3. This test can not be used for quantifying SARS-CoV-2, Influenza A or Influenza B antigen concentration.
4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
5. The test result must always be evaluated with other data available to the physician.
6. A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2, Influenza A or Influenza B infection, and should be confirmed by viral culture or molecular assay.
7. Positive test results do not rule out co-infections with other pathogens.

PERFORMANCE CHARACTERISTICS

■ Clinical evaluation

The clinical performance of the STANDARD Q COVID/Flu Ag Combo Test was evaluated in Korea.

The STANDARD Q COVID/Flu Ag Combo Test correctly identified 51 out of 55 SARS-CoV-2-positive individuals, and 194 out of 195 SARS-CoV-2-negative individuals. The relative diagnostic sensitivity and specificity for SARS-CoV-2 of the STANDARD Q COVID/Flu Ag Combo Test were calculated in comparison to the comparator method and summarized in table 1.

Table 1 SARS-CoV-2 performance against the comparator method

		RT-PCR		
		Positive	Negative	Total
STANDARD Q COVID/Flu Ag Combo Test	Positive	51	1	52
	Negative	4	194	198
	Total	55	195	250

Clinical Sensitivity: 92.73% (95%CI: 82.41% - 97.98%)
Clinical Specificity: 99.49% (95% CI: 97.18% - 99.99%)

The STANDARD Q COVID/Flu Ag Combo Test correctly identified 83 out of 90 Influenza virus A-positive individuals, and 195 out of 195 Influenza virus A-negative individuals. The relative diagnostic sensitivity and specificity for Influenza virus A of the STANDARD Q COVID/Flu Ag Combo Test are summarized in table 2.

Table 2 Influenza virus A performance against the comparator method

		RT-PCR		
		Positive	Negative	Total
STANDARD Q COVID/Flu Ag Combo Test	Positive	83	0	83
	Negative	7	195	202
	Total	90	195	285

Clinical Sensitivity: 92.22% (95% CI: 84.63% - 96.82%)
Clinical Specificity: 100% (95% CI: 98.13% - 100%)

The STANDARD Q COVID/Flu Ag Combo Test correctly identified 62 out of 68 Influenza virus B-positive individuals, and 194 out of 195 Influenza virus B-negative individuals. The relative diagnostic sensitivity and specificity for Influenza virus B of the STANDARD Q COVID/Flu Ag Combo Test are summarized in table 3.

Table 3 Influenza virus B performance against the comparator method

		RT-PCR		
		Positive	Negative	Total
STANDARD Q COVID/Flu Ag Combo Test	Positive	62	1	63
	Negative	6	194	200
	Total	68	195	263

Clinical Sensitivity: 91.18% (95% CI: 81.78% - 96.69%)
Clinical Specificity: 99.49% (95% CI: 97.18% - 99.99%)

■ Analytical performance

1. Limit of Detection (LoD)
The SARS-CoV-2, Influenza virus A or Influenza virus B positive specimen were prepared by spiking the respective inactivated virus into a negative clinical matrix using SARS-CoV-2, Influenza virus A and Influenza virus B negative nasopharyngeal swabs confirmed with RT-PCR or fluorescent immunoassay. LoDs are determined as shown in the below table for direct nasopharyngeal swabs by testing serially diluted positive specimens.

Virus strain	LoD ($TCID_{50}$/mL)
SARS-CoV-2, (2019-nCOV) NCCP 43326/2020/Korea	5.32×10^1
Influenza A, strain A/Brisbane/02/18 (H1N1 pdm)	3.17×10^1
Influenza B, strain B/Colorado/6/17 (Victoria lineage)	8.75×10^2

2. Endogenous Cross-reactivity & Interference
There was no endogenous cross-reactivity and interference with following substances at indicated concentrations:
Whole Blood (4%), Mucin (0.5%), Chloraseptic (Menthol/Benzocaine) (1.5 mg/mL), Naso GEL (Sodium Hyaluronate) (5% v/v), CVS Health Nasal Drops (Phenylephrine) (15% v/v), Afrin (Oxymetazoline) (15% v/v), CVS Health Oxymetazoline (15% v/v), NasalCrom Nasal Spray (Cromolyn) (15% v/v), Zicam (Oxymetazoline) (5% v/v), Homeopathic (Alkalol) (1:10 dilution), Sore Throat Phenol Spray (Phenol) (15% v/v), Tobramycin (4μg/mL), Mupirocin (10mg/mL), CVS Health Fluticasone Propionate (Glucocorticoid) (5% v/v), Tamiflu (Oseltavmivir Phosphate) (5 mg/mL), Nicotine (1 ug/mL)

