MIDAST

COVID-19 CATALOG

For Additional Information or Pricing please email Vincent Crandon at v.crandon@midast.com

CE Approved

3-PLY BFE 95 DISPOSABLE MASK

(GB/T32610-2016 Standard)

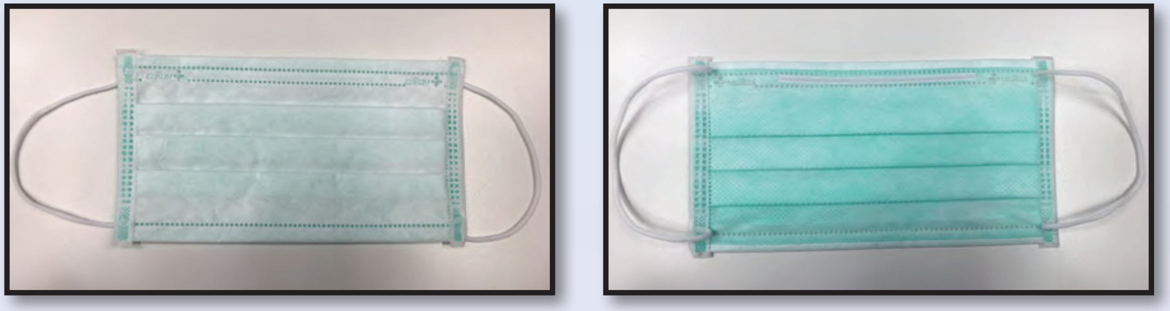
RNR
Disposable Protective Face Mask
一次性防护口罩
50PCS
50
25PCS
Disposable protective face mask
一次性防护口罩

- Availability: Up to 5 million pieces/week
- Sample standard product photo as attached
- Made in Malaysia

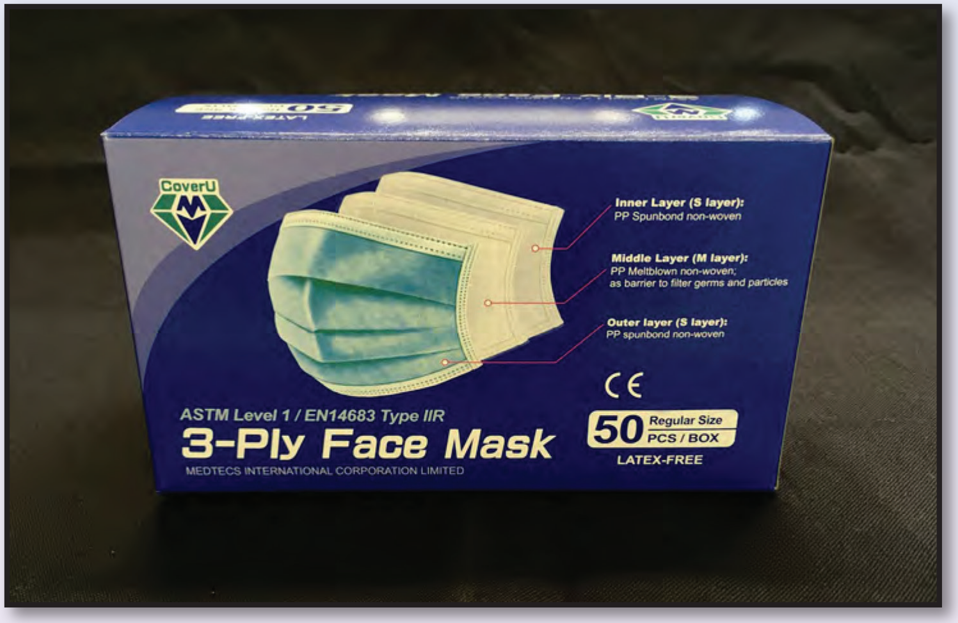
24th June 2020

CE/FDA Approved

3-PLY DISPOSABLE MASK



- 3-Ply Face Mask
- 50 pieces per box
- Made in the Philippines


CoverU
Inner Layer (S layer):
PP Spunbond non-woven
Middle Layer (M layer):
PP Meltblown non-woven;
as barrier to filter germs and particles
Outer layer (S layer):
PP spunbond non-woven
CE
ASTM Level 1 / EN14683 Type IIR
3-Ply Face Mask
MEDTECS INTERNATIONAL CORPORATION LIMITED
50 Regular Size PCS / BOX
LATEX-FREE

24th June 2020

CE & FDA Approved

BFE 95 MEDICAL MASK

(YY/T0969-2013, EN14683-2005 Standard)

一次性使用医用口罩
17.5cmx9.5cm–3层(蓝色)
BFE>95%
50

- Availability: Up to 4 million pieces/week
- Sample standard product photo as attached
- 50 pieces per box
- Made in South Korea

24th June 2020

FDA Approved Medical Grade Mask

Made in South Korea

Powerful filtering, excellent permeability

AirQUEEN Nano Mask

Masks are a must!
Introducing easy-to-breathe mask with exceptional filter

성인용 1pcs
Air QUEEN
나노마스크
WHITE
Nano mask
纳米口罩
ナノマスク
Nano mặt na
0.1µm
NANOFIBER FILTER MASK
얇고 가벼운 마스크
Thin and light
뛰어난 통기성으로 오염물질은 막아주고
호흡은 편하고, 가벼운 섬유소재
나노파이버 필터
Nanofiber filter
강력한 필터링 효과와 우수한
통기성의 나노파이버 적용
인체공학적 입체설계
Ergonomic design
코지지대 설계로 흘러내림 및
김서림을 방지
에어퀸 나노마스크

Because we need to wear it all day, we made it lighter.

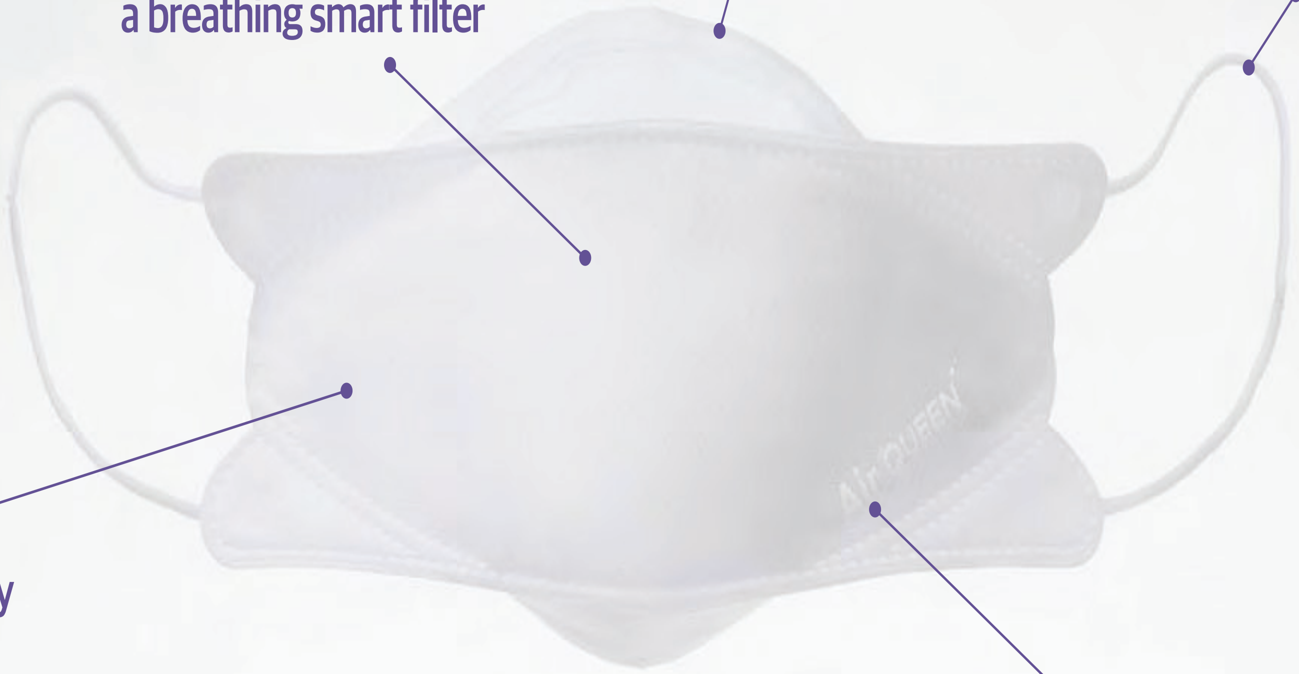
AirQUEEN Nano mask 3.71g

Lighter than a sheet of paper, so you won't even realize wearing it!

※ a sheet of paper = 4.72g

3D ergonomic design to fit perfectly on all face types.

Nose bridge prevents sliding or fogging up.



Wide nose bridge

Comfortable elastic
ear band

Nanofiber-
a breathing smart filter

High permeability
NO skin trouble

Light weight
for all-day wear

AirQUEEN Nano Mask is an industrial product that passed the tests of KEMTI and is [currently in process] of being approved by the MFDS

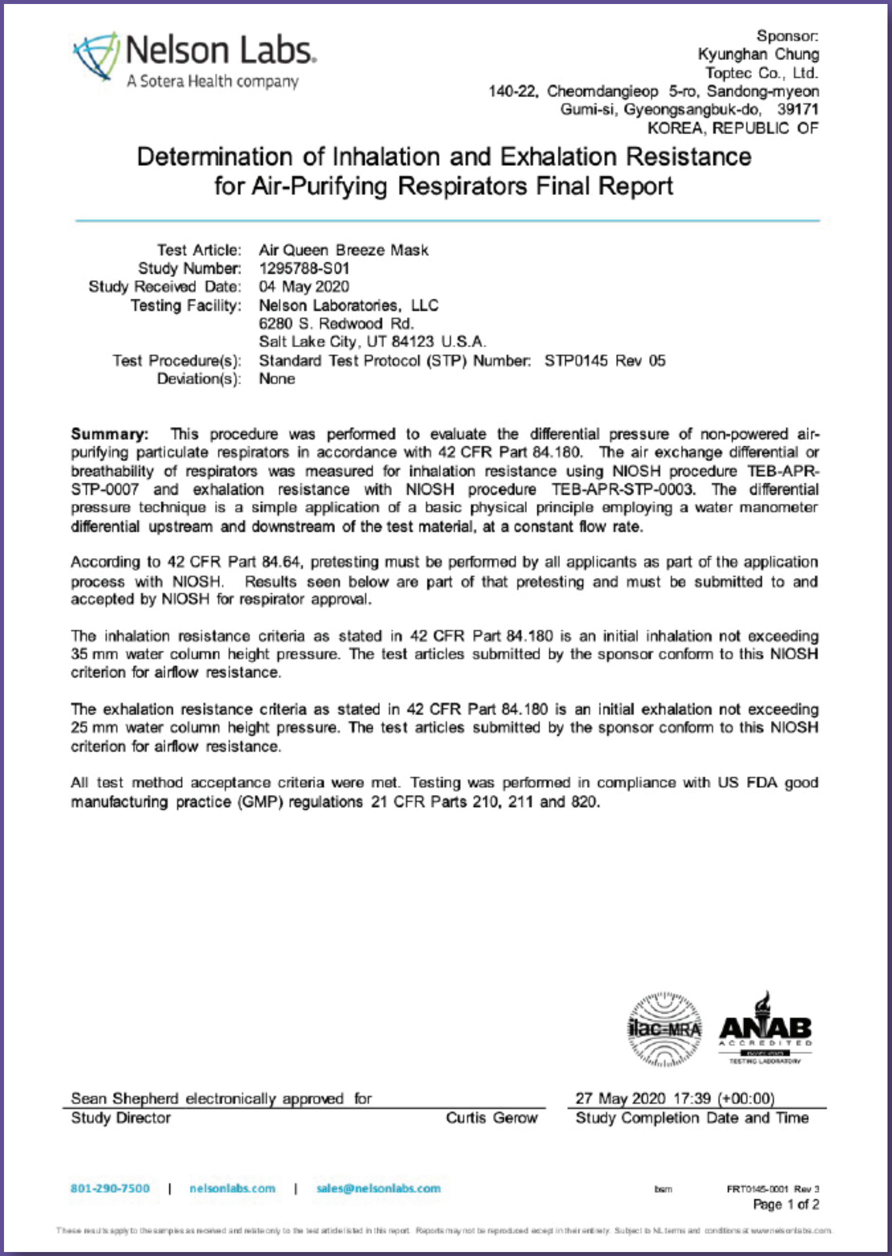
*Korea Environment Merchandise Testing Institute, KEMTI

