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 nasopharyngeal or combined nasopharyngeal/oropharyngeal samples. 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 in a cluster of pneumonia cases in 2019 and a pandemic was declared by the World Health Organization on March 11, 2020[1]. 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 targets the nucleocapsid protein to detect SARS-CoV-2. It 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 SARS-CoV-2 antigens are present in the sample. The intensity of the colored test line varies depending upon the amount of 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 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-COVID-19 antibody
- mAb anti-Chicken IgY
- mAb anti-COVID-19 antibody-gold conjugate
- Purified chicken IgY-gold conjugate

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

Warning:

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

Prevention:

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

Response:

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

For customers in the European Economic Area: Contains SVHC: octyl/nonylphenol ethoxylates. For use as part of an IVD method and under controlled conditions only – acc. to Art. 56.3 and 3.23 REACH Regulation.
- 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 buffer of 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 of all samples and materials used to perform the test as biohazard waste. Laboratory chemical and biohazard 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 moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.

Product safety labeling follows EU GHS guidance.
Contact phone: all countries: +49-621-7590
For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.
Safety data sheet available for professional user on request.

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 and buffer tube rack
- 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
- Micropipette (for preparing VTM sample)
- Personal protective equipment per local recommendations or requirements
- Biohazard container

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 (QRG, with illustrations) before performing a test.

Preparing for a test
Prior to starting the procedure, test devices and reagents must be equilibrated to operating temperature (15-30 °C / 59-86 °F).
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 immediately 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 3-4 times against the nasopharyngeal surface.
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. The sample should be tested as soon as possible after collection.
8. 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.
9. Do not use the sample if it has been frozen and thawed more than once or if the sample in VTM has been frozen and thawed more than 3 times.

Note: When collecting a combined NP/OP sample, follow steps 1-4 for collecting a NP sample with the first swab. Use a second swab to collect a OP sample. Insert the swab into the posterior pharynx and tonsillar areas. Rub the swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums. Insert both swabs into the extraction buffer tube and follow the steps 5-7 as described above.

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	– 70 °C
Recommended VTMs[a)]	12 hours	8 hours	3 months

a) Only use the following VTMs: Copan UTM™ Universal Transport Media 3 mL (REF 305C), BD™ Universal Viral Transport 3 mL (REF 220531), STANDARD™ Transport Medium 2 mL (REF 90-VTM-01).

ⓘ 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.

Preparing a sample from supplemented HBSS
In a clinical evaluation the following supplemented HBSS has been used:
HBSS 1 X 100 mL (GIBCO, REF 14170112) supplemented with FBS 0.4 mL, 5% NaHCO3 1 mL, 1M HEPES 1 mL, Penicillin (40000 U/mL) 0.5 mL, Gentamicin (4 mg/mL) 0.5 mL, Amphotericin B (1 mg/mL) 0.1 mL.

When using supplemented HBSS, the following workflow should be applied:
1. Insert the swab into 2 mL of supplemented HBSS.
2. Add 5 to 10 glass beads and vortex.
3. Transfer 200 µL into the extraction buffer using a micropipette.
4. Press the nozzle cap tightly onto the tube. Continue with step 3 as described in QRG.

Test procedure
1. Place the test device on a flat surface and apply 3 drops of extracted sample in a 90° angle 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 (SARS-CoV-2 Antigen 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 and combined nasopharyngeal/oropharyngeal 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
Clinical performance of the SARS-CoV-2 Rapid Antigen Test was evaluated using 976 upper respiratory samples in two prospective studies at two clinical centers, in Thailand and Switzerland. The patient cohorts in both countries included patients suspected of COVID-19 according to the local testing criteria. Site-specific, FDA EUA-authorized RT-PCR tests (cobas® SARS-CoV-2 in Switzerland and Allplex™ 2019-nCoV Assay in Thailand) were used as the comparator method in these studies. Particularly, the RT-PCR and antigen tests were performed from the same sample in the Thai study.

Test sensitivity & specificity
The following table correlates the performance of the SARS-CoV-2 Rapid Antigen Test in all RT-PCR-positive samples to the respective PCR comparator Ct values. The resulting overall relative sensitivity in both cohorts was 95.5 % (Ct value ≤ 30; 95 % CI: 91.8 % - 97.8 %). The overall relative specificity was 99.2 % (95 % CI: 98.2 % - 99.7 %). In the Swiss cohort, for patients for whom days post symptom onset was known, and was 0-5 days, the sensitivity was 91.1 % (95 % CI: 85.7 % - 94.9 %).

