SARS-CoV-2 Rapid Antigen Test

REF		SYSTEM
9901-NCOV-01G	25	visual reading

English

Intended use
The SARS-CoV-2 Rapid Antigen Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in the human nasopharynx. This test is intended to detect antigen from the SARS-CoV-2 virus in individuals suspected of COVID-19. This product is strictly intended for professional use in laboratory and Point of Care environments.

Summary
Coronaviruses 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, was discovered due to Wuhan viral pneumonia cases in 2019 and a pandemic was declared by the World Health Organization on March 11, 2020. WHO confirmed that COVID-19 can cause colds and more serious diseases such as severe acute respiratory syndrome (SARS).

Test principle
The SARS-CoV-2 Rapid Antigen Test has two pre-coated lines: A "C" Control line and a "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 samples. 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 the SARS-CoV-2 antigen device. During the test, the SARS-CoV-2 antigen in the sample interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making an antigen-antibody color particle complex. This complex migrates on the membrane via capillary action to the test line, where it is captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line becomes visible in the result window if anti-SARS-CoV-2 antigens are present in the sample. The intensity of the colored test line varies depending upon the amount of anti-SARS-CoV-2 antigen present in the sample.
Note: Even if the test line is very faint or not uniform the test result should be interpreted as a positive result. If anti-SARS-CoV-2 antigens are not present in the sample, no color appears in the test line. The control line is used for procedural control, and always appears if the test result is valid. If no control line is visible the test result should be considered as invalid.

Reagents
- mAb anti-COVID19 antibody
- mAb anti-Chicken IgY
- mAb anti-COVID-19 antibody-gold conjugate
- Purified chicken IgY-gold conjugate

Precautions and warnings
- Do not re-use the test kit.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- Do not use the extraction buffer tube of a different lot.
- Do not smoke, drink or eat while handling sample.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
- Clean up spills thoroughly using an appropriate disinfectant.
- Handle all samples as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose all samples and materials used to perform the test as biohazardous waste. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, state, and national regulations.
- Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the desiccant status indicator changes from yellow to green, the test device in the pouch should be discarded.

Storage and stability
Store the kit at 2-30 °C / 36-86 °F out of direct sunlight. Kit materials are stable until the expiry date printed on the outer box. Do not freeze the kit.

Materials provided
- Test device (individually in a foil pouch with desiccant)
- Extraction buffer tube
- Nozzle cap
- Sterile swab
- Film (can be attached to the test device when performing outdoor testing)
- Instructions for use
- Quick Reference Guide

Materials required (but not provided)
- Timer

Test preparation and sample collection
Carefully read the instructions for using the SARS-CoV-2 Rapid Antigen Test. Please also see the enclosed Quick Reference Guide (with illustrations) before performing a test.
Preparing for a test
1. Check the expiry date on the back of the foil pouch. Do not use the test, if the expiry date has passed.
2. Open the foil pouch and remove the test device and the desiccant package. Use the test immediatedly after opening the pouch.
3. Ensure that the test device is undamaged and that the desiccant status indicator shows valid (yellow).
4. Perform a QC as required according to the Instructions for Use of the QC material.

Collecting a sample (Nasopharyngeal swab)
1. To collect a nasopharyngeal swab sample, 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. Insert the swab into the provided 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. The sample should be tested as soon as possible after collection.
9. Samples may be stored at room temperature for up to 1 hour or at 2-8 °C/ 36-46 °F for up to 4 hours prior to testing.

Preparing a sample from viral transport media
Prepare a sample from a viral transport medium as shown in the QRG illustration.

Viral transport medium (VTM)	Recommended storage condition	
	2 °C to 8 °C	**25 °C**
Recommended VTMs[a)]	12 hours	8 hours

Viral transport medium (VTM)	Recommended storage condition	
	2 °C to 8 °C	**25 °C**

ⓘ When using viral transport medium (VTM), it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

a) Only use the following VTMs: Copan UTM™ Universal Transport Media, BD™ Universal Viral Transport, STANDARD™ Transport Medium.

