EN

REF Q-NCOV-01G

STANDARD Q
COVID-19 Ag

STANDARD™ Q COVID-19 Ag Test

PLEASE READ CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

The device is intended for use in patients within 7 days of symptom onset.

KIT CONTENTS

Test device (individually in a foil pouch with desiccant)

Extraction buffer tube

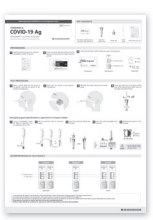
Nozzle cap

Sterile swab

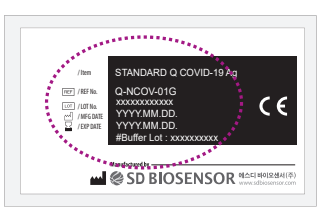
Instructions for use

PREPARATION

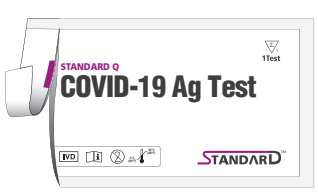
1 Carefully read instructions for using the STANDARD Q COVID-19 Ag Test.



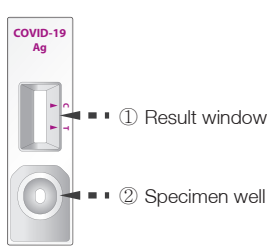
2 Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.



3 Check the test device and the desiccant pack in the foil pouch.



<Foil pouch>



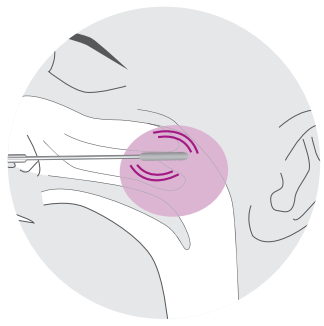
<Test device>

<Desiccant>

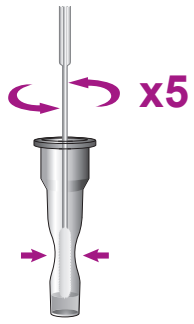
COLLECTION OF SPECIMEN

[Nasopharyngeal swab]

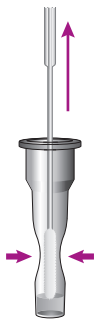
1 Insert a sterile swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. Withdraw the sterile swab from the nasal cavity.



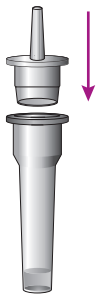
2 Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.