AirQUEEN Nano Mask is a product that applied for the KF approval at the MFDS early April of 202 after passing the test done by KEMTI, a testing institute designated by the MFDS.

It is manufactured with the same technology as Technoweb Disposable dustproof mask (KF94) from FTENE, the subsidiary company of TOPTEC, but if the manufacturer or brand is changed, the approval from the MFDS needs to be renewed, and until then, it cannot be publicly distributed.

However, after the KF certification, 80% of the supply will be distributed as public, so there might be a shortage.

We have FDA and N95 certification.



Nelson Labs.
A Sotera Health company

Sponsor:
Kyunghan Chung
Toptec Co., Ltd.
140-22, Cheomdangieop 5-ro, Sandong-myeon
Gumi-si, Gyeongsangbuk-do, 39171
KOREA, REPUBLIC OF

Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

Test Article: Air Queen Breeze Mask
Study Number: 1295788-S01
Study Received Date: 04 May 2020
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0145 Rev 05
Deviation(s): None

Summary: This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate respirators in accordance with 42 CFR Part 84.180. The air exchange differential or breathability of respirators was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003. The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

The inhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial inhalation not exceeding 35 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

The exhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial exhalation not exceeding 25 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Sean Shepherd electronically approved for
Study Director Curtis Gerow

27 May 2020 17:39 (+00:00)
Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

bsm FRT0145-0001 Rev 3
Page 1 of 2

These results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.

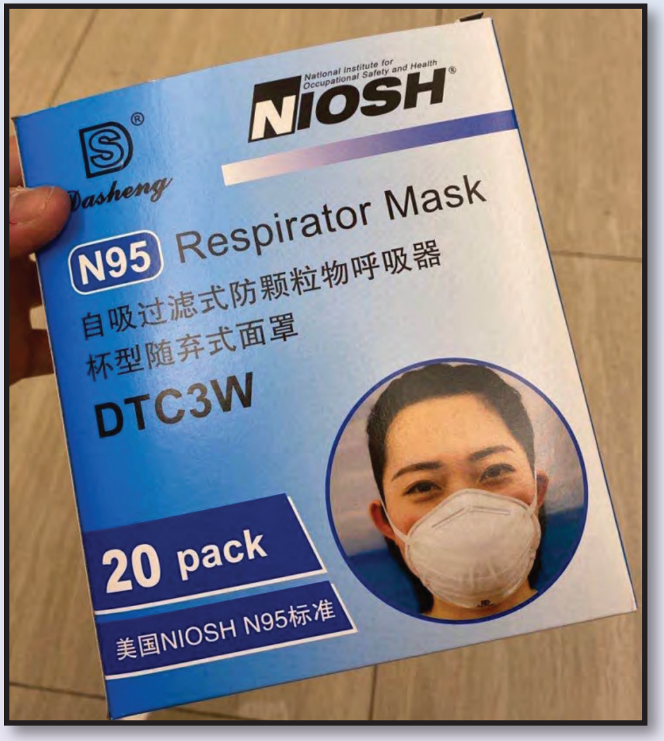
Quality Indication According to Electric Products and Household Safety Law

- Product: AirQUEEN Mask
- Manufactured in: Korea
- Manufacturer: TOPTEC
- Distributor: TOPTEC
- Weight: 4.38g
- Product Type: Mask
- Expiry Date: 36 months
- Storage Directions: closed container, in room temperature (1~30℃)
- Entire Ingredients:
  felt (outer fabric, filter, inner fabric), plastic sheath wire, polypropylene ring, nylon strap

성인용 1pcs
Air QUEEN
나노마스크
WHITE
Nano mask
納米口罩
ナノマスク
0.1μm
NANOFIBER FILTER MASK
얇고 가벼운 마스크
Thin and light
나노파이버 필터
Nanofiber filter
인체공학적 입체설계
Ergonomic design
에어퀸 나노마스크

CE, FDA, and NIOSH Approved

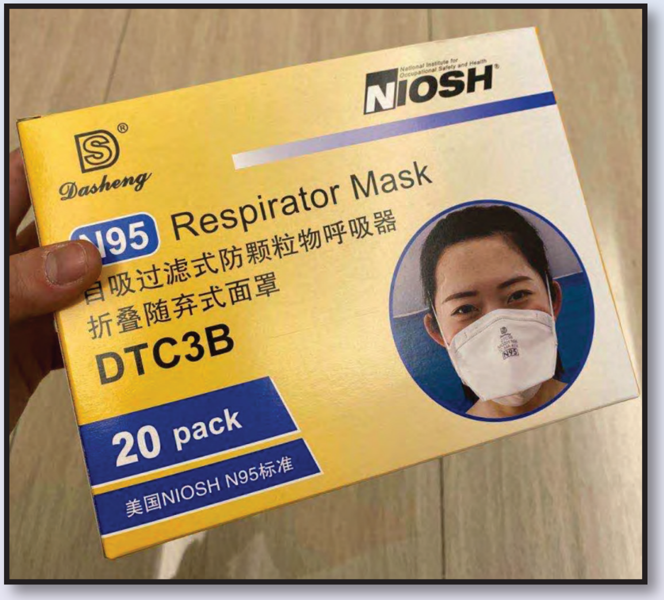
N95 RESPIRATOR MASK DTC3W


National Institute for Occupational Safety and Health
NIOSH
Dasheng
N95 Respirator Mask
自吸过滤式防颗粒物呼吸器
杯型随弃式面罩
DTC3W
20 pack
美国NIOSH N95标准

- Availability: Up to 2 million pieces/week
- Sample standard product photo as attached
- 20 per pack
- Made in South Korea

CE, FDA, and NIOSH Approved

N95 RESPIRATOR MASK DTC3B

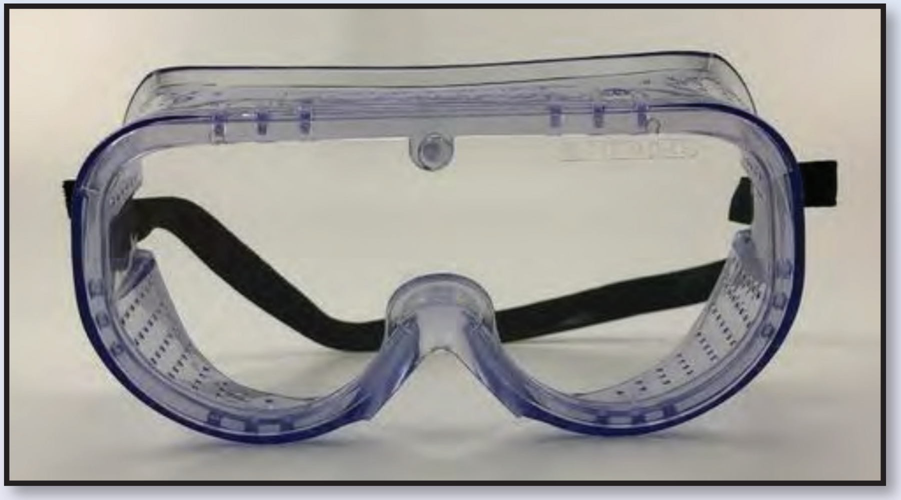

NIOSH
Dasheng
N95 Respirator Mask
自吸过滤式防颗粒物呼吸器
折叠随弃式面罩
DTC3B
20 pack
美国NIOSH N95标准

- Availability: Up to 3 million units/week
- Sample standard product photo as attached
- 20 per pack
- Made in South Korea

CE Approved

MEDICAL SAFETY GOGGLES

(Example EN 166:2001 or Similar Equivalent Standard)



- Availability: Up to 2.5 million pieces/week
- Sample standard product photo as attached
- Made in Malaysia

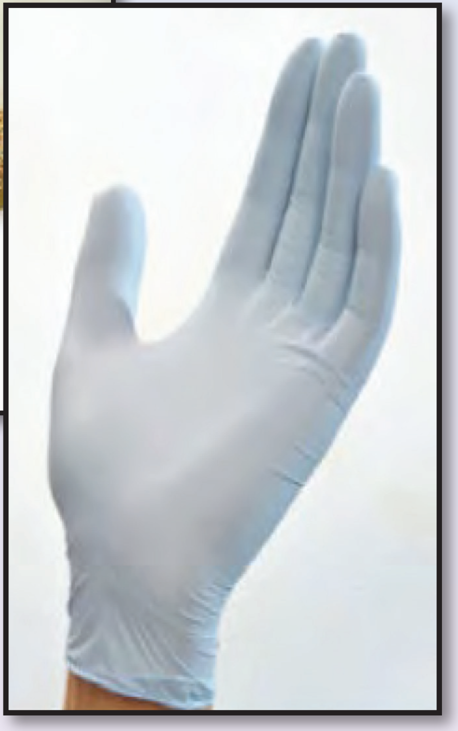
24th June 2020

CE & FDA Approved

DISPOSABLE NITRILE GLOVES

Nitrile Powder Free
Examination Gloves
gloveon
COATS
XS
S
M
L
XL

- Fingertip texture
- Powder free
- Chemo drugs tested



24th June 2020

CE & FDA Approved

AAMI Level 1 Isolation Gown

- Material: 55% PP / 45% PE
- Fabric Weight: 36gsm
- Color: White
- Made in Cambodia

