EN REF Q-NCOV-01G

Cat No. 09COV31D
Cat No. 09COV33D

STANDARD Q

COVID-19 Ag Test

STANDARD™ Q COVID-19 Ag Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS

Contents (Cat No. 09COV31D)	Quantity
Test device (individually in a foil pouch with desiccant)	25
Extraction buffer tube	25
Nozzle cap	25
Sterile swab	25
Buffer tube rack	2
Instructions for use	1

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Sterile swab	25
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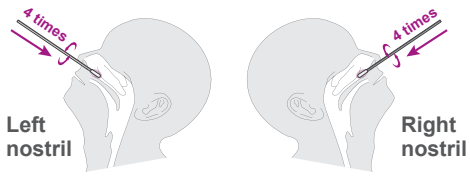
STANDARD COVID-19 Ag Positive Control swab	1
STANDARD Respiratory Negative Control swab	1
Instructions for use	1

SPECIMEN COLLECTION AND PREPARATION

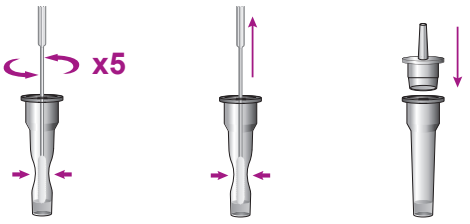
■ Specimen preparation

[Nasal swab]



1. Tile patient's head back slightly.
2. While rotating the swab, insert swab less than one inch (about 2cm) into nostril until resistance is met at turbinate.
3. Rotate the swab 4 times against nasal wall.
4. Repeat in other nostril using the same swab.

Specimens must be collected from both nostrils using the same swab.

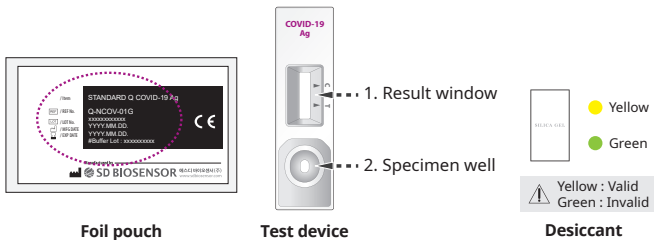


5. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.
6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
7. Press the nozzle cap tightly onto the tube.
8. Specimen should be tested as soon as possible after collection.
9. Specimens may be stored at room temperature (15 – 25°C) or 2-8°C/ 36-46°F for up to 4 hours prior to testing.

- Without the tube squeezing process, improper results may occur due to the large amount of buffer absorption by the swab.
- If the specimen storage condition is out of instructions as below, do not use.
  - The Nasal swab is stored in extraction buffer for more than 4 hours at 5±3°C or 20±5°C.
  - Freezing and thawing of Nasal swab is more than 1 cycle.

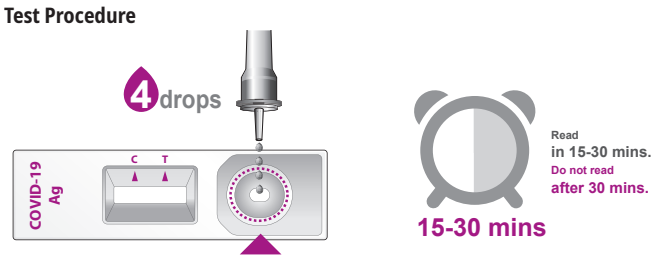
PREPARATION AND TEST PROCEDURE

■ Preparation



1. Carefully read instructions for using STANDARD Q COVID-19 Ag Test.
2. Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.
3. Check the test device and the desiccant pack in the foil pouch.

■ Test Procedure



1. Apply 4 drops of extracted specimen to the specimen well of the test device.
2. Read the test result in 15-30 minutes.

- Place the test device on a flat surface.
- Dispense the specimen at 90 degree angle to allow for free falling drops and avoid bubbles.
- Do not read test results after 30 minutes. It may give false results.