3 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

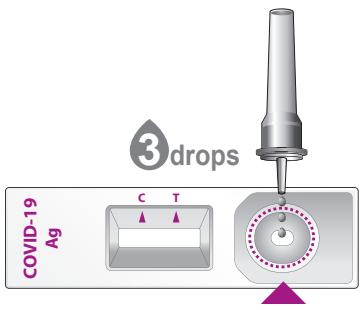


4 Press the nozzle cap tightly onto the tube.



ANALYSIS OF SPECIMEN

1 Apply 3 drops of extracted specimen to the specimen well of the test device.

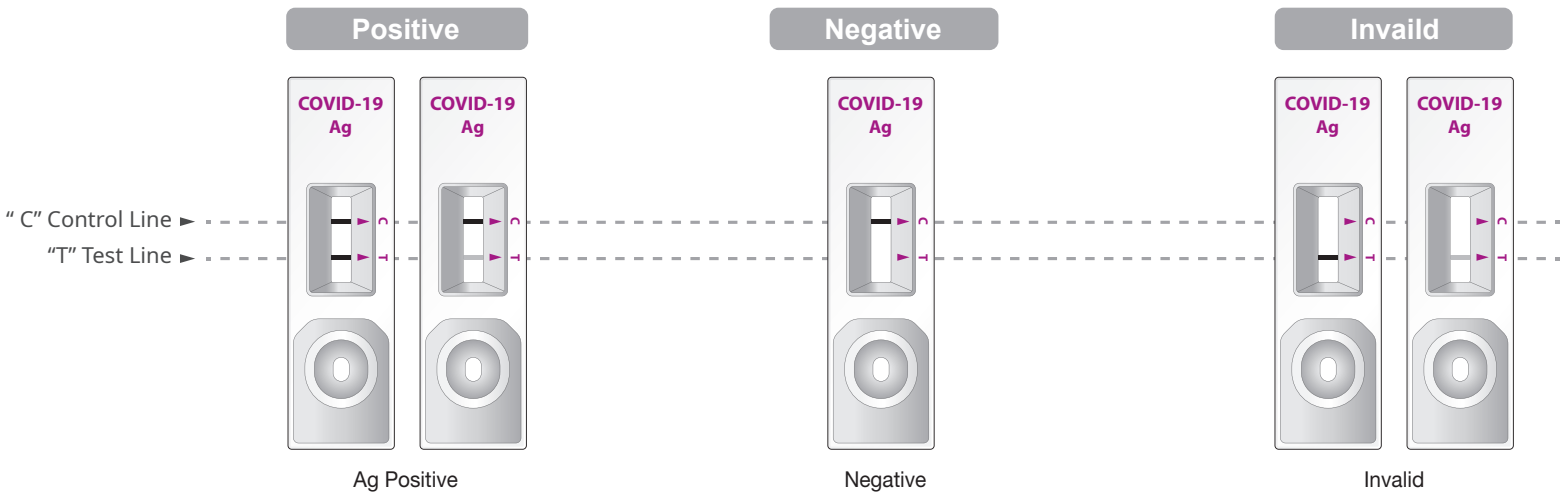


2 Read the test result in 15-30 minutes.

CAUTION

- Do not read test results after 30 minutes. It may give false results.

INTERPRETATION OF TEST RESULT



Ag Positive | Negative | Invalid

1. A 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 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.

*** 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.**

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, confirming that it can cause colds and the Middle East Respiratory Syndrome (MERS) and more serious diseases such as acute respiratory syndrome (SARS). This kit is helpful for the auxiliary diagnosis of coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone.

[Intended use]

STANDARD Q COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx. This test is for administration by healthcare workers and labs only, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with 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 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.

[Kit contents]

① Test device (individually in a foil pouch with desiccant) ② Extraction buffer tube ③ Nozzle cap
④ Sterile swab ⑤ Instructions for use

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. 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 tube of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. 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.
10. 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.

SPECIMEN COLLECTION AND PREPARATION

1. To collect a nasopharyngeal swab specimen, insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
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. Once the specimen has been placed in the extraction buffer, the test needs to be performed within 1 hour at 15°C to 25°C and 4 hour at 2°C to 8°C.
7. Specimens may be stored at room temperature for up to 1 hours or at 2-8°C/ 36-46°F for up to 4 hours prior to testing.

PERFORMANCE CHARACTERISTICS

[Clinical evaluation]

The sensitivity of the STANDARD Q COVID-19 Ag Test for rapid detection of SARS-CoV-2 antigen was established in prospective, multi institute, randomized, single-blinded study conducted at a trial site in Brazil and India during the 2020 SARS-CoV-2 pandemic. A total of 115 positive specimens were tested using the STANDARD Q COVID-19 Ag Test. These specimens consisted of nasopharyngeal swabs extracted directly from symptomatic patients. The specificity of STANDARD Q COVID-19 Ag Test was tested using 311 negative samples.The sensitivity and specificity of the STANDARD Q COVID-19 Ag Test was compared to a commercialized molecular assay.

[Test sensitivity and specificity]

The STANDARD Q COVID-19 Ag Test showed 96.52% of sensitivity and 99.68% of specificity.

Summary of the sensitivity and specificity of the STANDARD Q COVID-19 Ag Test compared to PCR.