Summary of sample characteristics and performances:

	Thailand	Switzerland	Combined[b)]
N	447	529	976
Sample type	combined NP/OP	NP	N/A
PCR positive, N (%)	58 (13.0 %)	191 (36.1 %)	249 (25.5 %)
PCR negative, N (%)	389 (87.0 %)	338 (63.9 %)	727 (74.5 %)
Positive agreement, % (95 % CI), N	98.3 % (CI, 90.8 % - 100 %), 58	89.0 % (CI, 83.7 % - 93.1 %), 191	91.2 % (CI, 86.9 % - 94.4 %), 249
Ct ≤ 24, Positive agreement, % (95% CI), N	100 % (CI, 88.8 % - 100 %), 31	97.0 % (CI, 92.5 % - 99.2 %), 133	97.6 % (CI, 93.9 % - 99.3 %), 164
Ct ≤ 27, Positive agreement, % (95% CI), N	100 % (CI, 91.2 % - 100 %), 40	95.6 % (CI, 91.1 % - 98.2 %), 159	96.5 % (CI, 92.9 % - 98.6 %), 199
Ct ≤ 30, Positive agreement, % (95% CI), N	100 % (CI, 92.3 % - 100 %), 46	94.3 % (CI, 89.7 % - 97.2 %), 174	95.5 % (CI, 91.8 % - 97.8 %), 220
Ct ≤ 33, Positive agreement, % (95% CI), N	98.2 % (CI, 90.3 % - 100 %), 55	91.8 % (CI, 86.8 % - 95.3 %), 183	93.3 % (CI, 89.3 % - 96.1 %), 238
Negative agreement, % (95% CI), N	98.7 % (CI, 97.0 % - 99.6 %), 389	99.7 % (CI, 98.4 % - 100 %), 338	99.2 % (CI, 98.2 % - 99.7 %), 727

b) Data from the two studies combined and analyzed.

More clinical evaluations under different settings conducted by independent investigators can be found under www.diagnostics.roche.com, SARS-CoV-2 Rapid Antigen Test.
Test performance was better in samples with lower Ct values (indicating a higher viral load), which are more likely to be correlated with virus culture positivity than samples with higher Ct values.[2,3,4]

Analytical performance

1. 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 for direct Nasopharyngeal swab, 5 x $10^{3.2}$ $TCID_{50}$/mL for Nasopharyngeal swab stored in VTM[f)] by testing serially diluted the mock positive specimen.

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/ 128-00	1/ 256-00
Concen-tration[c)]	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)[d)]	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)[e)]	NA	NA	NA	NA	NA	100% (20/2-0)	100% (20/2-0)	0% (0/2-0)	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										