INTERPRETATION OF TEST RESULTS

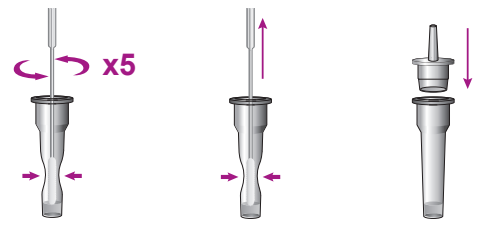
Test result	Example	Description
Negative		1. A purple colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C). 2. A purple colored band will appear in the lower section of the result window. This band is test line of SARS-CoV-2 antigen (T). 3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.
Positive		
		
Invalid		
		

* The presence of any line no matter how faint the result is considered positive.
* Positive results should be considered in conjunction with the clinical history and other data available.

CONTROL PREPARATION AND TEST PROCEDURE

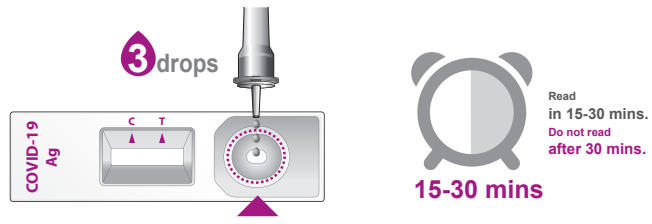
- Positive/Negative control

■ Preparation



1. Put the positive or negative control swab into an extraction buffer tube. Stir the swab more than 5 times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
3. Press the nozzle cap tightly onto the tube.

■ Test Procedure



1. Apply 3 drops of extraction buffer to the specimen well.
2. Read the test result in 15-30 minutes.

- Place the test device on a flat surface.
- Dispense the specimen at 90 degree angle to allow for free falling drops and avoid bubbles.
- Do not read test results after 30 minutes. It may give false results.

INTERPRETATION OF CONTROL TEST RESULT

STANDARD COVID-19 Ag Control Positive swab: Positive		
Result	**Interpretation**	**Follow up**
Test (T) Line Positive	PASS	-
Test (T) Line Negative	FAIL	Retest
No Control (C) Line	Invalid	Retest

STANDARD Respiratory Negative Control swab: Negative		
Result	**Interpretation**	**Follow up**
Test (T) Line Negative	PASS	-
Test (T) Line Positive	FAIL	Retest
No Control (C) Line	Invalid	Retest

EXPLANATION AND SUMMARY

■ Introduction

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "SARS-CoV-2 (COVID-19)", was discovered because of Wuhan Viral Pneumonia cases in 2019, and was named by the World Health Organization on January 12, 2020, confi rming that it can cause colds and the Middle East Respiratory Syndrome (MERS) and more serious diseases such as Severe Acute Respiratory Syndrome (SARS). These kits are helpful for the auxiliary diagnosis of coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confi rming or excluding cases alone.

■ Intended use

STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in human nasal or nasopharyngeal specimens. This product is intended for healthcare professionals at the clinical setup and point of care sites, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms of SARS-CoV-2 infection. It provides only an initial screening test result. This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

■ Test principle

STANDARD Q COVID-19 Ag test device has two pre-coated lines, "C" Control line, "T" Test line on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and mouse monoclonal anti-Chicken IgY antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 antibody conjugated with color particles are used as detectors for SARS-CoV-2 antigen device. During the test, SARS-CoV-2 antigen in the specimen interact with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making antigen-antibody color particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS-CoV-2 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.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Personal protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves)
2. Timer
3. Biohazard container

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 the kit.

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.
12. This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

    Warning:
    H317 May cause an allergic skin reaction.
    H412 Harmful to aquatic life with long lasting effects.
    H319 Causes serious eye irritation.

    Prevention:
    P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
    P273 Avoid release to the environment.
    P280 Wear eye protection/face protection.

    Response:
    P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
    P337 + P313 If eye irritation persists: Get medical advice/attention.
    P362 + P364 Take off contaminated clothing and wash it before reuse.

    For customers in the European Economic Area: Contains SVHC: octyl/nonylphenol ethoxylates. For use as part of an IVD method and under controlled conditions only – acc. to Art. 56.3 and 3.23 REACH Regulation.

