PURSUE THE QUALITY OF LIFE
Total Solution for POC Diagnostics

STANDARD Q COVID-19 Ag Test

SD BIOSENSOR

Product Introduction

Cédric Jo / International Project Coordinator

23 October 2020

Contents

01
About SD BIOSENSOR

About SD BIOSENSOR

SD BIOSENSOR has been developing and manufacturing innovative diagnostic solutions focused on

- **Immunoassay**
  Immunoassay reagent manufacturing
- **Molecular Diagnostic Development**
  Nucleic Acid Amplification reagent, POC molecular cartridge manufacturing,
  Nucleic Acid Extraction
- **Instruments Development**
  Development of POCT system, Retention of LIS/HIS-applied technology, Lab System

Chronic Care
BGMS/LipidoCare/
MultiCare

STANDARD Q
Rapid diagnostics test

STANDARD F
Fluorescent
immunoassay

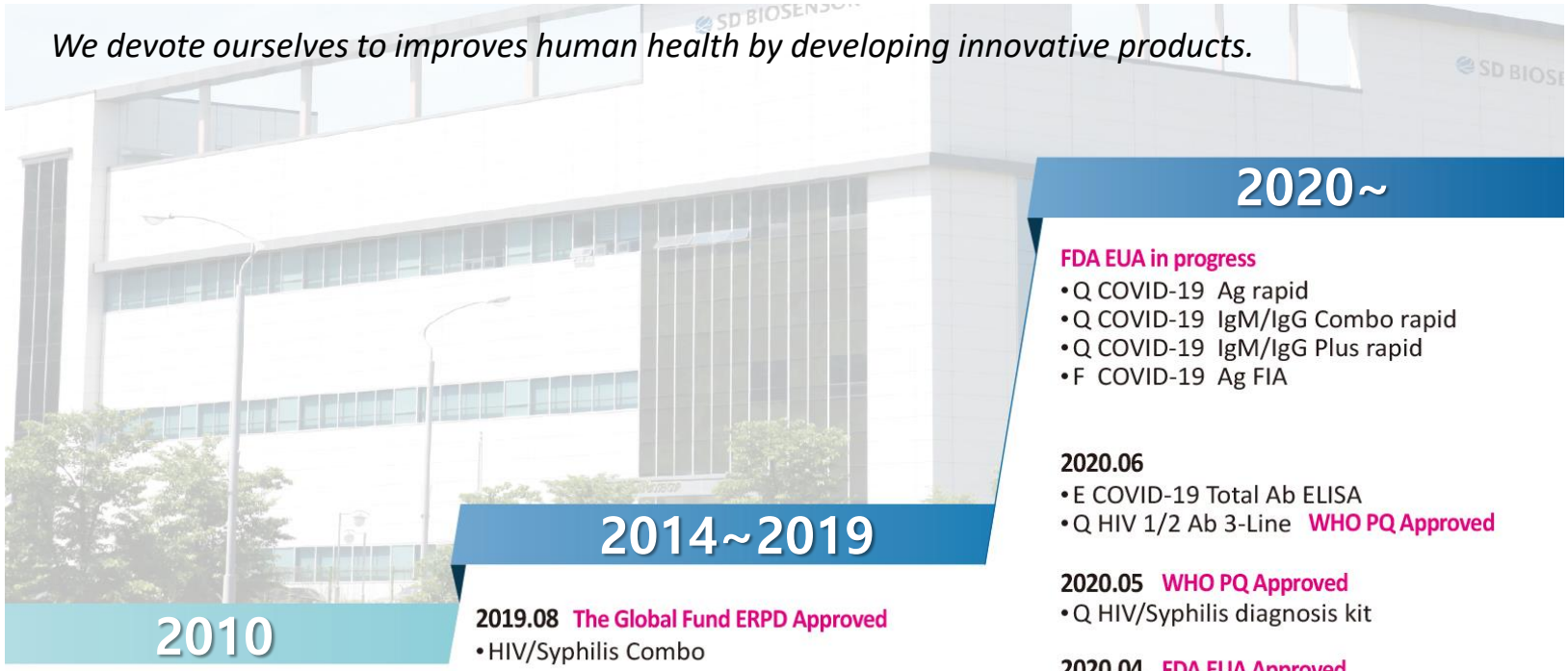
STANDARD E
ELISA

STANDARD M
Molecular POC system

Screening Test → **Confirmatory Test**

About SD BIOSENSOR

We devote ourselves to improves human health by developing innovative products.