		PCR		
		Positive	Negative	Total
STANDARD Q COVID-19 Ag Test	Positive	111	1	112
	Negative	4	310	314
	Total	115	311	426
Sensitivity		**96.52% (111/115, 95% CI 91.33% - 99.04%)**		
Specificity		**99.68% (310/311, 95% CI 98.22 - 99.99%)**		

ANALYTICAL PERFORMANCE

1. Limit of Detection (LoD): The study used "SARS-CoV-2 (2019-nCOV) NCCP 43326/2020 / Korea" strain. The titer of cultured virus was confirmed by PCR. The cell is inactivated and spiked into Nasopharyngeal swab specimen. The LoD is 1.25 X $10^{3.2}$ $TCID_{50}$/ml.

2019-nCoV Strain Tested	NCCP 43326/2020 / Korea								
Stock 2019-nCoV Titer	1 X $10^{6.2}$ $TCID_{50}$/ml								
Dilution	1/10	1/100	1/200	1/400	1/800	1/1600	1/3200	1/6400	1/12800
Concentration in Dilution tested (TCID50/ml)	1 X $10^{5.2}$	1 X $10^{4.2}$	5 X $10^{3.2}$	2.5 X $10^{3.2}$	1.25 X $10^{3.2}$	6.12 X$10^{2.2}$	3.06 X $10^{2.2}$	1.53 X $10^{2.2}$	7.1 X $10^{1.2}$
Call rate of 5 replicates	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	80% (4/5)	0% (0/5)	0% (0/5)	0% (0/5)
Call rates of 20 replicates near cut-off	NA	NA	NA	NA	100% (20/20)	56% (14/20)	0% (0/20)	NA	NA
Lowest Concentration with Uniform Positivity per Analyte	1.25 X $10^{3.2}$ $TCID_{50}$/ml								
Limit of Detection (LoD) per Virus Strain	1.25 X $10^{3.2}$ $TCID_{50}$/ml								

2. Cross-Reactivity: There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus.

Virus/Bacteria/ Parasite	Strain	Source/Specimen type	Concentration	Results
SARS-coronavirus	Urbani	BEI/inactivated virus	3.5 ug/ml	POS
MERS-coronavirus	Jeddah_1_2013	Bionote/recombinant protein	10 ug/ml	NEG
Adenovirus	Type 1	Korea Bank for Pathogenic Viruses / live	3 X 10^5 $TCID_{50}$/ml	NEG
	Type 3	National Culture Collection for pathogens / live	1.5 X 10^6 $TCID_{50}$/ml	NEG
	Type 5	Korea Bank for Pathogenic Viruses / live	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 7	Korea Bank for Pathogenic Viruses / live	1.5 X 10^6 $TCID_{50}$/ml	NEG
	Type 8	Korea Bank for Pathogenic Viruses / live	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 11	Korea Bank for Pathogenic Viruses / live	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 18	Korea Bank for Pathogenic Viruses / live	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 23	Korea Bank for Pathogenic Viruses / live	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 55	Korea Bank for Pathogenic Viruses / live	4 X 10^5 $TCID_{50}$/ml	NEG
Influenza A	H1N1 Denver	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 WS/33	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 Pdm-09	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 New Caledonia	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 New jersey	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
Influenza B	Nevada/03/2011	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
	B/Lee/40	ATCC/live virus	2.5 X 10^4 $TCID_{50}$/ml	NEG
	B/Taiwan/2/62	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
Respiratory syncytial virus	Type A	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
Respiratory syncytial virus	Type B	ATCC/live virus	3 X 10^5 $TCID_{50}$/ml	NEG
Legionella pneumophila	Bloomington-2	ATCC/live virus	5 X 10^4 cells/ml	NEG
	Los Angeles-1	ATCC/live virus	5 X 10^4 cells/ml	NEG
	82A3105	ATCC/live virus	5 X 10^4 cells/ml	NEG
Mycobacterium tuberculosis	K	Yonsei Univ. / inactivated and filter	5 X 10^4 cells/ml	NEG
	Erdman		5 X 10^4 cells/ml	NEG
	HN878		5 X 10^4 cells/ml	NEG
	CDC1551		5 X 10^4 cells/ml	NEG
	H37Rv		5 X 10^4 cells/ml	NEG
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	ATCC/live	5 X 10^4 cells/ml	NEG
	178 [Poland 23F-16]	ATCC/live	5 X 10^4 cells/ml	NEG
	262 [CIP 104340]	ATCC/live	5 X 10^4 cells/ml	NEG
	Slovakia 14-10 [29055]	ATCC/live	5 X 10^4 cells/ml	NEG
Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	ATCC/live	5 X 10^4 cells/ml	NEG
Mycoplasma pneumoniae	Mutant 22	ATCC/live	5 X 10^4 cells/ml	NEG
	FH strain of Eaton Agent [NCTC 10119]	ATCC/live	5 X 10^4 cells/ml	NEG
	M129-B7	ATCC/live	5 X 10^4 cells/ml	NEG
Pooled human nasal wash - *to represent diverse microbial flora in the human respiratory tract*	NA	Bionote / Normal pooled human nasal wash from healthy employees SD biosensor / Normal pooled human nasal wash from healthy employees	NA	NEG
Coronavirus	229E	Zeptomatrix/inactivaed	1 X $10^{4.5}$$TCID_{50}$/ml	NEG
	OC43	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG
	NL63	Zeptomatrix/inactivaed	1 X 10^4 $TCID_{50}$/ml	NEG
MERS-Coronavirus	Florida/USA-2_Saudi Arabia_2014	Zeptomatrix/inactivaed	4 X 10^4 $TCID_{50}$/ml	NEG
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG
Parainfluenza virus	Type 1	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG
	Type 2	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG
	Type 3	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG
	Type 4A	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG
Rhinovirus A16	N/A	Zeptomatrix/inactivaed	1 X 10^5 $TCID_{50}$/ml	NEG