3. Microbial Cross-reactivity & Interference
There was no microbial cross-reactivity and interference with following microorganisms at indicated concentrations. The in-silico analysis shows low probability for cross reactivity for HCoV-HKU1, Pneumocystis jroveci (PJP) *Mycobacterium tuberculosis*, human Bocavirus and Epstien-Barr virus. However, the in-silico analysis for SARS-CoV shows high probability of cross reactivity with SARS-CoV-2.
Human coronavirus 229E (2.41 x 10^5 PFU/mL), Human coronavirus OC43 (3.40 x 10^5 PFU/mL), Human coronavirus NL63 (1.15 x 10^5 PFU/mL), MERS-coronavirus (2.83 x 10^5 PFU/mL), SARS-coronavirus (recombinant N protein) (17.2ng/mL), Adenovirus Type 1 (1.75 x 10^6 PFU/mL), Adenovirus Type 2 (7.13 x 10^5 PFU/mL), Adenovirus Type 5 (2.76 x 10^7 PFU/mL), Adenovirus Type 6 (1.32 x 10^7 PFU/mL), Adenovirus Type 7A (7.13 x 10^5 PFU/mL), Adenovirus Type 11 (1.32 x 10^7 PFU/mL), Adenovirus Type 14 (2.83 x 10^5 PFU/mL), Adenovirus Type 40 (2.58 x 10^6 PFU/mL), Human Metapneumovirus 3 type B1 (1.49 x 10^6 PFU/mL), Human Metapneumovirus 16 type A1 (2.58 x 10^6 PFU/mL), Parainfluenza virus 1 (8.56 x 10^5 PFU/mL), Parainfluenza virus 2 (1.03 x 10^6 PFU/mL), Parainfluenza virus 3 (2.30 x 10^5 PFU/mL), Parainfluenza virus 4A (2.58 x 10^6 PFU/mL), Enterovirus type 68 09/2014 Isolate 4 (1.03 x 10^5 PFU/mL), Respiratory syncytial virus A (7.13 x 10^5 PFU/mL), Respiratory syncytial virus B (3.40 x 10^5 PFU/mL), Rhinovirus 1A (1.15 x 10^5 PFU/mL), Rhinovirus A16 (8.56 x 10^5 PFU/mL), Rhinovirus B42 (7.13 x 10^5 PFU/mL), Epstein Barr Virus (B95-8) (2.62 x 10^8 cp/mL), Cytomegalovirus (AD-169) (4.49 x 10^6 PFU/mL), Measles Virus (4.00 x 10^5 PFU/mL), Mumps Virus (8.56 x 10^5 PFU/mL), *Haemophilus influenzae* (NCCP 13815) (2.46 x 10^7 CFU/mL), *Haemophilus influenzae* (NCCP 13819) (3.29 x 10^7 CFU/mL), *Haemophilus influenzae* (NCCP 14581) (3.98 x 10^7 CFU/mL), *Haemophilus influenzae* (NCCP 14582) (1.03 x 10^{10} CFU/mL), *Streptococcus pneumoniae* type1 (KCCM 41568) (1.85 x 10^6 CFU/mL), *Streptococcus pneumoniae* type2 (KCCM 40410) (1.51 x 10^6 CFU/mL), *Streptococcus pneumoniae* type3 (KCCM 41569) (2.25 x 10^6 CFU/mL), *Streptococcus pneumoniae* type5 (KCCM 41570) (9.70 x 10^7 CFU/mL), *Streptococcus pyogenes* (ATCC 12344) (6.74 x 10^7 CFU/mL), *Bordetella pertussis* (NCCP 13671) (6.05 x 10^7 CFU/mL), *Mycoplasma pneumoniae* (ATCC 15531) (3.30 x 10^7 CFU/mL), *Chlamydia pneumoniae* (ATC VR-2282) (8.83 x 10^7 CFU/mL), *Legionella pneumophila* (ATCC 33155) (1.54 x 10^{10} CFU/mL), *Staphylococcus aureus* (NCCP 14647) (8.73 x 10^6 CFU/mL), *Staphylococcus epidermidis* (NCCP 35494) (6.03 x 10^6 CFU/mL), *Corynebacterium* sp. (KCCM 43306) (3.21 x 10^6 CFU/mL), *Lactobacilus* sp. (KCCM 32821) (1.78 x 10^7 CFU/mL), *Moraxella catarrhalis* (KCCM 42707) (2.43 x 10^6 CFU/mL), *Mycobacterium tuberculosis* (KIT 87190) (3.04 x 10^7 CFU/mL), *Neisseria meningitides* (KCCM 41562) (1.86 x 10^7 CFU/mL), *Streptococcus mitis* (KCCM 42740) (9.61 x 10^6 CFU/mL), *Neisseria* sp. (KCCM 42783) (4.04 x 10^6 CFU/mL), *Pseudomonas aeruginosa* (NCCP 14640) (9.70 x 10^6 CFU/mL), *Streptococcus salivarius* (KCCM 11926) (3.23 x 10^8 CFU/mL), *Candida albicans* (KCCM 50651) (1.80 x 10^8 CFU/mL).

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SYMBOL

REF	Catalogue number (Reference number)	⚠	Caution		Use-by date	LOT	Batch code		Consult instructions for Use		Do not re-use
IVD	*In vitro* diagnostic medical device		Note		Manufacturer		Date of manufacture		Contains sufficient for <n> tests		Keep away from sunlight
	Indicate that you should keep the product dry		To indicate the temperature limitations in which the transport package has to be kept and handled.		Do not use if packaging is damaged	CE	This product fulfills the requirements of the European Directive 98/79/EC.	EC REP	Authorized representative in the European Community		

CE IVD

EC REP **Authorized Representative**
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