2010

2010.12

· **Founding of SD BIOSENSOR**

2014~2019

2019.08 **The Global Fund ERPD Approved**
- HIV/Syphilis Combo

2019.04 **UNICEF long term supply agreement signed**
- Arbo Panel I (Zika, Dengue, Chikungunya, Yellow fever)

2016.09
- Zika IgG/IgM

2015.04 **World 1st**
- MERS-CoV Antigen

2014.12 **WHO EUAL**
- Ebola *Zaire* Antigen

2020~

FDA EUA in progress
- Q COVID-19 Ag rapid
- Q COVID-19 IgM/IgG Combo rapid
- Q COVID-19 IgM/IgG Plus rapid
- F COVID-19 Ag FIA

2020.06
- E COVID-19 Total Ab ELISA
- Q HIV 1/2 Ab 3-Line **WHO PQ Approved**

2020.05 **WHO PQ Approved**
- Q HIV/Syphilis diagnosis kit

2020.04 **FDA EUA Approved**
- M nCoV Real-time detection kit

2020.03
- Q HCV Ab **WHO PQ approved**
- Q Malaria Ag **WHO PQ approved**

CE registration
- Q COVID-19 Ag rapid
- Q COVID-19 IgM/IgG Combo rapid
- F COVID-19 Ag FIA
- F COVID-19 IgM/IgG Combo FIA

2020.02 **CE registration /KFDA EUA Approved**
- M nCoV Real-time detection kit

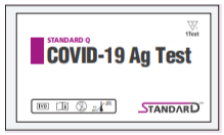
02

STANDARD Q COVID-19 Ag Test : Specifications

① Kit introduction

Contents & specification

INTRODUCTION FOR USE



TEST DEVICE

EXTRACTION BUFFER

NOZZLE CAP

STERILE SWAB

Category	Details
Intended use	**Rapid chromatographic immunoassay for qualitative detection** of specific SARS-CoV-2 antigen
Contents (25T/kit)	• Test device (individual aluminum pouch) x 25 • Sterile swab x 25 • Extraction buffer x 25 • Nozzle cap x 25 • IFU
Sample type	**Nasopharyngeal swab** ** Nasal swab will be added soon
Sample volume	3 drops of mixed specimen with extraction buffer
Testing time	**15 ~ 30 minutes** (Do not read test results after 30 mins.)
Storage temperature	2~30℃ (36~104℉)
Operating temperature	15~30℃ (59~86℉) ** We plan to improve operating temperature until 40 ºC
Cat. no.	09COV30D (25T/kit)

Clinical Evaluation

	Brazil	Germany	Overall
Sensitivity (Ct ≤ 25)	95.92% (47/49, 95% CI 86.02-99.50%)	100% (21/21, 95% CI 83.89-100%)	97.14% (68/70, 95% CI 90.06-99.65%)
Sensitivity (Ct ≤ 33)	91.92% (91/99, 95% CI 84.70-96.45%)	87.80% (36/41, 95% CI, 73.80-95.92%)	90.71% (127/140, 95% CI 84.64-94.96%)
Sensitivity (0 ≤ from the symptom onset days ≤ 3)	95% (19/20, 95% CI 75.13-99.87%)	85.71% (18/21, 95% CI, 63.66-96.95%)	90.24% (37/41, 95% CI 76.87 – 97.28%)
Sensitivity (from the symptom onset days ≤ 7)	90.7% (88/97, 95% CI 83.12-95.67%)	80% (28/35, 95% CI 63.06-91.56%)	87.88% (116/132, 95% CI 81.06-92.91%)
Clinical Sensitivity	88.68% (94/106, 95% CI 81.06-94.01%)	76.6% (36/47, 95% CI 61.97-87.70%)	84.97% (130/153, 95% CI 78.3-90.23%)
Clinical Specificity	97.6% (287/294, 95% CI 95.2-98.8%)	99.3% (1203/1212, 95% CI 98.6-99.6%)	98.94% (1490/1506, 95% CI 98.28-99.39%)

https://www.finddx.org/wp-content/uploads/2020/10/SDQ-Ag-Public-Report_20201016-v1-1.pdf

Analytical Performance

Limit of Detection (LoD)

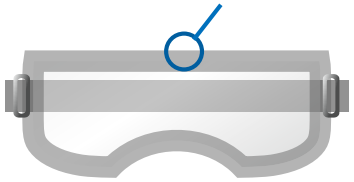
- The SARS-CoV-2 positive specimen was prepared by spiking Inactivated SARS-CoV-2 (2019-nCOV) NCCP 43326/2020/Korea strain to SARS-CoV-2 negative nasopharyngeal swab confirmed with PCR.
- LOD is determined as 3.12 x $10^{2.2}$ $TCID_{50}$/ml(1.12 x 10^{2} PFU/ml) for direct Nasopharyngeal swab, 5 x $10^{3.2}$ $TCID_{50}$/ml for Nasopharyngeal swab stored in VTM by testing serially diluted the mock positive specimen.