24th June 2020

CE & FDA Approved

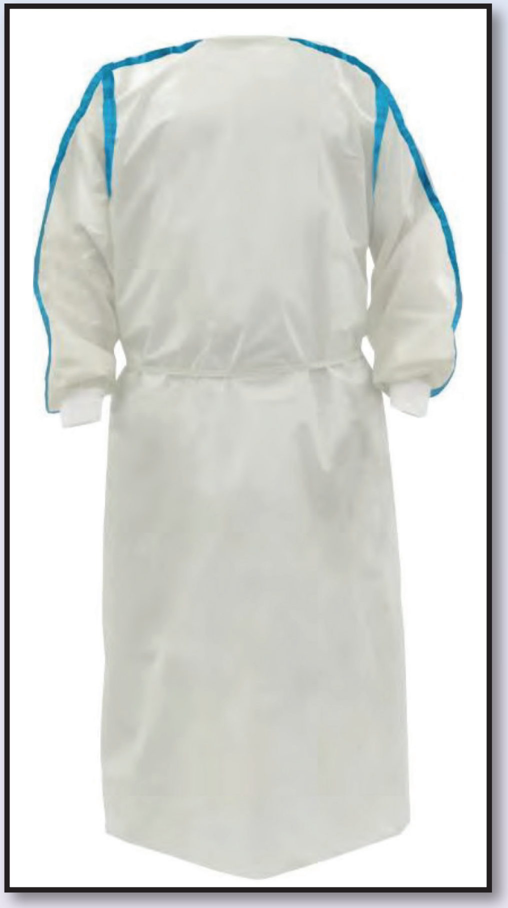
AAMI Level 2 Isolation Gown

- Material: 100% PP SMMS
- Fabric Weight: 30gsm
- Color: White
- Made in Cambodia

24th June 2020

CE & FDA Approved

AAMI Level 4 Isolation Gown

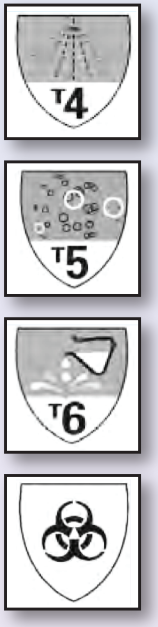


- Material: 55% PP / 45% PE
- Fabric Weight: 63gsm
- Color: White
- Made in Cambodia

24th June 2020

CE & FDA Approved

Medical Breathable Protective Coverall

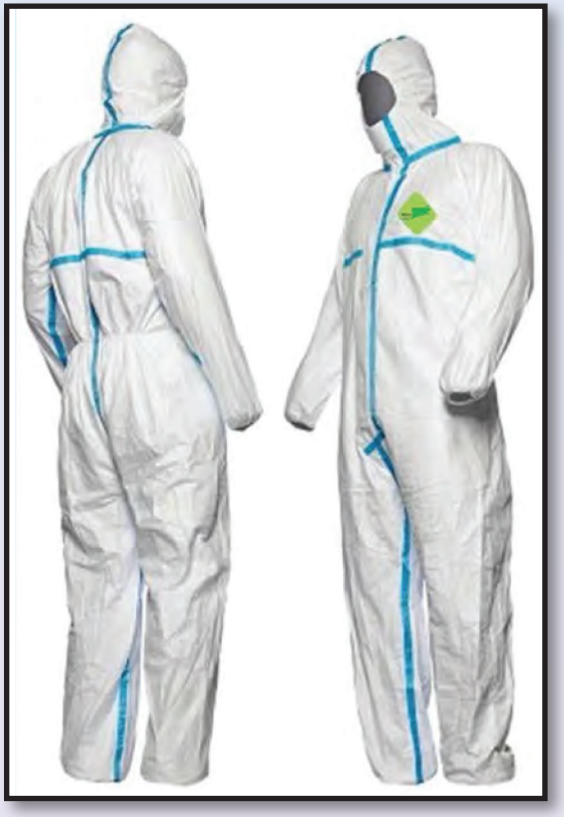


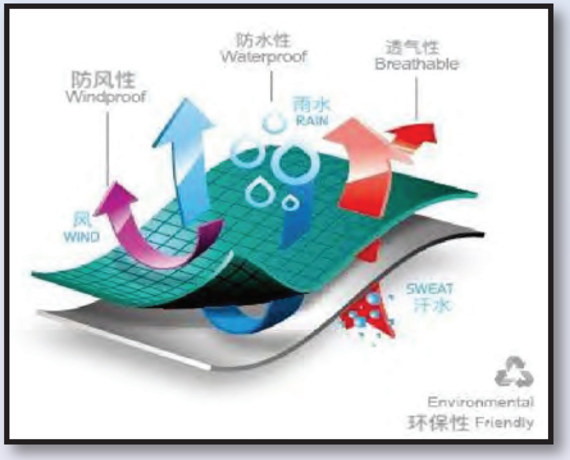
- Material: PPSB laminated w/breathable PE film
- Fabric Weight: 63gsm
- Color: White
- Made in Cambodia

24th June 2020

CE & FDA Approved

Medical Breathable Protective Coverall




防水性
Waterproof
透气性
Breathable
防风性
Windproof
雨水
RAIN
风
WIND
SWEAT
汗水
Environmental
环保性 Friendly

- Material: 55% PP / 45% PE
- Fabric Weight: 36gsm
- Color: White
- Made in Cambodia

24th June 2020

CE & FDA Approved

Disposable Bouffant Caps

- Material: 100% PP SMMS
- Fabric Weight: 14gsm
- Color: White, Blue and Green
- Made in Cambodia

24th June 2020

CE & FDA Approved

Anti-skid Shoe Cover

- Material: 100% PP SMMS
- Color: Blue
- Made in Cambodia

24th June 2020

Forehead Thermometer

M 23
36.8
Body temp 体温

- CE certified: Available upon LOI
- Availability: Up to 250,000 units/week
- Sample standard product photo as attached
- Made in South Korea

24th June 2020

CE & FDA Approved

Hand Sanitizer 480ml

(Example EN 1040:2005 or Similar Equivalent Standard)

CE FDA
Hand Sanitizer Gel
75% Ethanol Kills germs 99%
480mL (16.23 oz)

- CE/FDA certified: Available upon LOI
- Availability: Up to 3 million units/week
- Sample standard product photo as attached
- Made in Malaysia

24th June 2020

CE Approved

Hand Sanitizer 350ml

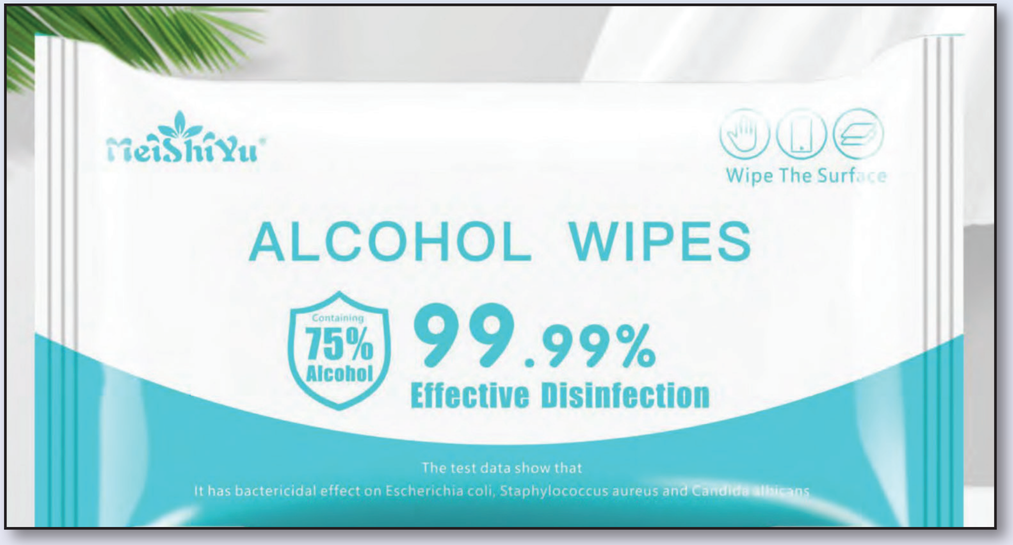
(Example EN 1276:2009 or Similar Equivalent Standard)

GOTDYA™
BACTERIOSTATIC RATE
99.9%
DISPOSABLE
GOTDYA™
Rinse-free Hand Sanitizer

- CE certified: Available upon LOI
- Availability: Up to 4 million units/week
- Sample product photo as attached
- Made in Malaysia

24th June 2020

Sanitizing Wipes

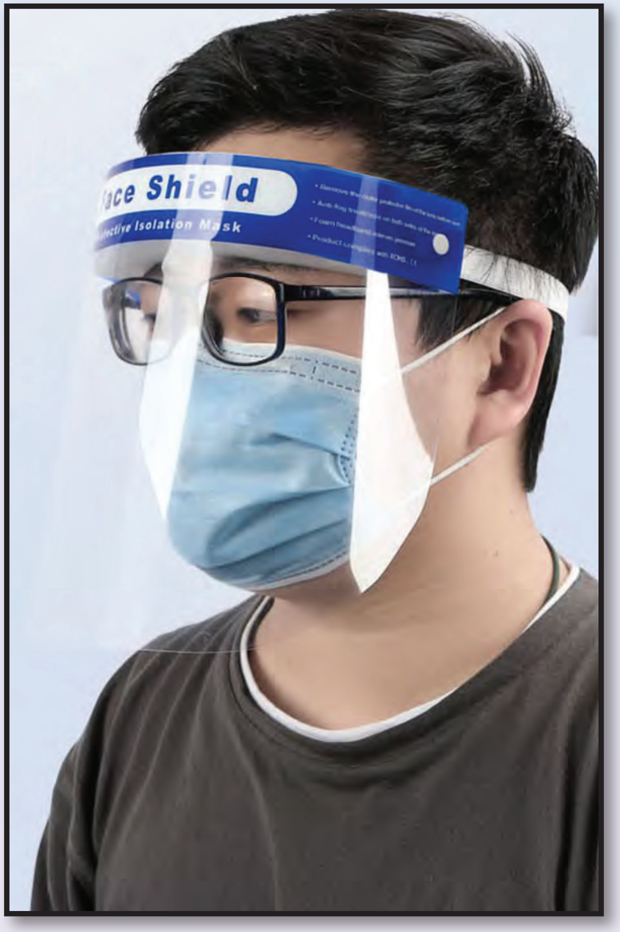

MeiShiYu
Wipe The Surface
ALCOHOL WIPES
Containing
75%
Alcohol
99.99%
Effective Disinfection
The test data show that
It has bactericidal effect on Escherichia coli, Staphylococcus aureus and Candida albicans