PERFORMANCE CHARACTERISTICS

■ Clinical evaluation

Clinical performance of STANDARD Q COVID-19 Ag Test was evaluated using 503 nasal specimens at Central Research Lab in Bangalore, India. FDA EUA-authorized RT-PCR test (EURO Real Time SARS-CoV-2) was used as the comparator method in the study.

■ Test sensitivity & specificity

The positive percent agreement of STANDARD Q COVID-19 Ag Test using nasal swab as specimen and RT-PCR Test as reference assay is 97.12% (95% CI, 91.86 – 99.01%) and the negative percent agreement is 100% (95% CI, 99.05 – 100%).

Table 1. STANDARD Q COVID-19 Ag Test result by India.

		EURO Real Time SARS-CoV-2		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	101	0	101
	Negative	3	399	402
	Total	104	399	503
	Result	**Sensitivity: 97.12% (95% CI, 91.86% – 99.01%)** **Specificity: 100% (95% CI, 99.05% – 100%)**		

ANALYTICAL PERFORMANCE

■ Limit of Detection (LoD)

The SARS-CoV-2 positive specimen was prepared by spiking inactivated SARS-CoV-2 (2019-nCOV) NCCP 43326/2020/Korea strain to SARS-CoV-2 negative nasal swab confirmed with PCR. LoD is determined as 9.25 X $10^{1.2}$ $TCID_{50}$/mL for direct nasal swab by testing serially diluted mock positive specimens.

■ Cross-reactivity & microbial interference

There was no cross-reactivity and interference with the following microbes at indicated concentrations: Human coronavirus 229E (2.18 x 10^5 PFU/ml), Human coronavirus OC43 (4.06 x 10^7 PFU/ml), Human coronavirus NL63 (1.17 x 10^5 PFU/ml), MERS-coronavirus (2.87 x 10^5 PFU/ml), Adenovirus Type1 (1.77 x 10^8 PFU/ml), Adenovirus Type2 (7.93 x 10^6 PFU/ml), Adenovirus Type5 (2.33 x 10^7 PFU/ml), Adenovirus Type6 (1.34 x 10^7 PFU/ml), Adenovirus Type7A (9.74 x 10^4 PFU/ml), Adenovirus Type11 (1.34 x 10^7 PFU/ml), Adenovirus Type14 (1.69 x 10^5 PFU/ml), Adenovirus Type40 (2.62 x 10^6 PFU/ml), Human Metapneumovirus3 type B1 (1.5 x 10^6 PFU/ml), Human Metapneumovirus16 type A1 (6.58 x 10^6 PFU/ml), Parainfluenza virus 1 (2.13 x 10^8 PFU/ml), Parainfluenza virus 2 (8.68 x 10^5 PFU/ml), Parainfluenza virus 3 (4.55 x 10^6 PFU/ml), Parainfluenza virus 4A (2.62 x 10^6 PFU/ml), Influenza A H1N1 pdm/Michigan/45/15 (8.68 x 10^5 PFU/ml), Influenza A H1N1 Brisbane/59/07 (4.99 x 10^5 PFU/ml), Influenza A H3N2 Singapore/INFIMH-16-0019/16 (3.22 x 10^4 PFU/ml), Influenza A H3N2 South Australia/55/14 (8.1 x 10^4 PFU/ml), Influenza A H3N2 Hong Kong/8/68 (3.45 x 10^5 PFU/ml), Influenza A H3N2 Victoria/361/11 (9.74 x 10^4 PFU/ml), Influenza B Massachusetts/2/12 (1.69 x 10^5 PFU/ml), Influenza B Malaysia/2506/04 (2.87 x 10^5 PFU/ml), Influenza B Lee/40 (1.69 x 10^5 PFU/ml), Influenza B Yamagata/16/88 (1.69 x 10^5 PFU/ml), Influenza B Victoria/2/87 (1.28 x 10^4 PFU/ml), Influenza B Texas/6/11 (2.62 x 10^6 PFU/ml), Influenza B Colorado/6/17 (3.22 x 10^4 PFU/ml), Influenza B Florida/02/06 (2.62 x 10^6 PFU/ml), Enterovirus type 68 09/2014 Isolate 4 (2.44 x 10^5 PFU/ml), Respiratory syncytial virus A (2.62 x 10^6 PFU/ml), Respiratory syncytial virus B (3.45 x 10^5 PFU/ml), Rhinovirus 1A (2.44 x 10^6 PFU/ml), Rhinovirus A16 (8.68 x 10^6 PFU/ml), Rhinovirus B42 (7.24 x 10^5 PFU/ml), Haemophilus influenzae (NCCP 13815) (2.54 x 10^7 CFU/mL), Haemophilus influenzae (NCCP 13819) (3.39 x 10^7 CFU/mL), Haemophilus influenzae (NCCP 14581) (4.10 x 10^7 CFU/mL), Haemophilus influenzae (NCCP 14582) (1.06 x 10^7 CFU/mL), Streptococcus pneumoniae type1 (KCCM 41560) (1.54 x 10^6 CFU/mL), Streptococcus pneumoniae type2 (KCCM 40410) (1.04 x 10^7 CFU/mL), Streptococcus pneumoniae type3 (KCCM 41569) (1.34 x 10^7 CFU/mL), Streptococcus pneumoniae type5 (KCCM 41570) (1.24 x 10^7 CFU/mL), Streptococcus pyogenes (ATCC 12344) (3.22 x 10^7 CFU/mL), Candida albicans (ATCC 10231) (1.78 x 10^6 CFU/mL), Bordetella pertussis (NCCP 13671) (6.24 x 10^7 CFU/mL), Mycoplasma pneumoniae (ATCC 15531) (2.48 x 10^9 CFU/mL), Chlamydia pneumoniae (ATCC VR-2282) (9.1 x 10^7 IFU/mL), Legionella pneumophila (ATCC 33155) (1.9 x 10^8 CFU/mL), Staphylococcus aureus (NCCP 14647) (1.00 x 10^9 CFU/mL), Staphylococcus epidermidis (KCCM 35494) (6.22 x 10^8 CFU/mL).