② Biosafety requirements

Material Required (Not provided)

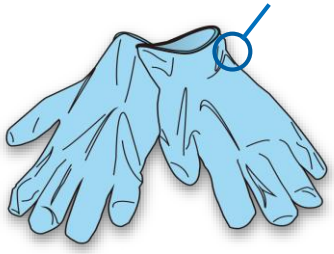
All the Personal Protective Equipment is disposable

Safety goggles

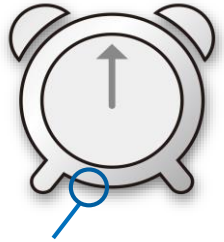


Respirator-style face mask

Gloves



Protective suits



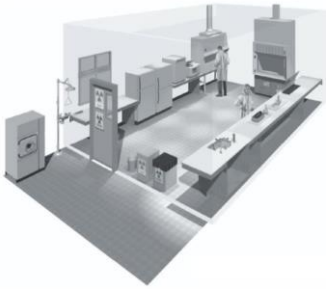
Timer

Disposable container

② Biosafety requirements

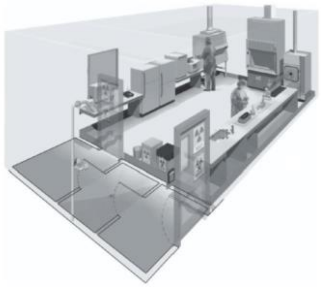
Recommendation of
Centers for Disease Control and Prevention

[A Biosafety Level 2 (BSL-2) Facility]



Agents	Risk Group 2
Practices	BSL-1 plus: -Limited access -Biohazard signage -Sharps precautions -Biosafety manual
Safety Equipment	-Use of BSCs for aerosol protection -PPE-lab coats, gloves, face/eye protection
Facilities	BSL-1 plus: -Autoclave available -Directional air

[A Biosafety Level 3 (BSL-3) Facility]



Agents	Risk Group 3
Practices	BSL-2 plus: -Controlled access - Decon of all waste and linens -Medical Surveillance
Safety Equipment	-Use of BSC's for all work -PPE-protective clothing, gloves, respiratory protection if needed
Facilities	BSL-2 plus: -Physical separation -Self-closing, double-door access -Negative airflow

Image source: WHO Laboratory Biosafety Manual, 3rd edition

"STANDARD Q COVID-19 Ag Test"
Can be used in the field

※ SARS-CoV-2 in Extraction Buffer Inactivation Test

Extraction buffer	1) Virus spiking	Result	
STANDARD Q COVID-19 Extraction Buffer	O	1 minute incubation : 2)CPE	Virus Activated
	O	2 ~ 40 minutes incubation : No CPE	Virus Inactivated
	X	No CPE	Negative Control

1) SARS-CoV-2 titer : 2.5 X $10^{4.3}$ $TCID_{50}$/mL 2) CPE : Cytopathic effect

" The SARS-CoV-2 virus will be inactivated "
by extraction buffer within 2 minutes.

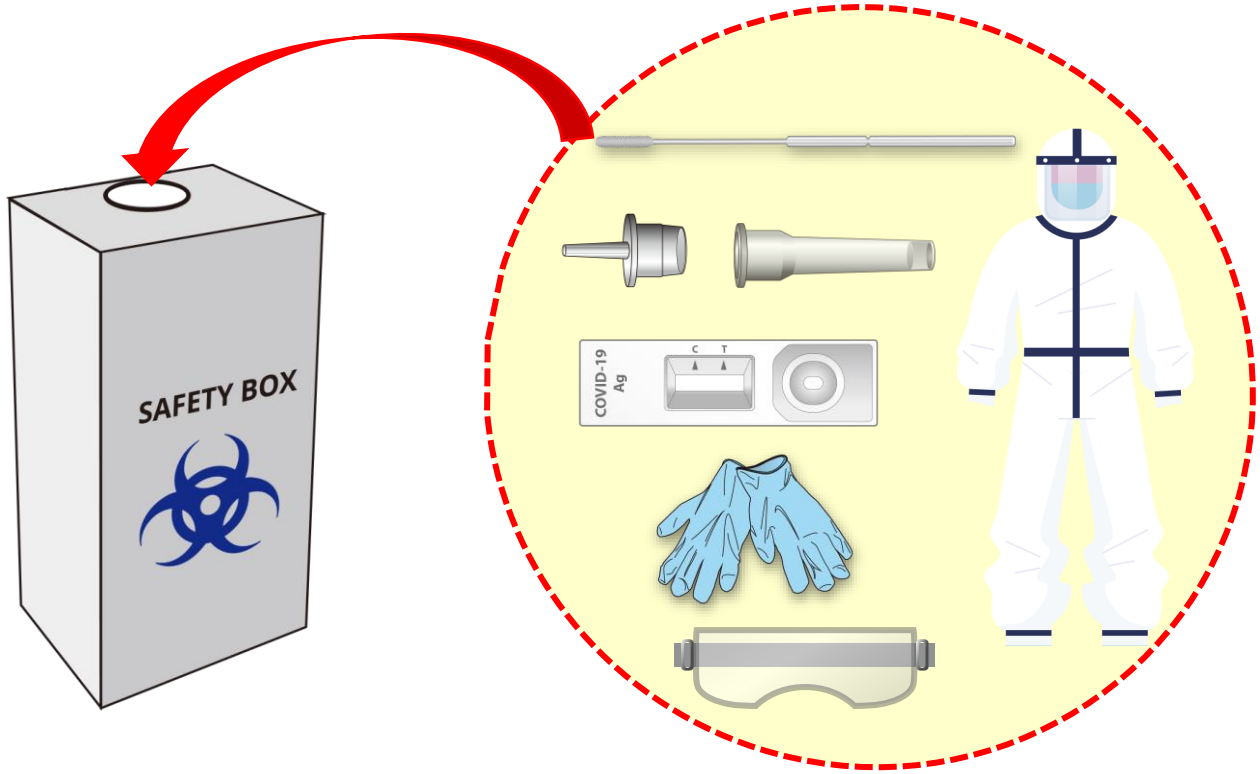
https://escolifesciences.co.kr/news/1998/