- Availability: Up to 3 million units/week
- Sample product photo as attached
- Made in Malaysia

24th June 2020

CE Approved

FACE SHIELD PROTECTIVE ISOLATION MASK



- Availability: Up to 1 million units/week
- Sample product photo as attached
- Made in South Korea

24th June 2020

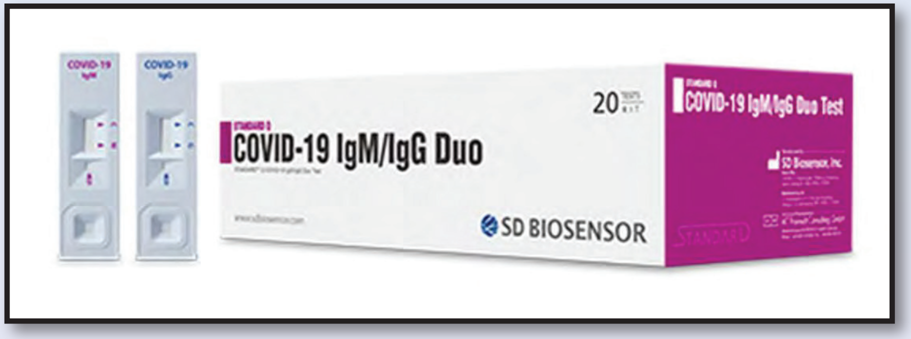
COVID-19 TESTING KITS

Made in South Korea

FDA/CE Approved

STANDARD Q COVID-19 IgM/IgG

Rapid immunochromatography test Kit


COVID-19 IgM
COVID-19 IgG
STANDARD Q
COVID-19 IgM/IgG Duo
20 TESTS KIT
SD BIOSENSOR
COVID-19 IgM/IgG Duo Test
SD Biosensor, Inc.

STANDARD Q COVID-19 IgM/IgG Duo Test Kit is a rapid immunochromatography test designed for the qualitative presumptive detection of specific IgM and IgG to SARS-CoV-2 in humoral fluid. Certified by CE.

It tests for the antibody, and each box has 25 test kits. One kit would serve one person. You test with blood, and it only takes 10 minutes. Has 80% accuracy, so this is suitable for drive-thru test. This is to be stored in the room temperature. One person shall use 1 unit, the accuracy of this test is 80%. You shall test with blood, and the result will come out in 10 mins. Though we recommend you to use in drive-thru.

- Rapid testing for SARS-CoV-2 antibodies within 10 minutes
- Just 10ul of specimen: Whole blood, serum, plasma
- Suitable for Point of Care Testing. No need for extra equipment
- MOQ: 10,000 tests
- 20 tests per box

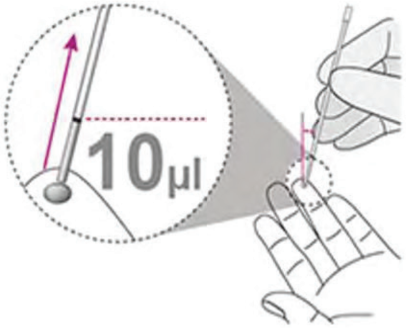
Instructions for use

TEST PROCEDURE - Be sure to test both STANDARD Q COVID-19 IgM and IgG simultaneously.

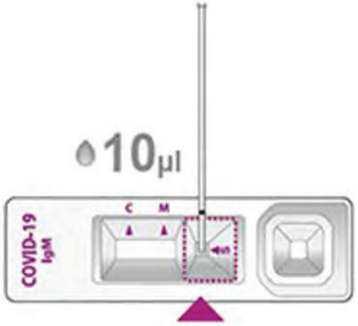
The test procedures for both COVID-19 IgM and IgG are the same.

Using Capillary whole blood

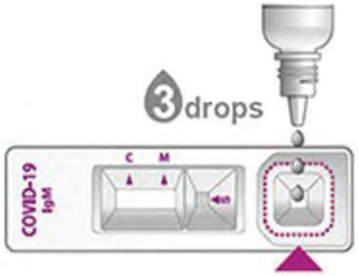
1 Collecting of Specimen
Using a capillary tube, collect the 10µl of capillary whole blood to the black line of the capillary tube.



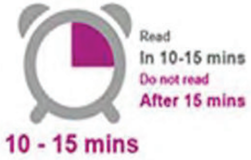
2 Adding of Specimen
Add the collected capillary whole blood to the specimen well of the test device.


10µl
C
M
COVID-19
IgM

3 Dropping of buffer
Add 3 drops (90µl) of buffer vertically into the buffer well of the test device.


3drops
C
M
COVID-19
IgM

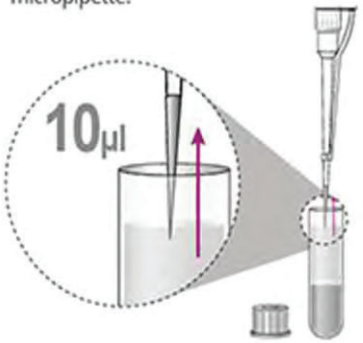
4 Reading Time
Read test result at 10~15 minutes.


Read
In 10-15 mins
Do not read
After 15 mins
10 - 15 mins

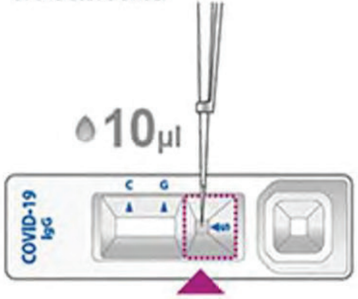
⚠ CAUTION
- Do not read test results after 15 minutes. It may give false results.

Using serum/plasma/venous whole blood

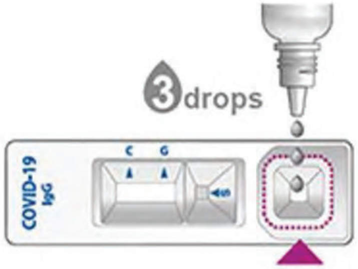
1 Collecting of Specimen
Using a micropipette, collect the 10µl of serum, plasma or venous whole blood with micropipette.



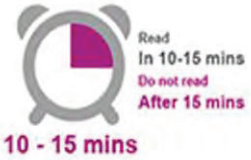
2 Adding of Specimen
Add the collected serum, plasma or venous whole blood to the specimen well of the test device.


10µl
C
G
COVID-19
IgG

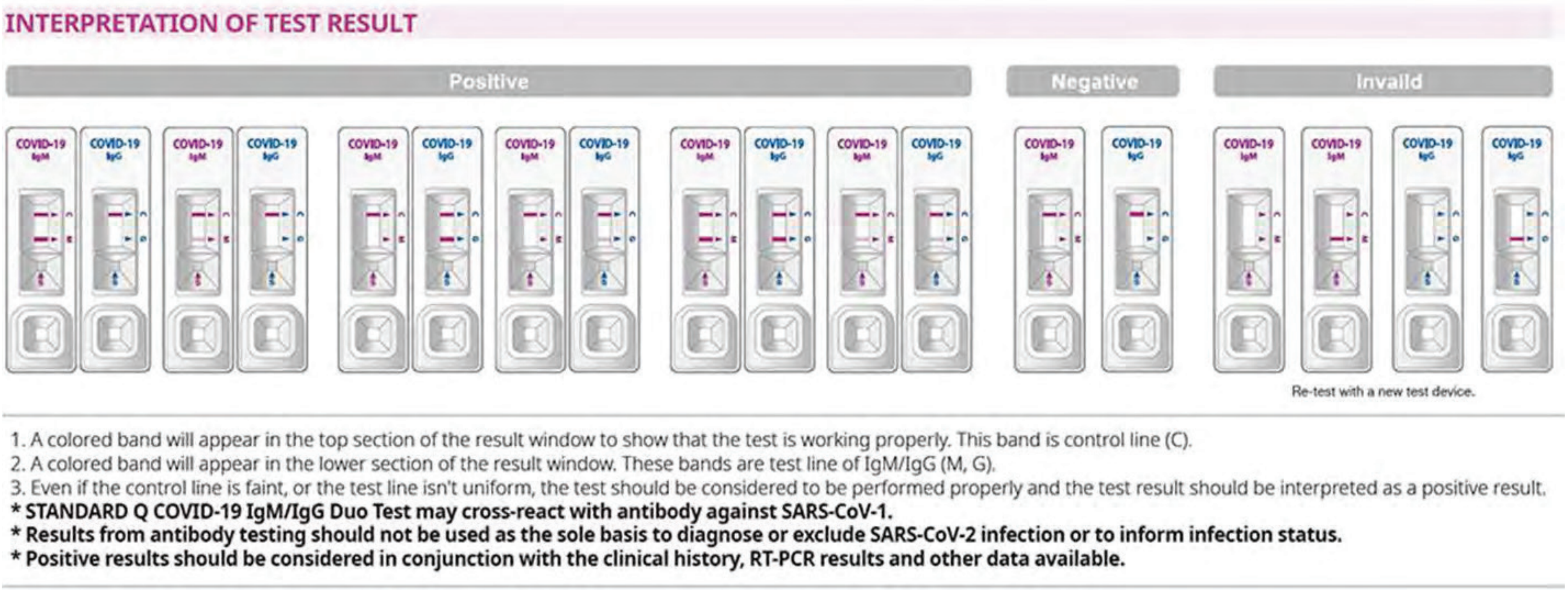
3 Dropping of buffer
Add 3 drops (90µl) of buffer vertically into the buffer well of the test device.


3drops
C
G
COVID-19
IgG

4 Reading Time
Read test result at 10~15 minutes.


Read
In 10-15 mins
Do not read
After 15 mins
10 - 15 mins

⚠ CAUTION
- Do not read test results after 15 minutes. It may give false results.



INTERPRETATION OF TEST RESULT

Re-test with a new test device.

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. These bands are test line of IgM/IgG (M, G).
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.

*** STANDARD Q COVID-19 IgM/IgG Duo Test may cross-react with antibody against SARS-CoV-1.**
*** Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.**
*** Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.**

PERFORMANCE CHARACTERISTICS

[Clinical evaluation]

Test were performed according to instructions for use of 'STANDARD Q COVID-19 IgM/IgG Duo Test' with residual serum from 33 positive patients confirmed by real-time PCR (2019-nCoV Real-time PCR kit) method and 30 healthy donors.