Cross-reactivity was observed for SARS-CoV.

Human coronavirus HKU1, *Pneumocystis jirovecii* (PJP) and Mycobacterium tuberculosis have not been tested. There can be cross-reaction with human coronavirus HKU1, PJP or TB, even though the percentage identity of the nucleocapsid protein sequence of HKU1, and proteins of PJP and TB with the nucleocapsid protein sequence of SARS-CoV-2 was 31.6 %, 12.3 % and 13.0 %, respectively, which is considered as low homology.

■ Exogenous / endogenous interference substances studies

There was no interference with the following substances at indicated concentrations:
Chloraseptic (Menthol/Benzocaine) (1.5 mg/mL), Naso GEL (NeilMed) (5 % v/v), CVS Health Nasal Drops (Phenylephrine) (15 % v/v), Afrin (Oxymetazoline) (15 % v/v), CVS Health Oxymetazoline (15 % v/v), CVS Health Nasal Spray (Cromolyn) (15 % v/v), Zicam (5 % v/v), Homeopathic (Alkalol) (1:10 dilution), Sore Throat Phenol Spray (15 % v/v), Tobramycin (4 µg/mL), Mupirocin (10 mg/mL), CVS Health Fluticasone Propionate (5 % v/v), Tamiflu (Oseltamivir Phosphate) (5 mg/mL), Whole Blood (4 %), Mucin (0.5 %).

■ High-dose hook effect

SARS-CoV-2 cultured virus was spiked into specimens. SARS-CoV-2 cultured virus did not show hook effect up to 1 X $10^{6.2}$ $TCID_{50}$/mL. A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

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 antigen in human nasal swab specimens only, other specimen types have not been validated.
3. This test can not be used for quantifying SARS-CoV-2 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 infection, and should be confirmed by viral culture or molecular assay.
7. Positive test results do not rule out co-infections with other pathogens.

BIBLIOGRAPHY

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2. Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020
3. Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020

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Reference number | *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | Note | Do not re-use. | To indicate the temperature limitations in which the transport package has to be kept and handled. | Use by | Batch code | Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices | Manufacturer | Date of manufacture | Indicate that you should keep the product dry | Keep away from sunlight | Do not use if packaging is damaged