② Biosafety requirements

Appropriate disinfection requirements

※ It is recommended to handle safely according to the recommendations of each region

Discard used sterile swab, extraction tube, test device, gloves, protective glasses, and protective suit into the disposal container



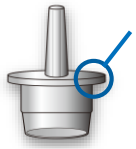
③ Test Handling

Test Kit Components (25 Tests)

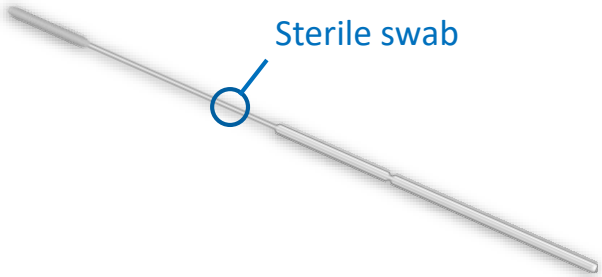
COVID-19 Ag Test device
(individually in a foil pouch
with desiccant)

Extraction buffer tube

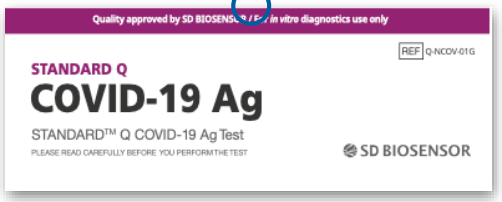
Nozzle cap



Sterile swab



Instructions for use



※ Positive & Negative controls are provided separately (*subject to be included in the kit soon)

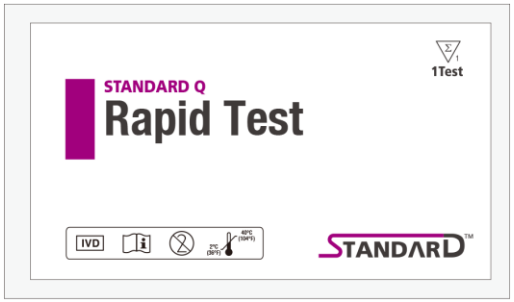
③ Test Handling

Storage & Transportation Requirements

Test device & Buffer tube must be stored at …

2-30℃

36-86℉



- 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.

③ Test Kit Handling

Sample Requirement

Nasopharyngeal swab collected by sterile swab must be tested immediately

③ Test Kit Handling

Precautions on testing assay handling

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.