[Data table]

Positive specimens

No.	Onset of Symptom date	Confirmation Test date	Blood collection date	Days after symptom onset	STANDARD Q COVID-19 IgM/IgG Duo Test result	
					IgM	IgG
1	Unknown	Feb. 09, 2020	Feb. 17, 2020	Unknown	Positive	Pos weak
2	Unknown	Jan. 30, 2020	Feb. 17, 2020	Unknown	Positive	Positive
3	Unknown	Feb. 02, 2020	Feb. 17, 2020	Unknown	Positive	Positive
4	Feb. 15, 2020	Feb. 23, 2020	Feb. 23, 2020	8	Pos weak	Pos weak
5	Feb. 15, 2020	Feb. 23, 2020	Feb. 27, 2020	12	Pos weak	Positive
6	Feb. 15, 2020	Feb. 23, 2020	Mar. 03, 2020	17	Pos weak	Positive
7	Feb. 06, 2020	Feb. 09, 2020	Feb. 13, 2020	7	Negative	Negative
8	Feb. 06, 2020	Feb. 09, 2020	Feb. 21, 2020	15	Pos weak	Positive
9	Feb. 06, 2020	Feb. 09, 2020	Mar. 03, 2020	26	Pos weak	Positive
10	Feb. 18, 2020	Feb. 19, 2020	Feb. 19, 2020	1	Negative	Negative
11	Feb. 18, 2020	Feb. 19, 2020	Feb. 26, 2020	8	Negative	Positive
12	Feb. 19, 2020	Feb. 19, 2020	Feb. 23, 2020	4	Negative	Negative
13	Feb. 15, 2020	Feb. 23, 2020	Feb. 23, 2020	8	Positive	Positive
14	Feb. 06, 2020	Feb. 09, 2020	Mar. 03, 2020	26	Positive	Positive
15	Jan. 30, 2020	Feb. 01, 2020	Feb. 09, 2020	10	Negative	Negative
16	Jan. 25, 2020	Feb. 01, 2020	Feb. 12, 2020	18	Positive	Positive
17	Feb. 25, 2020	Feb. 25, 2020	Mar. 03, 2020	7	Negative	Positive
18	Feb. 15, 2020	Feb. 23, 2020	Feb. 25, 2020	10	Positive	Positive
19	Feb. 06, 2020	Feb. 09, 2020	Feb. 21, 2020	15	Positive	Positive
20	Jan. 30, 2020	Feb. 01, 2020	Feb. 13, 2020	14	Positive	Positive
21	Jan. 25, 2020	Feb. 01, 2020	Feb. 09, 2020	15	Trace	Positive
22	Feb. 15, 2020	Feb. 23, 2020	Feb. 26, 2020	11	Positive	Positive
23	Feb. 06, 2020	Feb. 09, 2020	Feb. 17, 2020	11	Positive	Positive
24	Jan. 30, 2020	Feb. 01, 2020	Feb. 06, 2020	7	Negative	Negative
25	Feb. 18, 2020	Feb. 21, 2020	Feb. 26, 2020	8	Negative	Negative
26	Feb. 15, 2020	Feb. 23, 2020	Feb. 27, 2020	12	Positive	Positive
27	Feb. 06, 2020	Feb. 09, 2020	Mar. 01, 2020	24	Positive	Positive
28	Jan. 25, 2020	Feb. 01, 2020	Feb. 17, 2020	23	Positive	Positive
29	Feb. 25, 2020	Feb. 25, 2020	Mar. 02, 2020	6	Negative	Positive
30	Feb. 15, 2020	Feb. 23, 2020	Feb. 29, 2020	14	Positive	Positive
31	Feb. 22, 2020	Feb. 24, 2020	Mar. 06, 2020	13	Negative	Positive
32	Feb. 04, 2020	Feb. 04, 2020	Feb. 20, 2020	16	Negative	Positive
33	Feb. 04, 2020	Feb. 04, 2020	Feb. 20, 2020	16	Negative	Positive

Negative specimens

No.	Blood collection date	STANDARD Q COVID-19 IgM/IgG Duo Test result	
		IgM	IgG
1	Mar. 06, 2020	Negative	Negative
2	Feb. 20, 2020	Negative	Negative
3	Mar. 04, 2020	Negative	Negative
4	Mar. 05, 2020	Negative	Negative
5	Mar. 09, 2020	Negative	Negative
6	Mar. 07, 2020	Negative	Negative
7	Mar. 11, 2020	Negative	Negative
8	Mar. 05, 2020	Negative	Negative
9	Mar. 11, 2020	Negative	Negative
10	Mar. 07, 2020	Negative	Negative
11	Mar. 09, 2020	Negative	Negative
12	Mar. 06, 2020	Negative	Negative
13	Mar. 04, 2020	Negative	Negative
14	Feb. 20, 2020	Negative	Negative
15	Feb. 19, 2020	Negative	Negative
16	Feb. 18, 2020	Negative	Negative
17	Feb. 25, 2020	Negative	Negative
18	Feb. 20, 2020	Negative	Negative
19	Feb. 25, 2020	Negative	Pos weak
20	Feb. 17, 2020	Negative	Negative
21	Feb. 20, 2020	Negative	Negative
22	Feb. 20, 2020	Negative	Negative
23	Feb. 20, 2020	Negative	Negative
24	Feb. 19, 2020	Negative	Negative
25	Feb. 13, 2020	Negative	Negative
26	Feb. 10, 2020	Negative	Negative
27	Feb. 10, 2020	Negative	Negative
28	Feb. 02, 2020	Negative	Negative
29	Feb. 12, 2020	Negative	Negative
30	Feb. 06, 2020	Negative	Negative

- **Due to the differing inter-patient time response to the virus, any individual positive result of IgM or IgG should be read as a positive result for SARS-CoV-2 and the combined positive test results are used to calculate total Duo test sensitivity.**

Combined positive test results are used to calculate total Duo test sensitivity

		PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 IgM+IgG	Positive	27	1	28
	Negative	6	29	35
Total		33	30	63

Sensitivity : 81.8%, Specificity : 96.7%

- **STANDARD Q COVID-19 IgM + IgG showed 81.8% of sensitivity and 96.7% of specificity.**
- **Based on result of test with positive specimens, it was found that IgM antibody diagnosis with STANDARD Q COVID-19 IgM/IgG Duo Test was effective for diagnosis SARS-CoV-2 from the time when after about 7 days from the date of symptom onset. And STANDARD Q COVID-19 IgM/IgG Duo Test showed a high specificity in the test with negative specimens.**

- **Test study analysis of the specimens collected after 8 days and 10 days from the date of symptom onset below.**

Test result of the specimens collected after 8 days from the date of symptom onset

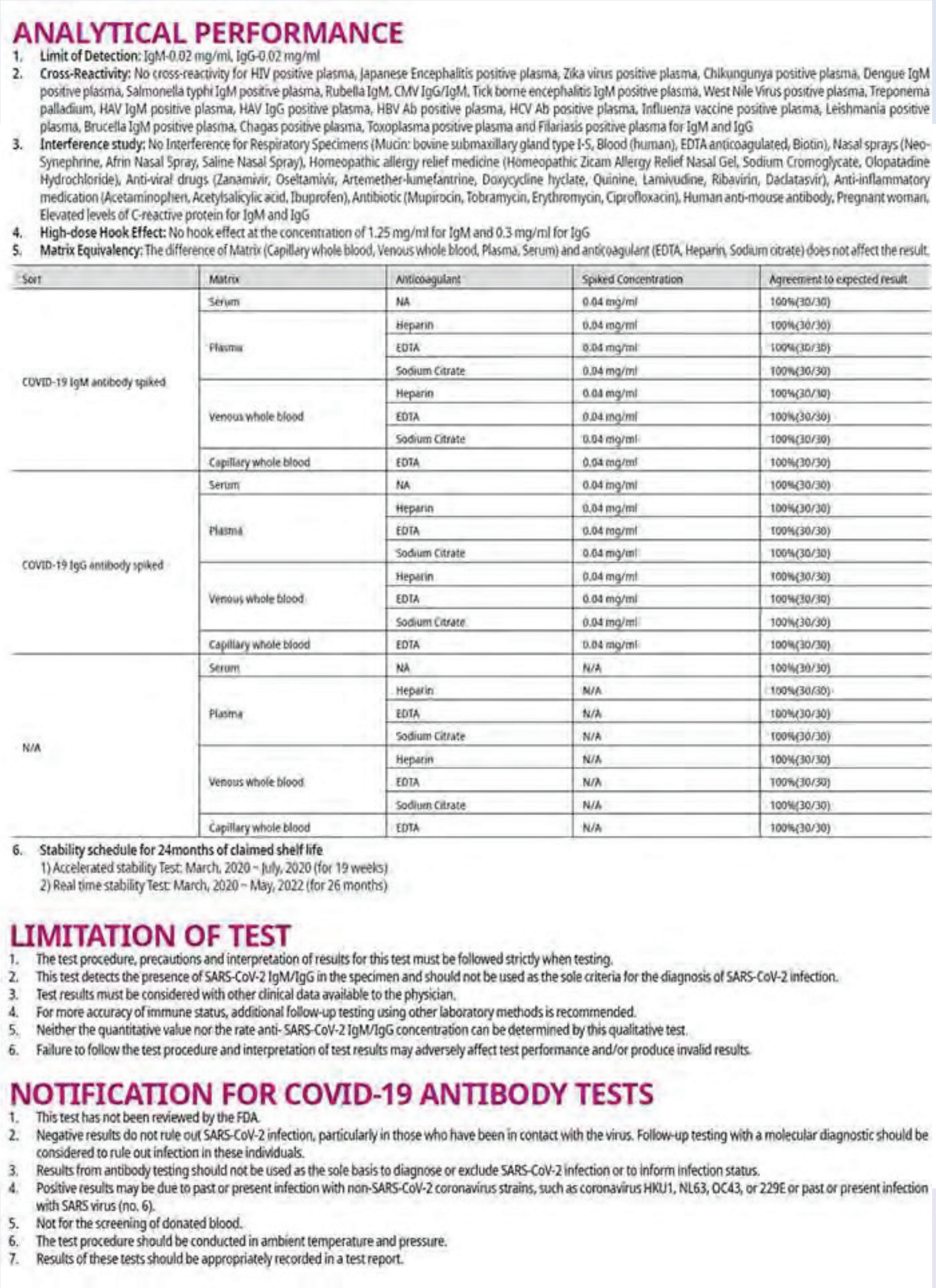
		PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 IgM+IgG	Positive	25	1	26
	Negative	2	29	31
Total		27	30	57

Sensitivity : 92.6%, Specificity : 96.7%

Test result of the specimens collected after 10 days from the date of symptom onset

		PCR		Total
		Positive	Negative	
STANDARD Q COVID-19 IgM+IgG	Positive	22	1	23
	Negative	1	29	30
Total		23	30	53

Sensitivity : 95.7%, Specificity : 96.7%



ANALYTICAL PERFORMANCE

1. **Limit of Detection:** IgM-0.02 mg/ml, IgG-0.02 mg/ml
2. **Cross-Reactivity:** No cross-reactivity for HIV positive plasma, Japanese Encephalitis positive plasma, Zika virus positive plasma, Chikungunya positive plasma, Dengue IgM positive plasma, Salmonella typhi IgM positive plasma, Rubella IgM, CMV IgG/IgM, Tick borne encephalitis IgM positive plasma, West Nile Virus positive plasma, Treponema palladium, HAV IgM positive plasma, HAV IgG positive plasma, HBV Ab positive plasma, HCV Ab positive plasma, Influenza vaccine positive plasma, Leishmania positive plasma, Brucella IgM positive plasma, Chagas positive plasma, Toxoplasma positive plasma and Filariasis positive plasma for IgM and IgG
3. **Interference study:** No Interference for Respiratory Specimens (Mucin: bovine submaxillary gland type I-S, Blood (human), EDTA anticoagulated, Biotin), Nasal sprays (Neo-Synephrine, Afrin Nasal Spray, Saline Nasal Spray), Homeopathic allergy relief medicine (Homeopathic Zicam Allergy Relief Nasal Gel, Sodium Cromoglycate, Olopatadine Hydrochloride), Anti-viral drugs (Zanamivir, Oseltamivir, Artemether-lumefantrine, Doxycycline hyclate, Quinine, Lamivudine, Ribavirin, Daclatasvir), Anti-inflammatory medication (Acetaminophen, Acetylsalicylic acid, Ibuprofen), Antibiotic (Mupirocin, Tobramycin, Erythromycin, Ciprofloxacin), Human anti-mouse antibody, Pregnant woman, Elevated levels of C-reactive protein for IgM and IgG
4. **High-dose Hook Effect:** No hook effect at the concentration of 1.25 mg/ml for IgM and 0.3 mg/ml for IgG
5. **Matrix Equivalency:** The difference of Matrix (Capillary whole blood, Venous whole blood, Plasma, Serum) and anticoagulant (EDTA, Heparin, Sodium citrate) does not affect the result.