Test procedure
1. Apply 3 drops of extracted sample to the specimen well of the test device.
2. Read the test result at 15-30 minutes.
⚠Do not read test results after 30 minutes. It may give false results.

Reading and interpreting results:
- A colored line appears in the top section of the result window to show that the test is working properly. This line is the control line (C). Even if the control line is faint or not uniform, the test should be considered to be performed properly. If no control line is visible the test result should be considered as invalid.
- In case of a positive result, a colored line appears in the lower section of the result window. This line is the test line of the SARS-CoV-2 antigen (T). Even if the test line is very faint or not uniform the test result should be interpreted as a positive result.

QC
A control kit including positive and negative quality control is available separately from Roche (STANDARD™ COVID-19 Ag Control, SD Biosensor).

Limitations
- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- The test should be used for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab samples.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- The immune response cannot be assessed with this test and needs other testing methods.
- The test result should not be used as a sole basis for treatment or patient management decisions, and should be considered in the context of the patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- A negative result may occur if the concentration of antigen in a sample is below the detection limit of the test or if the sample 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 a molecular assay or ELISA, if necessary for patient management.
- Positive test results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.
- Negative test results are not intended to rule in or rule out other coronavirus infection.

Specific performance data

Clinical evaluation
The sensitivity of the SARS-CoV-2 Rapid Antigen Test for rapid detection of SARS-CoV-2 antigen was established in prospective, randomized, single blinded studies conducted during the SARS-CoV-2 pandemic in Brazil and India. A total of 115 positive samples were tested using the SARS-CoV-2 Rapid Antigen Test. These samples consisted of nasopharyngeal swabs from symptomatic and asymptomatic patients. The specificity of the SARS-CoV-2 Rapid Antigen Test was tested using 311 negative samples. The sensitivity and specificity of the SARS-CoV-2 Rapid Antigen Test was compared to commercialized molecular assays.
Test sensitivity & specificity
The SARS-CoV-2 Rapid Antigen Test showed 96.52 % of sensitivity and 99.68 % of specificity.

		PCR		
		Positive	**Negative**	**Total**
SARS-CoV-2 Rapid Antigen 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 the "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 a nasopharyngeal swab sample. The LoD is 3.12 x $10^{2.2}$ $TCID_{50}$/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	1/1280-0	1/2560-0
Concen-tration[b)]	1 X $10^{5.2}$	1 X $10^{4.2}$	5 X $10^{3.2}$	2.5 X $10^{3.2}$	1.25 X $10^{3.2}$	6.25 X $10^{2.2}$	3.12 X $10^{2.2}$	1.56 X $10^{2.2}$	7.8 X $10^{1.2}$	3.9 X $10^{1.2}$
Call rate (5)[c)]	100-% (5/5)	100-% (5/5)	100-% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	0% (0/5)	0% (0/5)	0% (0/5)
Call rate (20)[d)]	NA	NA	NA	NA	NA	100% (20/2-0)	100% (20/2-0)	0% (0/20)	NA	NA
Lowest concentration with uniform positivity per parameter: 3.12 X $10^{2.2}$ $TCID_{50}$/ml										
Limit of Detection (LoD) per virus strain: 3.12 X $10^{2.2}$ $TCID_{50}$/ml										

b) in dilution tested $TCID_{50}$/ml

c) of 5 replicates

d) of 20 replicates near cut-off

2. Cross-reactivity:
There was no cross-reaction with potential cross-reactive substances except SARS coronavirus. Cross-reactivity testing with SARS-CoV-2 negative samples:

Virus/ Bacteria/ Parasite	**Strain**	**Concentration**	**Results**
SARS Coronavirus	Urbani[e)]	3.5 µg/ml	POS
MERS Coronavirus	Jeddah_1_2013[f)]	10 µg/ml	NEG