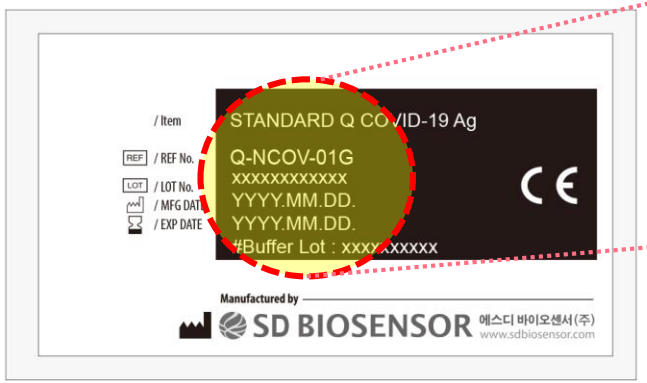
④ Test Procedure

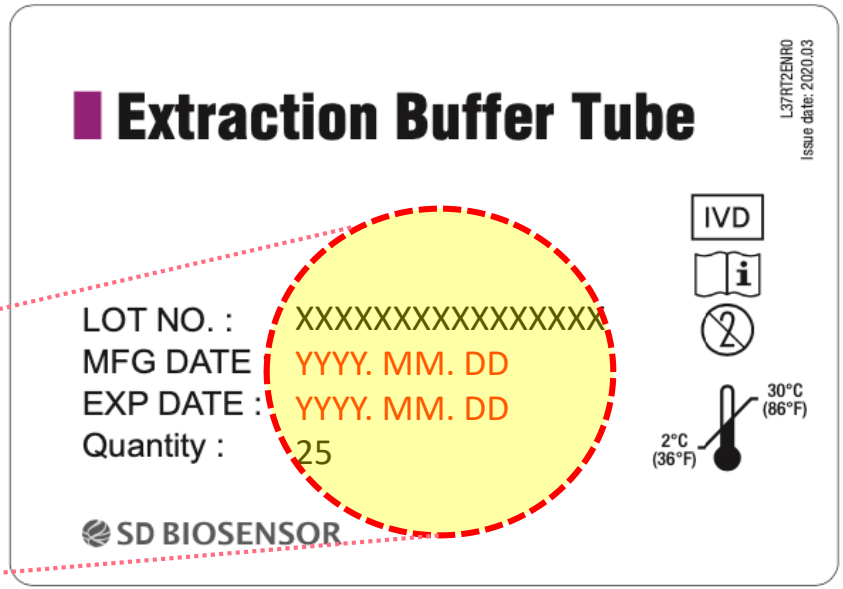
Preparation

1. Test device & Extraction buffer tube must check the expiry date

The front

The back





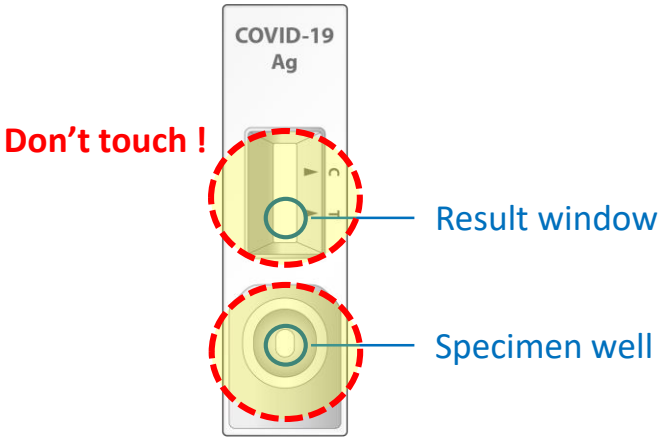
④ Test Procedure

Preparation

2. Check the test device and the desiccant

<Foil pouch>

<Test device>



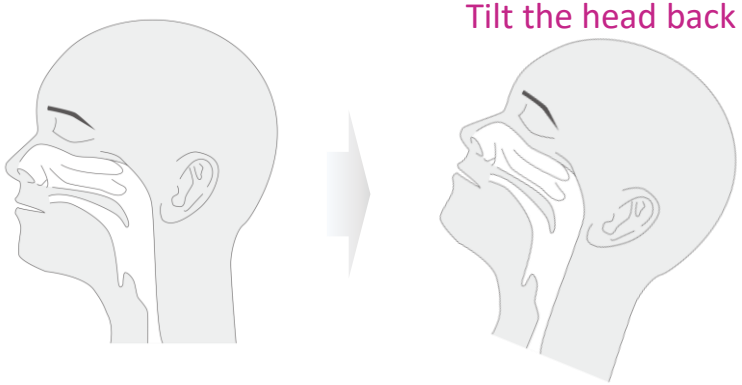
<Desiccant>

④ Test Procedure

Collection of specimen

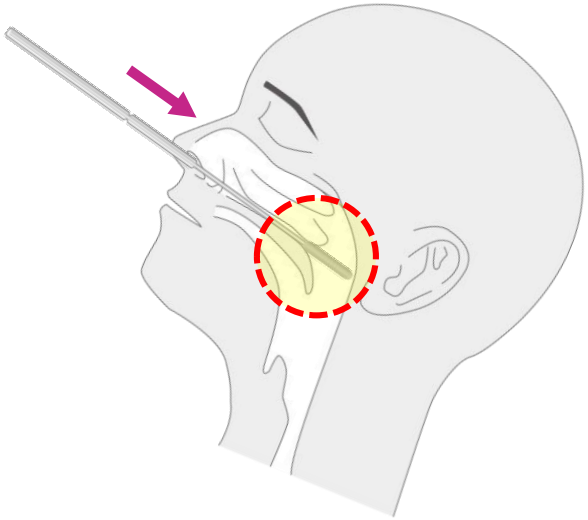
3. Collect nasopharyngeal specimen using provided sterile swab