Sort	Matrix	Anticoagulant	Spiked Concentration	Agreement to expected result
COVID-19 IgM antibody spiked	Serum	NA	0.04 mg/ml	100%(30/30)
	Plasma	Heparin	0.04 mg/ml	100%(30/30)
		EDTA	0.04 mg/ml	100%(30/30)
		Sodium Citrate	0.04 mg/ml	100%(30/30)
	Venous whole blood	Heparin	0.04 mg/ml	100%(30/30)
		EDTA	0.04 mg/ml	100%(30/30)
		Sodium Citrate	0.04 mg/ml	100%(30/30)
	Capillary whole blood	EDTA	0.04 mg/ml	100%(30/30)
COVID-19 IgG antibody spiked	Serum	NA	0.04 mg/ml	100%(30/30)
	Plasma	Heparin	0.04 mg/ml	100%(30/30)
		EDTA	0.04 mg/ml	100%(30/30)
		Sodium Citrate	0.04 mg/ml	100%(30/30)
	Venous whole blood	Heparin	0.04 mg/ml	100%(30/30)
		EDTA	0.04 mg/ml	100%(30/30)
		Sodium Citrate	0.04 mg/ml	100%(30/30)
	Capillary whole blood	EDTA	0.04 mg/ml	100%(30/30)
N/A	Serum	NA	N/A	100%(30/30)
	Plasma	Heparin	N/A	100%(30/30)
		EDTA	N/A	100%(30/30)
		Sodium Citrate	N/A	100%(30/30)
	Venous whole blood	Heparin	N/A	100%(30/30)
		EDTA	N/A	100%(30/30)
		Sodium Citrate	N/A	100%(30/30)
	Capillary whole blood	EDTA	N/A	100%(30/30)

6. **Stability schedule for 24months of claimed shelf life**
   1) Accelerated stability Test: March, 2020 ~ July, 2020 (for 19 weeks)
   2) Real time stability Test: March, 2020 ~ May, 2022 (for 26 months)

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate anti- SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

NOTIFICATION FOR COVID-19 ANTIBODY TESTS

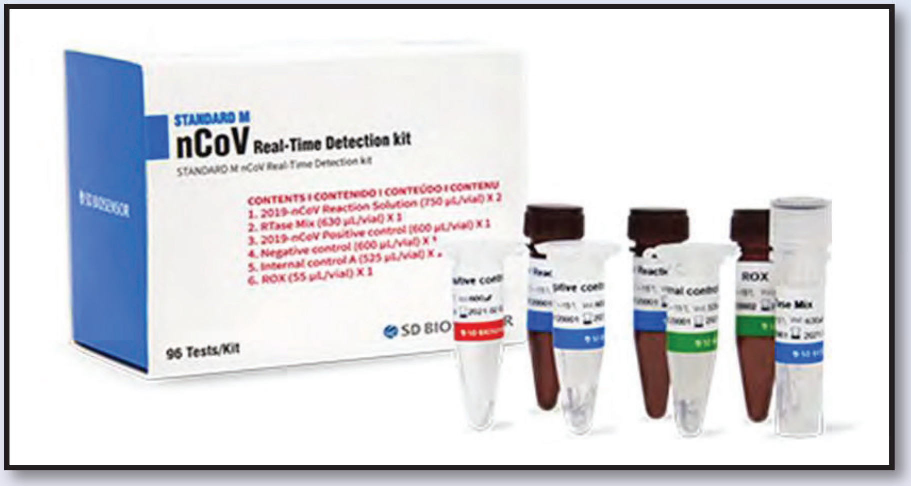
1. This test has not been reviewed by the FDA.
2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E or past or present infection with SARS virus (no. 6).
5. Not for the screening of donated blood.
6. The test procedure should be conducted in ambient temperature and pressure.
7. Results of these tests should be appropriately recorded in a test report.

STANDARD Q COVID-19 IgM/IgG

EUA Approved

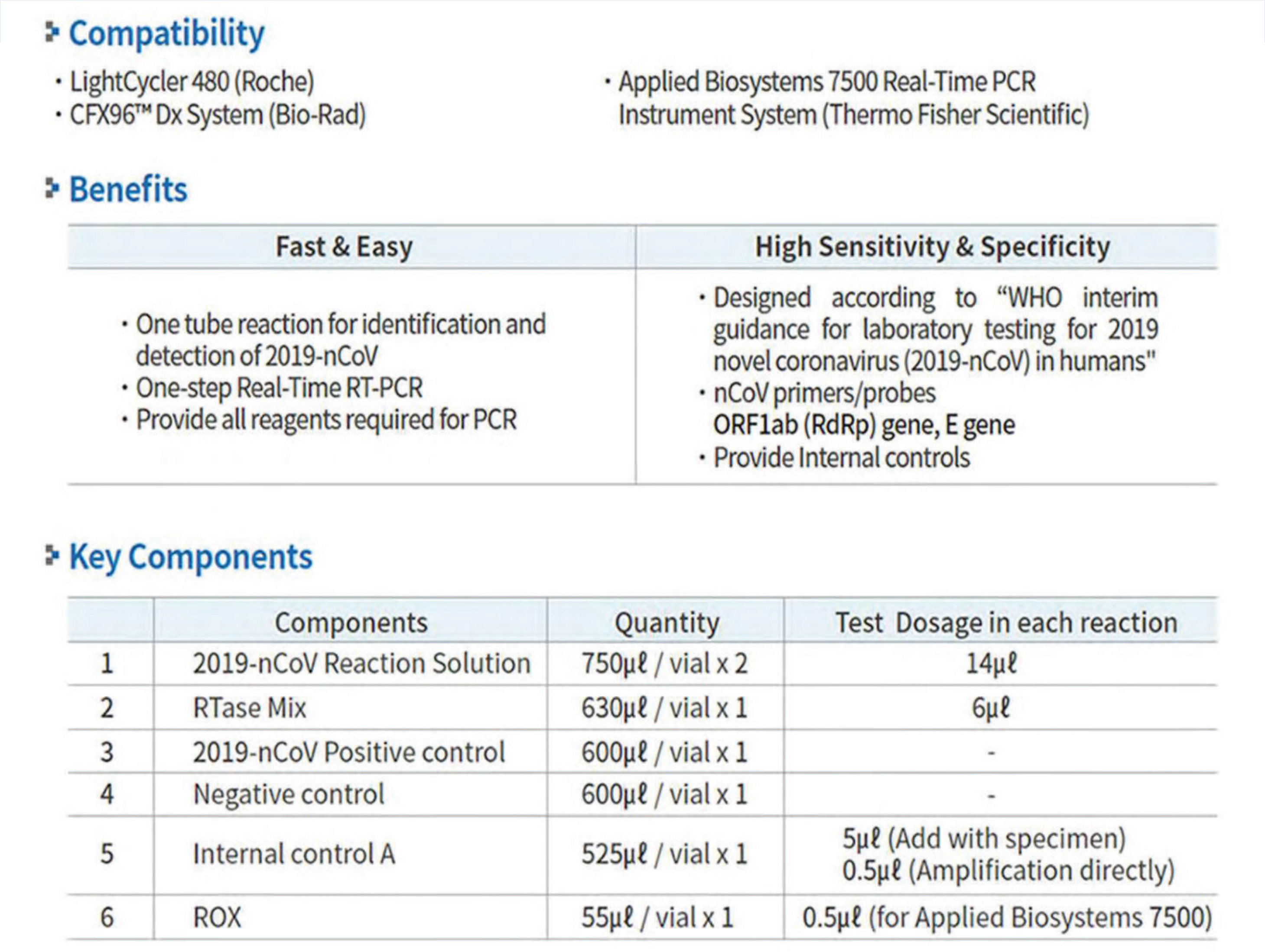
STANDARD M COVID-19

Rapid immunochromatography test Kit



RT-PCR Test (96 tests/kit) - These tests test actual virus whether you have virus or not. The test takes several hours. The results are 90 minutes and accuracy is over 95%.