Virus/ Bacteria/ Parasite	**Strain**	**Concentration**	**Results**
Adenovirus	Type 1[g)]	3 X 10^5 $TCID_{50}$/ml	NEG
	Type 3[g)]	1.5 X 10^6 $TCID_{50}$/ml	NEG
	Type 5[g)]	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 7[g)]	1.5 X 10^6 $TCID_{50}$/ml	NEG
	Type 8[g)]	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 11[g)]	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 18[g)]	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 23[g)]	4 X 10^5 $TCID_{50}$/ml	NEG
	Type 55[g)]	4 X 10^5 $TCID_{50}$/ml	NEG
Influenza A	H1N1 Denver[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 WS/33[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 Pdm-09[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 New Caledonia[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
	H1N1 New Jersey[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
Influenza B	Nevada/03/2011[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
	B/Lee/40[h)]	2.5 X 10^4 $TCID_{50}$/ml	NEG
	B/Taiwan/2/62[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
Respiratory syncytial virus	Type A[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
Respiratory syncytial virus	Type b[h)]	3 X 10^5 $TCID_{50}$/ml	NEG
Legionella pneumophila	Bloomington-2[h)]	5 X 10^4 cells/ml	NEG
	Los Angeles-1[h)]	5 X 10^4 cells/ml	NEG
	82A3105[h)]	5 X 10^4 cells/ml	NEG
Mycobacterium tuberculosis	K[i)]	5 X 10^4 cells/ml	NEG
	Erdman[i)]	5 X 10^4 cells/ml	NEG
	HN878[i)]	5 X 10^4 cells/ml	NEG
	CDC1551[i)]	5 X 10^4 cells/ml	NEG
	H37Rv[i)]	5 X 10^4 cells/ml	NEG
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17][h)]	5 X 10^4 cells/ml	NEG
	178 [Poland 23F-16][h)]	5 X 10^4 cells/ml	NEG
	262 [CIP 104340][h)]	5 X 10^4 cells/ml	NEG
	Slovakia 14-10[h)] [29055]	5 X 10^4 cells/ml	NEG
Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130][h)]	5 X 10^4 cells/ml	NEG
Mycoplasma pneumoniae	Mutant 22[h)]	5 X 10^4 cells/ml	NEG
	FH strain of Eaton Agent [NCTC 10119][h)]	5 X 10^4 cells/ml	NEG
	M129-B7[h)]	5 X 10^4 cells/ml	NEG
Pooled human nasal wash[j)]	NA[k)]	NA	NEG
Coronavirus	229E[l)]	1 X $10^{4.5}$ cells/ml	NEG
	OC43[l)]	1 X 10^5 cells/ml	NEG
	NL63[l)]	1 X 10^4 cells/ml	NEG
MERS Coronavirus	Florida /USA-2_Saudi Arabia_2014[l)]	4 X 10^4 $TCID_{50}$/ml	NEG
Human Meta-pneumo virus 3 (Type B1)	Peru2-2002[l)]	1 X 10^5 cells/ml	NEG
Human Meta-pneumovirus 16 (Type A1)	IA10-2003[l)]	1 X 10^5 cells/ml	NEG
Parainfluenzavirus	Type 1[l)]	1 X 10^5 cells/ml	NEG
	Type 2[l)]	1 X 10^5 cells/ml	NEG
	Type 3[l)]	1 X 10^5 cells/ml	NEG
	Type 4/A[l)]	1 X 10^5 cells/ml	NEG
Rhinovirus A16	N/A[l)]	1 X 10^5 cells/ml	NEG

e) BEI / inactivated virus

f) Bionote / recombinant protein

g) Korea Bank for Pathogenic Viruses / live

h) ATCC / live virus

i) Yonsei Univ. / inactivated and filter

j) to represent diverse microbial flora in the human respiratory tract

k) Bionote / Normal pooled human nasal wash from healthy employees
SD biosensor / Normal pooled human nasal wash from healthy employees

l) Zeptomatrix / inactivated

Note: 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 on the test result from potentially interfering substances listed below. SARS-CoV-2 positive and negative samples were tested.
a) Results from interference testing with SARS-CoV-2 negative samples:

Potential interfering substance	**Concentration**	**Results**
Respiratory samples		
Mucin: bovine submaxillary gland, type I-S	100 µg/ml	NEG
Blood (human), EDTA anticoagulated	5 % (v/v)	NEG
Biotin	100 µg/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 µM	NEG
Doxycycline hyclate (Malaria)	70 µM	NEG
Quinine (Malaria)	150 µM	NEG
Lamivudine (Retroviral medication)	1 mg/ml	NEG
Ribavirin (HCV)	1 mg/ml	NEG
Daclatasvir (HCV)	1 mg/ml	NEG
Anti-inflammatory medication		
Acetaminophen	200 µM	NEG
Acetylsalicylic acid	3.7 mM	NEG
Ibuprofen	2.5 mM	NEG
Antibiotic		
Mupirocin	10 mg/ml	NEG
Tobramycin	5 µg/ml	NEG
Erythromycin	81.6 µM	NEG
Ciprofloxacin	30.2 µM	NEG

b) Results from interference testing with SARS-CoV-2 positive samples:

Potential interfering substance	**Concentration**	**Viral strain level[m)]**	**Results[n)]**
Respiratory samples			
Mucin: bovine submaxillary gland, type I-S	100 µg/ml	SARS-CoV-2 cultured virus media [o)]	POS
Blood (human) EDTA anticoagulated	5 % (v/v)		POS
Biotin	100 µg/ml		POS
Nasal sprays or drops			
Neo-Synephrine (Phenylephrine)	10 % (v/v)	SARS-CoV-2 cultured virus media [o)]	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 [o)]	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 [o)]	POS
Oseltamivir (Influenza)	10 mg/ml		POS
Artemether-lumefantrine (Malaria)	50 µM		POS
Doxycycline hyclate (Malaria)	70 µM		POS
Quinine (Malaria)	150 µM		POS
Lamivudine (Retroviral medication) 1 mg/ml	1 mg/ml		POS
Ribavirin (HCV) 1 mg/ml	1 mg/ml		POS
Daclatasvir (HCV)	1 mg/ml		POS
Anti-inflammatory medication			
Acetaminophen	200 µM	SARS-CoV-2 cultured virus media [o)]	POS
Acetylsalicylic acid	3.7 mM		POS
Ibuprofen	2.5 mM		POS
Antibiotic			
Mupirocin	10 mg/ml	SARS-CoV-2 cultured virus media [o)]	POS
Tobramycin	5 µg/ml		POS
Erythromycin	81.6 µM		POS
Ciprofloxacin	31 µM		POS

m) in multiples of LoD

n) detected X/3

o) 1/800 dilution (1.25 X $10^{3.2}$ $TCID_{50}$/ml)

4. High-dose hook effect:
SARS-CoV-2 cultured virus was spiked into sample. SARS-CoV-2 cultured virus did not show hook-effect at 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.

Symbols

REF	Reference number
LOT	Batch code
IVD	in vitro diagnostic medical device
CE	This product fulfills the requirements of the European Directive 98/79/EC
	Caution
	Consult instructions for use
Σ	Contains sufficient for <n> tests
	Use-by date
	Temperature limit
SYSTEM	Analyzers/Instruments on which reagents can be used
GTIN	Global Trade Item Number
	Do not re-use
UDI	Unique Device Identifier
	Do not use if package is damaged
	Date of manufacturing
	Manufacturer
	Keep away from sunlight
	Keep product dry

Additions, deletions or changes are indicated by a change bar in the margin.

CE

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