3-1



- Tilt the patient's head back slightly and support it with your dominant hand

3-2



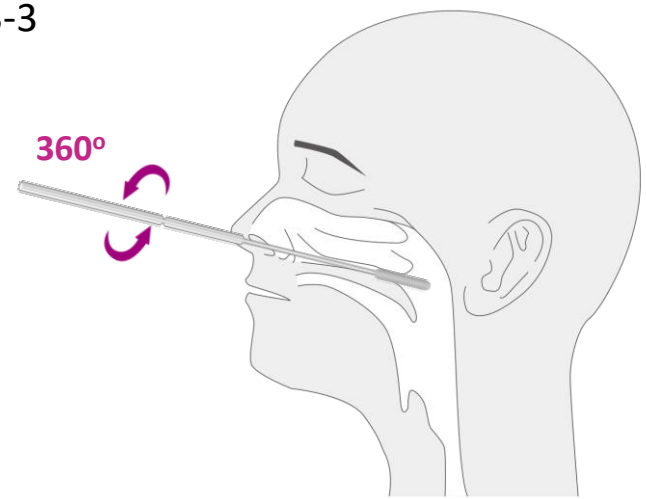
- Insert the swab into nasopharyngeal cavity

④ Test Procedure

Collection of specimen

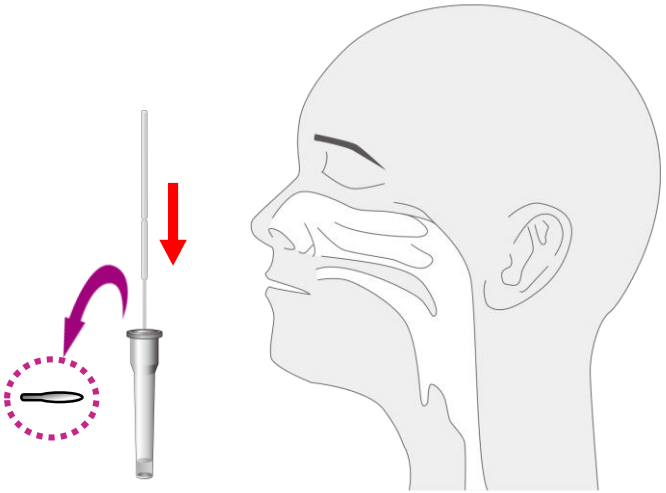
3. Collect nasopharyngeal specimen using provided sterile swab

3-3



- Once swab is in location, rotate the swab
- Rotate the swab more than 5 times to saturate the swab tip

3-4



- Remove the aluminum cover of extraction buffer tube
- Remove the swab from the nasal cavity
- Insert the swab into an extraction buffer tube

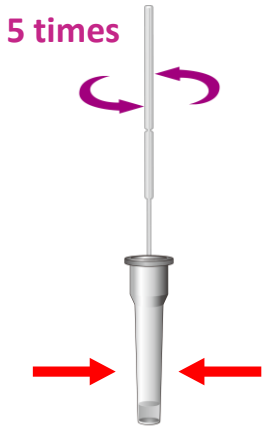
④ Test Procedure

Collection of specimen

4. Extract the specimen

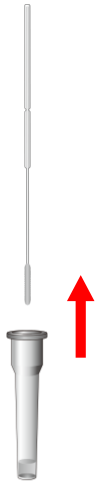
Mix the nasopharyngeal specimen with an extraction buffer tube

4-1



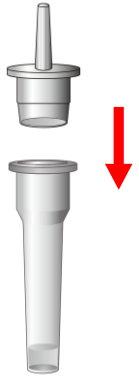
- Stir the swab more than 5 times.
- While stirring the swab, squeeze the buffer tube to extract specimen completely

4-2



- Remove the swab

4-3



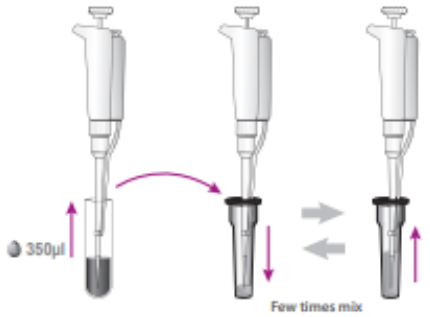
- Assemble the nozzle cap tightly with the tube.

④ Test Procedure

Collection of specimen

[Specimens in transport media]

1)



※ Available transport medium

Virus Transport Medium(VTM)	Recommended Storage Condition	
	2°C to 8°C	25°C
Copan UTM™ Universal Transport Media	12 hours	8 hours
BD™ Universal Viral Transport	12 hours	8 hours
STANDARD™ Transport Medium	12 hours	8 hours

- Using a micropipette, collect the 350µl of specimen from the collection cup or VTM.

- Mix the specimen with an extraction buffer.

2)

- Assemble the nozzle cap tightly with the tube.

④ Test Procedure

Collection of specimen

Precautions

If the specimen storage condition is out of instructions as below, do not use.