- There needs to be cold-chain storage (less than 20 degrees). Should always be stored in -20 degrees all the time.
- Can't be tested during the incubation period
- You test with reagent, which is enough to test 96-100 times, can be used on different people (One drop of reagent/one test)
- Specimen: Nasopharyngeal swab, Oropharyngeal swab, Sputum
- Results within 90 minutes
- MOQ: 10,000 tests
- 96 tests per box



Compatibility

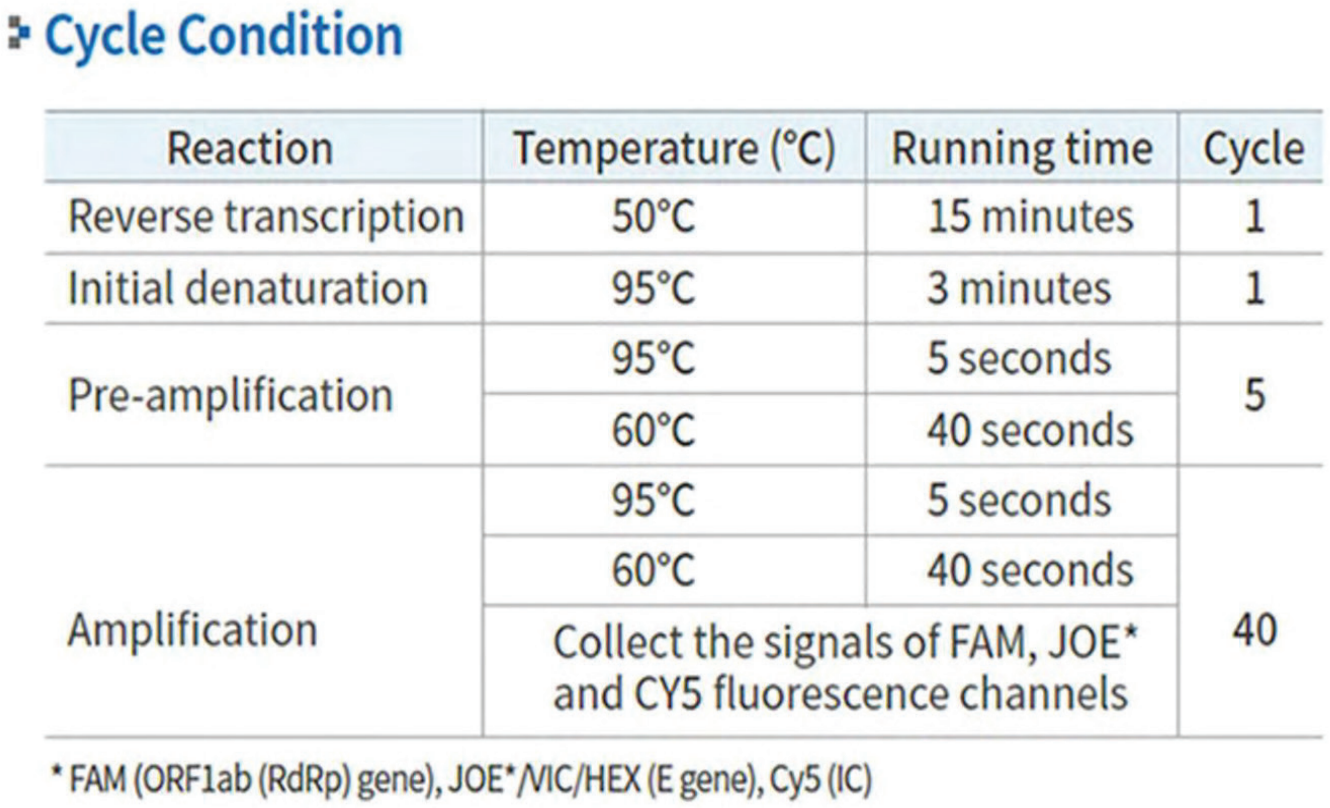
- LightCycler 480 (Roche)
- CFX96™ Dx System (Bio-Rad)
- Applied Biosystems 7500 Real-Time PCR Instrument System (Thermo Fisher Scientific)

Benefits

Fast & Easy	High Sensitivity & Specificity
• One tube reaction for identification and detection of 2019-nCoV • One-step Real-Time RT-PCR • Provide all reagents required for PCR	• Designed according to “WHO interim guidance for laboratory testing for 2019 novel coronavirus (2019-nCoV) in humans" • nCoV primers/probes **ORF1ab (RdRp) gene, E gene** • Provide Internal controls

Key Components

	Components	Quantity	Test Dosage in each reaction
1	2019-nCoV Reaction Solution	750μℓ / vial x 2	14μℓ
2	RTase Mix	630μℓ / vial x 1	6μℓ
3	2019-nCoV Positive control	600μℓ / vial x 1	-
4	Negative control	600μℓ / vial x 1	-
5	Internal control A	525μℓ / vial x 1	5μℓ (Add with specimen) 0.5μℓ (Amplification directly)
6	ROX	55μℓ / vial x 1	0.5μℓ (for Applied Biosystems 7500)



Cycle Condition

Reaction	Temperature (°C)	Running time	Cycle
Reverse transcription	50°C	15 minutes	1
Initial denaturation	95°C	3 minutes	1
Pre-amplification	95°C	5 seconds	5
	60°C	40 seconds	
Amplification	95°C	5 seconds	40
	60°C	40 seconds	
	Collect the signals of FAM, JOE* and CY5 fluorescence channels		

* FAM (ORF1ab (RdRp) gene), JOE*/VIC/HEX (E gene), Cy5 (IC)

FDA/CE Approved

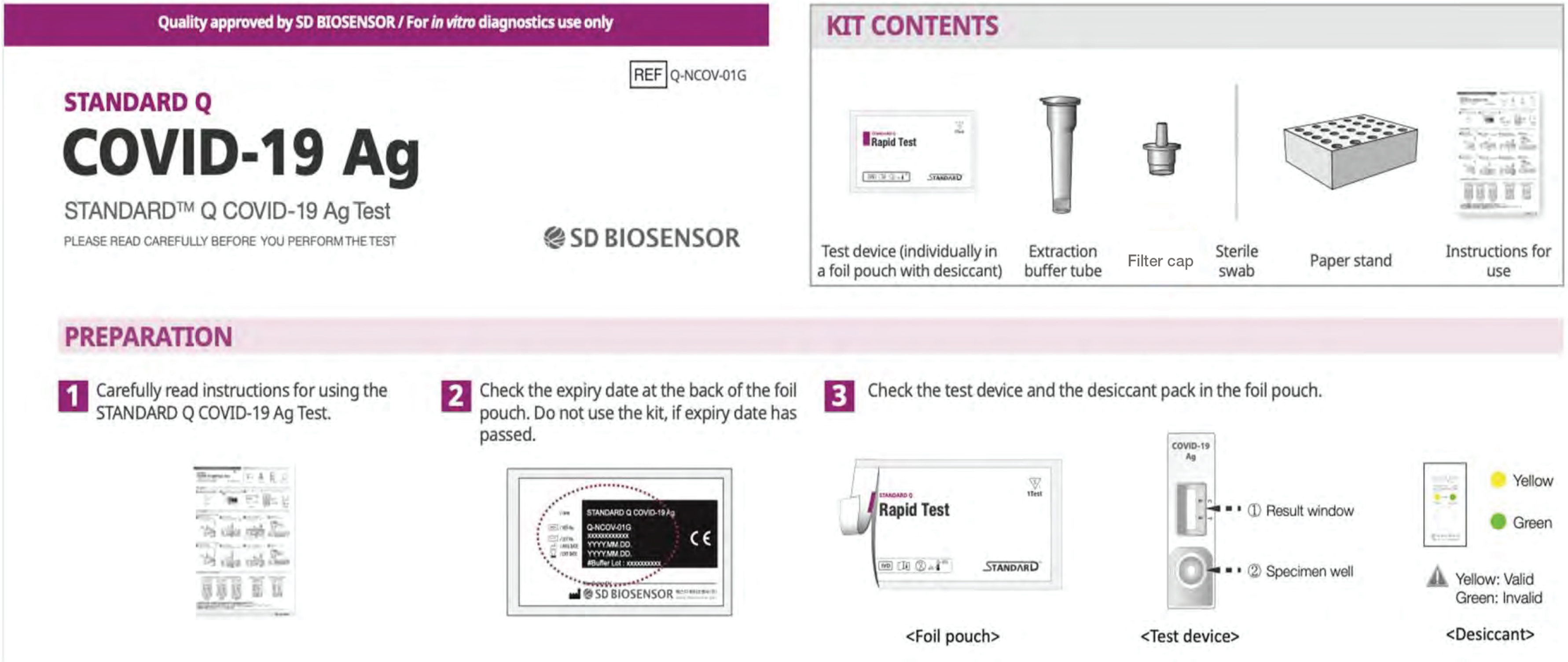
STANDARD Q COVID-19 Ag

Rapid chromatographic immunoassay test Kit

COVID-19 Ag
STANDARD Q
COVID-19 Ag
25 TESTS KIT
COVID-19 Ag Test
SD BIOSENSOR

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.

- Fast results within 15-30 mins.
- Easy to use
- Specimen : Nasopharyngeal swab
- All necessary reagents provided & no equipment needed
- MOQ: 10,000 tests
- 25 tests per box



Quality approved by SD BIOSENSOR / For *in vitro* diagnostics use only

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

KIT CONTENTS

Test device (individually in a foil pouch with desiccant)	Extraction buffer tube	Filter cap	Sterile swab	Paper stand	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.

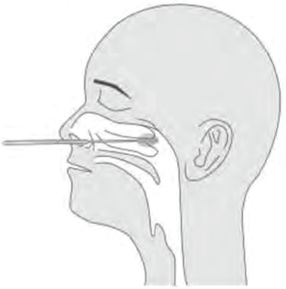
Rapid Test
STANDARD
COVID-19 Ag
① Result window
② Specimen well
● Yellow
● Green

Yellow: Valid
Green: Invalid

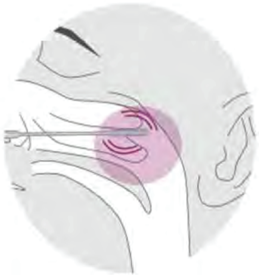
<Foil pouch> <Test device> <Desiccant>

TEST PROCEDURE

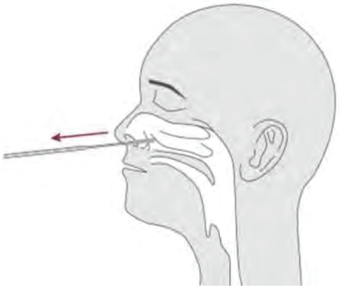
1 Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.



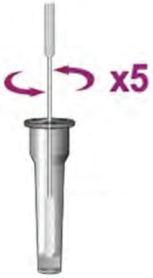
2 Swab over the surface of the posterior nasopharynx.



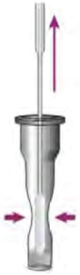
3 Withdraw the sterile swab from the nasal cavity.



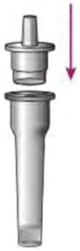
4 Insert the sterile swab into an extraction buffer tube. Swirl the swab at least five times.



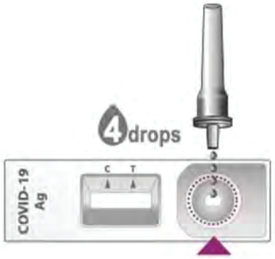
5 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



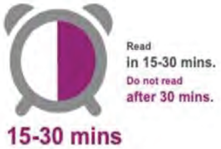
6 Press the filter cap tightly onto the tube.