*Human coronavirus HKU1 has not been tested. The % identity of the nucleocapsid protein sequence between HKU1 and SARS-CoV-2 is below 35%.

3. Endogenous/Exogenous Interference Substances Studies: There was no interference for potential interfering substances listed below.

Potential Interfering Substance	Concentration	Results
Respiratory Specimens		
Mucin: bovine submaxillary gland, type I-S	100 ug/ml	NEG
Blood (human), EDTA anticoagulated	5% (v/v)	NEG
Biotin	100 ug/ml	NEG
Nasal sprays or drops		
Neo-Synephrine (Phenylephrine)	10% (v/v)	NEG
Afrin Nasal Spray (Oxymetazoline)	10% (v/v)	NEG
Saline Nasal Spray	10% (v/v)	NEG
Homeopathic allergy relief medicine		
Homeopathic Zicam Allergy Relief Nasal Gel	5% (v/v)	NEG
Sodium Cromoglycate	20 mg/ml	NEG
Olopatadine Hydrochloride	10 mg/ml	NEG
Anti-viral drugs		
Zanamivir (Influenza)	5 mg/ml	NEG
Oseltamivir (Influenza)	10 mg/ml	NEG
Artemether-lumefantrine (Malaria)	50 uM	NEG
Doxycycline hyclate (Malaria)	70 uM	NEG
Quinine (Malaria)	150 uM	NEG
Lamivudine (Retroviral medication)	1 mg/ml	NEG
Ribavirin (HCV)	1 mg/ml	NEG
Daclatasvir (HCV)	1 mg/ml	NEG
Anti-inflammatory medication		
Acetaminophen	199 uM	NEG
Acetylsalicylic acid	3.62 mM	NEG
Ibuprofen	2.425 mM	NEG
Antibiotic		
Mupirocin	10 mg/ml	NEG
Tobramycin	5 ug/ml	NEG
Erythromycin	81.6 uM	NEG
Ciprofloxacin	30.2 uM	NEG