1. The Nasopharyngeal swab is stored in extraction buffer for more than 4 hours at 5±3℃ or 1 hour at 20±5℃.

2. Freezing and thawing of Nasopharyngeal swab or the specimen in UTM is usable for less than 3 cycles.

3. The Nasopharyngeal swab is stored in UTM for more than 12 hours at 5±3℃ or 8 hours at 20±5℃.

④ Test Procedure

Collection of specimen

Criteria for rejection of specimens

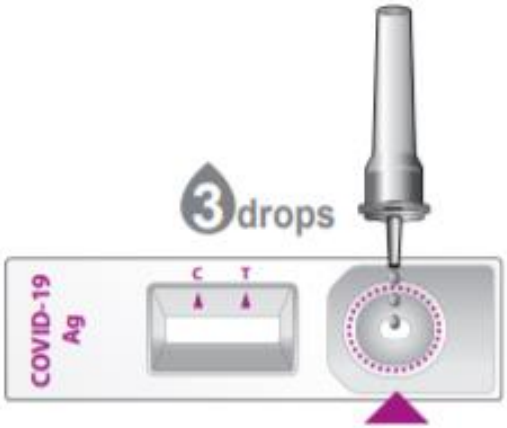
- Unaccepted specimen type. Only nasopharyngeal
- Not refrigerated or frozen properly.
- Insufficient specimen volume. (Recommendation“3 drop (90 ul) ~ 4 drop (120 ul)”)
- Failure to follow specific shipping and packaging requirements.

https://www.doh.wa.gov/Portals/1/Documents/5240/SCSI-2019-nCoV.pdf

④ Test Procedure

6. Apply the extracted specimen

6-1



- Apply 3 drops of extracted specimen to the specimen well of the test device

6-2

- Read the test result in 15-30 minutes

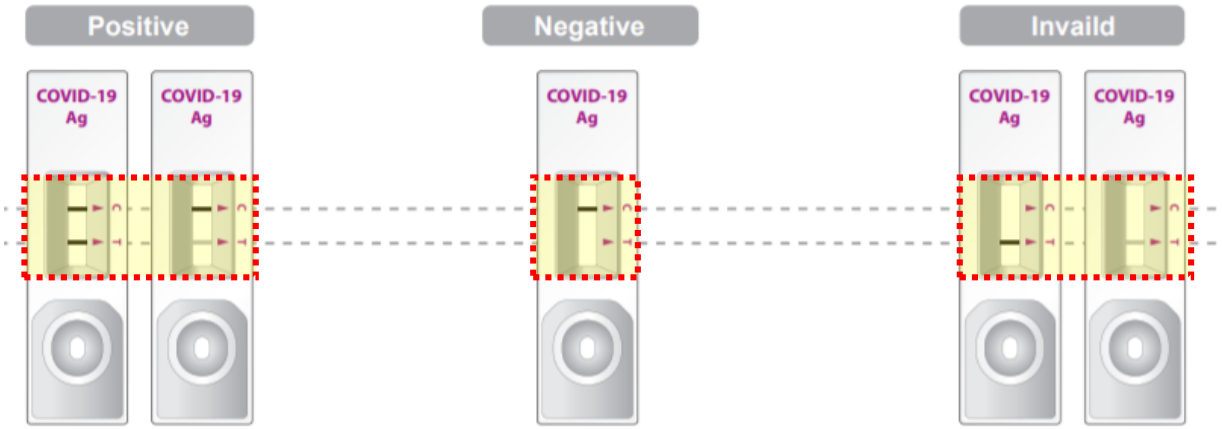
- Place the test device on a flat surface.
- Dispense the specimen at 90 degree angle to allow for free falling drops and avoid bubbles.

7. Running of the assay

Read the test result in 15 - 30 minutes

INTERPRETATION OF TEST RESULT

* "C“ Control Line "T Test line



Do not read test result after 30 minutes. It may show false result.
In case of invalid, we recommend re-test

④ Test Procedure

Factors that affects FALSE or Invalid results

- Concentration of specimen
- Insufficient drop of mixed buffer
- The factors that affected cross-reactivity & Interference

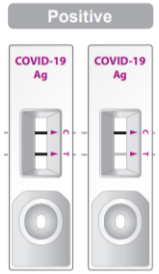
03

QC and QA, Performance

STANDARD Q COVID-19 Ag Test

Control and Performance

1. Internal controls



- We have internal/procedural control on test device.
- The test result is valid if control line appears

2. Control solution

- A separate kit is available for sale (10 positive and 10 negative tablets).
- This control tablet is to be used on test device.
- Control swab will be included in the test kit in near future.