7 Apply 4 drops of extracted specimen to the specimen well of the test device.


4drops
COVID-19
Ag
C
T

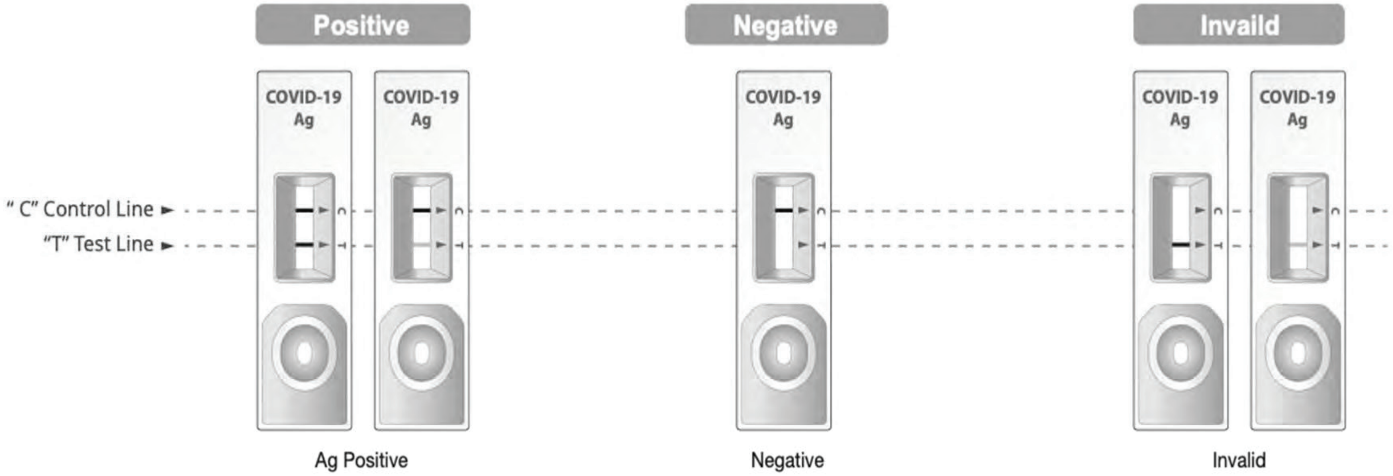
8 Read the test result in 15-30 minutes.


Read
in 15-30 mins.
Do not read
after 30 mins.
15-30 mins

⚠ **CAUTION**

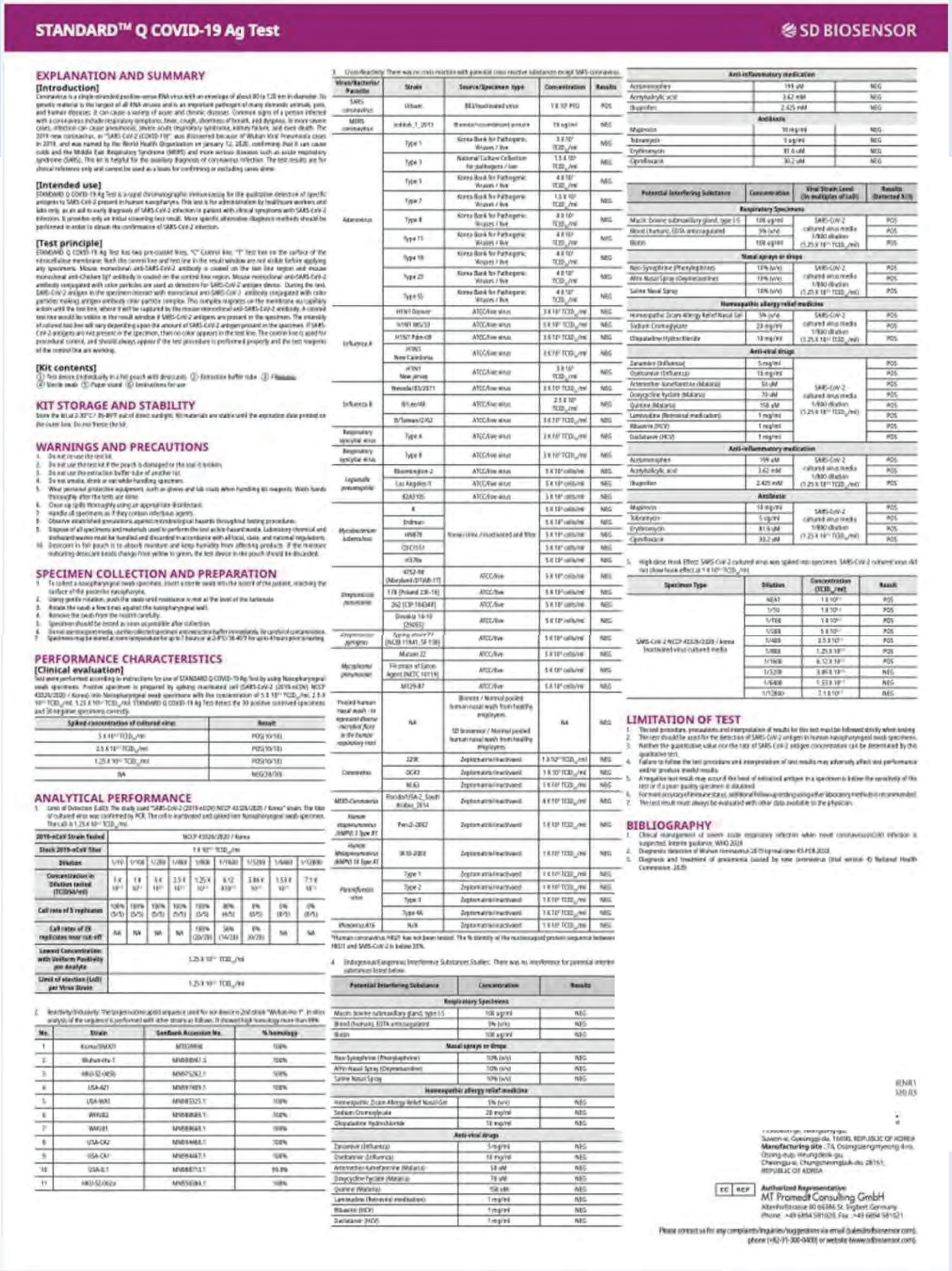
- Do not read test results after 30 minutes. It may give false results.

INTERPRETATION OF TEST RESULT


Positive
Negative
Invaild
COVID-19 Ag
" C" Control Line
"T" Test Line
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.**



STANDARD™ Q COVID-19 Ag Test

SD BIOSENSOR

EXPLANATION AND SUMMARY

[Introduction]

[Intended use]

[Test principle]

[Kit contents]

KIT STORAGE AND STABILITY

WARNINGS AND PRECAUTIONS

SPECIMEN COLLECTION AND PREPARATION

PERFORMANCE CHARACTERISTICS

[Clinical evaluation]

ANALYTICAL PERFORMANCE

LIMITATION OF TEST

BIBLIOGRAPHY

STANDARD Q COVID-19 Ag

FDA/CE Approved

COVID-19 IgG/IgM

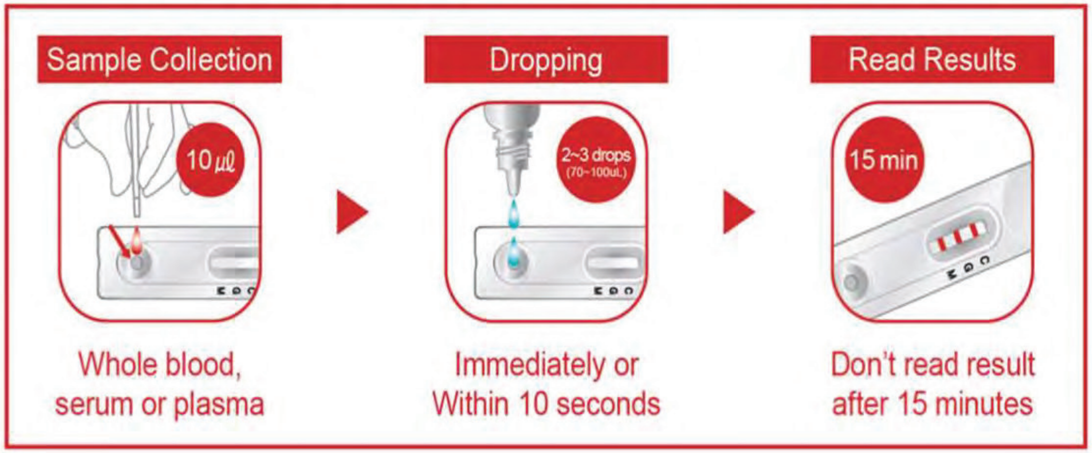
Immunochromatography Assay

COVID-19 IgG/IgM test is suitable for patient showing negative PCR result with mild pneumonia symptoms or have persisted pneumonia symptoms for more than 5 days.

- Storage : 1 - 30 degrees
- Kit components: Test device, extraction buffer, 10uL of capillary tube, instruction manual
- Highest sensitivity
- High correlation with RT-PCR
- Results within 15 minutes
- MOQ: 10,000 tests
- 25 tests per box

Test Procedure

Requires minimal hands-on time, Follows 3 Steps and Provides a result in 15 minutes



Sample Collection

Whole blood, serum or plasma

Dropping

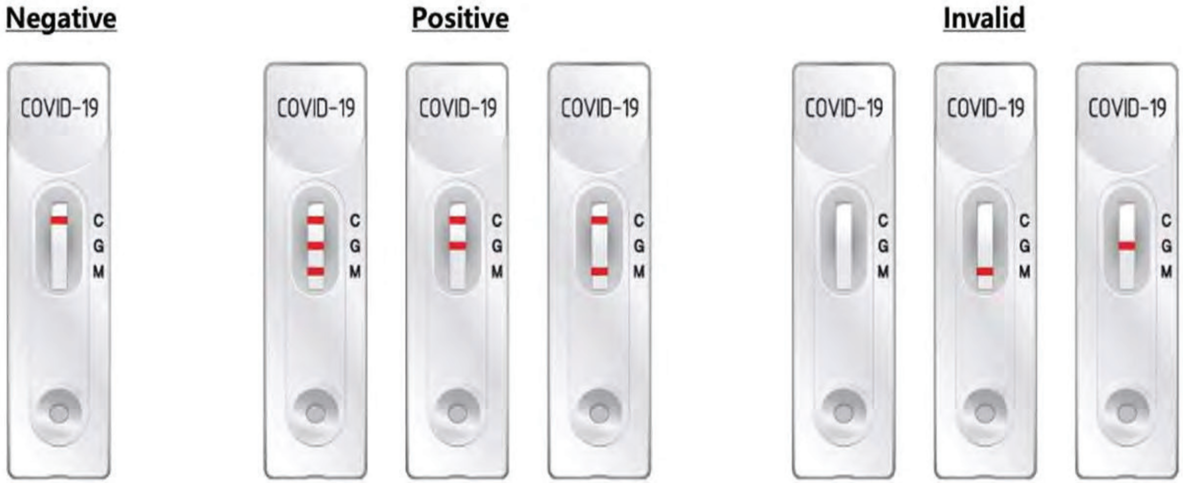
Immediately or Within 10 seconds

Read Results

Don't read result after 15 minutes

10 µℓ
2~3 drops
(70~100uL)
15 min
C
G
M

Interpretation



Negative
Positive
Invalid
COVID-19
C
G
M