Potential Interfering Substance	Concentration	Viral Strain Level (In multiples of LoD)	Results (Detected X/3)
Respiratory Specimens			
Mucin: bovine submaxillary gland, type I-S	100 ug/ml	SARS-CoV-2 cultured virus media 1/800 dilution (1.25 X $10^{3.2}$ $TCID_{50}$/ml)	POS
Blood (human), EDTA anticoagulated	5% (v/v)		POS
Biotin	100 ug/ml		POS
Nasal sprays or drops			
Neo-Synephrine (Phenylephrine)	10% (v/v)	SARS-CoV-2 cultured virus media 1/800 dilution (1.25 X $10^{3.2}$ $TCID_{50}$/ml)	POS
Afrin Nasal Spray (Oxymetazoline)	10% (v/v)		POS
Saline Nasal Spray	10% (v/v)		POS
Homeopathic allergy relief medicine			
Homeopathic Zicam Allergy Relief Nasal Gel	5% (v/v)	SARS-CoV-2 cultured virus media 1/800 dilution (1.25 X $10^{3.2}$ $TCID_{50}$/ml)	POS
Sodium Cromoglycate	20 mg/ml		POS
Olopatadine Hydrochloride	10 mg/ml		POS
Anti-viral drugs			
Zanamivir (Influenza)	5 mg/ml	SARS-CoV-2 cultured virus media 1/800 dilution (1.25 X $10^{3.2}$ $TCID_{50}$/ml)	POS
Oseltamivir (Influenza)	10 mg/ml		POS
Artemether-lumefantrine (Malaria)	50 uM		POS
Doxycycline hyclate (Malaria)	70 uM		POS
Quinine (Malaria)	150 uM		POS
Lamivudine (Retroviral medication)	1 mg/ml		POS
Ribavirin (HCV)	1 mg/ml		POS
Daclatasvir (HCV)	1 mg/ml		POS
Anti-inflammatory medication			
Acetaminophen	199 uM	SARS-CoV-2 cultured virus media 1/800 dilution (1.25 X $10^{3.2}$ $TCID_{50}$/ml)	POS
Acetylsalicylic acid	3.62 mM		POS
Ibuprofen	2.425 mM		POS
Antibiotic			
Mupirocin	10 mg/ml	SARS-CoV-2 cultured virus media 1/800 dilution (1.25 X $10^{3.2}$ $TCID_{50}$/ml)	POS
Tobramycin	5 ug/ml		POS
Erythromycin	81.6 uM		POS
Ciprofloxacin	30.2 uM		POS

4. High-dose Hook Effect: SARS-CoV-2 cultured virus was spiked into specimen. SARS-CoV-2 cultured virus did not show hook-effect at 1 X $10^{6.2}$ $TCID_{50}$/ml.

Specimen Type	Dilution	Concentration ($TCID_{50}$/ml)	Result
SARS-CoV-2 NCCP 43326/2020 / korea Inactivated virus cultured media	NEAT	1 X $10^{6.2}$	POS
	1/10	1 X $10^{5.2}$	POS
	1/100	1 X $10^{4.2}$	POS
	1/200	5 X $10^{3.2}$	POS
	1/400	2.5 X $10^{3.2}$	POS
	1/800	1.25 X $10^{3.2}$	POS
	1/1600	6.12 X $10^{2.2}$	POS
	1/3200	3.06 X $10^{2.2}$	NEG
	1/6400	1.53 X $10^{2.2}$	NEG
	1/12800	7.1 X $10^{1.2}$	NEG

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 nasopharyngeal swab specimens.
3. Neither the quantitative value nor the rate of SARS-CoV-2 antigen concentration can be determined by this qualitative test.
4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
5. A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
6. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
7. The test result must always be evaluated with other data available to the physician.
8. A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA.
9. Positive test results do not rule out co-infections with other pathogens.
10. Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV.
11. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

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

Information about sponsor

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Issue date: 2020.09

REF Reference number
IVD *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
LOT Batch code
CE 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