Control and Performance

3. Use of software to manage

- STANDARD PASS Mobile application can be used

Compatible product	**STANDARD Q/F COVID-19 Ag Test** (It will be updated for other COVID-19 product lines soon)
Target	Patients who diagnosed with STANDARD Q/F COVID-19 Ag Test product (In case of negative result, Identity assurance by issuing a STANDARD Pass)
Development schedule	**Until 2020/12 (launch goal)**

4. Status of Certification & Registration of STANDARD Q COVID-19 Ag Test

Product Certification	**WHO EUL, CE, TGA**
Countries of Registration	 and other 8 countries

- SD BIOSENSOR distributors can support local training and A/S

05
Trouble shooting

STANDARD Q COVID-19 Ag Test

Trouble shooting

- Verify labeling, IFU and procedures
- Have the same operator to re-test the specimen
- Repeat blind test by another operator
- Confirm against the reference test (WHO EUL approved PCR)

06
How to order

STANDARD Q COVID-19 Ag Test

How to request purchase

- **SD BIOSENSOR Homepage (www.sdbiosensor.com/xe/covid)**

Submit "COVID-19 Order Information"

Title / Name / E-mail / Account / Consignee

Quantity / Incoterms / Message

- **Distributor**

  - You can contact SD Biosensor distributor in your country

- **International organization**

  - This kit is eligible for procurement in different platforms (ie. WHO, Global Fund, UNICEF, AMSP Etc.)

Thank You

Cédric Jo, International Project Coordinator
cedric@sdbiosensor.com

http://www.sdbiosensor.com/xe/covid

Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
Contact : sales@sdbiosensor.com | www.sdbiosensor.com

06
FAQ

STANDARD Q COVID-19 Ag Test

FAQs

Q1. Should I use only nasopharyngeal swab specimen for the STANDARD Q COVID-19 Ag Test?

A. Nasopharyngeal swab and VTM(UTM) containing the specimen can be used as the sample.

Available Transport Medium

Virus Transport Medium(VTM)	Recommended Storage Condition	
	2°C to 8°C	25°C
Copan UTM™ Universal Transport Media	12 hours	8 hours
BD™ Universal Viral Transport	12 hours	8 hours
STANDARD™ Transport Medium	12 hours	8 hours

Test procedure for using VTM sample

1) Collect the 350ul of specimen from the VTM. Mix the specimen with an extraction buffer
2) Press the nozzle cap tightly onto the tube.
3) Apply 3 drops of extracted specimen to the specimen well of the test device.
4) Read the test result in 15-30 minutes

FAQs

Q2. How can I transport the specimen without VTM?

A. The specimen in an extraction buffer can be stored up to 1 hour at 20 ± 5℃ and up to 4 hours at 5 ± 3℃.

If the specimen is not tested immediately, it is better to store the specimen at the - 20℃ up to 1 cycle.
(Do not freeze-thawing repeat)

FAQs

Q3. It is represented that the results should be interpreted between 15 – 30 mins.

Is there an optimum time?

A. Interpreting the test result is available from 15 minutes.

However, it is better to read at 30 minutes as the color scale becomes more visible to interpret.

FAQs

Q4. Is there any recommendation for handling the sample and the extraction buffer?

(E.g. inside a BSL-2-cabinet)

A. We recommend that it is essential to follow proper infection control measures when specimen are collected from patients with a suspected CORONAVIRUS infection.

The examiner should wear an N95 respirator mask, gown, protective glasses and gloves.

Viral testing of specimens can be handled in a BSL-2 laboratory.

It is recommend that when you mixed the specimen with an extraction buffer, you have to perform the test within an hour.

FAQs

Q5. Does the extraction buffer contains any kind of substance that inactivate viable viral particles? I'm asking because if so, according to biosafety regulations, the test can be done outside a BSL-2 cabinet.

A. The SARS-CoV-2 virus will be inactivated by extraction buffer within 2 minutes.

※ SARS-CoV-2 in Extraction Buffer Inactivation Test

Extraction buffer	1) Virus spiking	Result	
STANDARD Q COVID-19 Extraction Buffer	O	1 minute incubation : 2)CPE	Virus Activated
	O	2 ~ 40 minutes incubation : No CPE	Virus inactivated
	X	No CPE	Negative control

1) SARS-CoV-2 titer : 2.5 X $10^{4.3}TCID_{50}$/mL

2) CPE : Cytopathic effect

- It's enough to inactivate the virus at least 2 minutes incubation time.

FAQs

Q6. The transport in the buffer is a little tricky because of the nozzle cap.

Do they keep the swab inside of the extraction buffer (cut the ends) and then extract just before doing the test or do they transport the sample already extracted with the nozzle cap?

A. Please perform the test at the point of care.

FAQs

Q7. Have you performed the test from Amies solution?

A. Interference has been reported in Amies solution produced by several manufacturers.

It is understood as a phenomenon that appears because the composition is slightly different for each manufacturer.