c) in dilution tested $TCID_{50}$/mL

d) of 5 replicates

e) of 20 replicates near cut-off

2. Cross-reactivity & microbial interference:
There was no cross-reaction and interference with the potential cross-reacting microorganisms listed below except SARS-CoV:
SARS Coronavirus:
Urbani (3.5 µg/mL)
MERS Coronavirus:
Florida/USA-2_Saudi Arabia_2014 (4 X 10^4 $TCID_{50}$/mL)
Human Coronavirus:
229E (1 X $10^{4.5}$ $TCID_{50}$/mL), OC43 (1 X 10^5 $TCID_{50}$/mL), NL63 (1 X 10^4 $TCID_{50}$/mL)
Influenza A:
H1N1 Denver (3 X 10^5 $TCID_{50}$/mL), H1N1 WS/33 (3 X 10^5 $TCID_{50}$/mL), H1N1 Pdm-09 (H1N1 Pdm-09), H1N1 New Caledonia (3 X 10^5 $TCID_{50}$/mL)
Influenza B:
Nevada/03/2011 (3 X 10^5 $TCID_{50}$/mL), B/Lee/40 (2.5 X 10^4 $TCID_{50}$/mL), B/Taiwan/2/62 (3 X 10^5 $TCID_{50}$/mL)
Respiratory syncytial virus:
Type A (3 X 10^5 $TCID_{50}$/mL), Type B (3 X 10^5 $TCID_{50}$/mL)
Human Metapneumovirus (hMPV):
hMPV 3 Type B1 / Peru2-2002 (1 X 10^5 $TCID_{50}$/mL), hMPV 16 Type A1 / IA10-2003 (1 X 10^5 $TCID_{50}$/mL)
Parainfluenza virus:
Type 1 (1 X 10^5 $TCID_{50}$/mL), Type 2 (1 X 10^5 $TCID_{50}$/mL), Type 3 (1 X 10^5 $TCID_{50}$/mL), Type 4A (1 X 10^5 $TCID_{50}$/mL)
Rhinovirus:
A16 (1 X 10^5 $TCID_{50}$/mL), B42 (1 X 10^4 $TCID_{50}$/mL)
Enterovirus:
68 (1 X 10^4 $TCID_{50}$/mL), (09/2014 isolate 4) (1 X 10^4 $TCID_{50}$/mL)
Adenovirus:
Type 1 (3 X 10^5 $TCID_{50}$/mL), Type 3 (1.5 X 10^6 $TCID_{50}$/mL), Type 5 (4 X 10^5 $TCID_{50}$/mL), Type 7 (1.5 X 10^6 $TCID_{50}$/mL), Type 8 (4 X 10^5 $TCID_{50}$/mL), Type 11 (4 X 10^5 $TCID_{50}$/mL), Type 18 (4 X 10^5 $TCID_{50}$/mL) ,Type 23 (4 X 10^5 $TCID_{50}$/mL), Type 55 (4 X 10^5 $TCID_{50}$/mL)
Human immunodeficiency virus lysate:
BaL (10 µg/mL)
Mycobacterium tuberculosis:
K (5 X 10^4 cells/mL), Erdman (5 X 10^4 cells/mL), HN878 (5 X 10^4 cells/mL), CDC1551 (5 X 10^4 cells/mL), H37Rv (5 X 10^4 cells/mL)
Haemophilus influenzae
NCTC 4560 (5 X 10^4 cells/mL)
Mycoplasma pneumoniae:
Mutant 22 (5 X 10^4 cells/mL), FH strain of Eaton Agent [NCTC 10119] (5 X 10^4 cells/mL), M129-B7 (5 X 10^4 cells/mL)
Streptococcus pneumonia:
4752-98 [Maryland (D1)6B-17] (5 X 10^4 cells/mL), 178 [Poland 23F-16] (5 X 10^4 cells/mL), 262 [CIP 104340] (5 X 10^4 cells/mL), Slovakia 14-10 [29055] (5 X 10^4 cells/mL)
Streptococcus pyrogens:
Typing strain T1 [NCIB 11841, SF 130] (5 X 10^4 cells/mL)
Legionella pneumophila:
Bloomington-2 (5 X 10^4 cells/mL), Los Angeles-1 (5 X 10^4 cells/mL), 82A3105 (5 X 10^4 cells/mL)
Bordetella pertussis:
NCCP 13671 (5 X 10^4 cells/mL)
Moraxella catarrhalis:
N9 (5 X 10^4 cells/mL)
Pseudomonas aeruginosa:
R. Hugh 813 (5 X 10^4 cells/mL)
Staphylococcus epidermidis:
FDA strain PCI 1200 (5 X 10^4 cells/mL)
Streptococcus salivarius
S21B [IFO 13956] (5 X 10^4 cells/mL)
Chlamydia pneumoniae:
TWAR strain TW-183 (1 X 10^5 cells/mL)
Candida albicans:
3147 (5 X 10^4 cells/mL)
Pooled human nasal wash:
N/A (N/A)

Note: Human coronavirus HKU1 and Pneumocystis jirovecii (PJP) have not been tested. There can be cross-reaction with Human coronavirus HKU1 and Pneumocystis jirovecii (PJP), even though the % identity of the nucleocapsid protein sequence of HKU1 and PJP with the nucleocapsid protein sequence of SARS-CoV-2 was 35.22 % and 16.2 % which is considered as low homology.

3. Exogenous / endogenous interference substances studies:
There was no interference for potential interfering substances listed below.
a) Exogenous factor:
Relevant medicines:
Zanamivir (Influenza) (5 mg/mL), Oseltamivir (Influenza) (10 mg/mL), Artemether-lumefantrine (Malaria) (50 µM), Doxycycline hyclate (Malaria) (70 µM), Quinine (Malaria) (150 µM), Lamivudine (Retroviral medication) (1 mg/mL), Ribavirin (HCV) (1 mg/mL), Daclatasvir (HCV) (1 mg/mL)
Anti-inflammatory medication:
Acetaminophen (200 µM), Acetylsalicylic acid (3.7 mM), Ibuprofen (2.5 mM)
Antibiotic:
Mupirocin (10 mg/mL), Tobramycin (5 µg/mL), Erythromycin (antibiotic) (81.6 µM), Ciprofloxacin (antibiotic) (31 µM)
Nasal sprays or drops:
Neo-Synephrine (Phenylephrine) (10 % (v/v)), Neo-Synephrine (Phenylephrine) (10 % (v/v)), Saline Nasal Spray (10 % (v/v)), Rhinocort (Nasal corticosteroids - Budesonide) (10 % (v/v))
Homeopathic allergy relief medicine:
Homeopathic Zicam Allergy Relief Nasal Gel (5 % (v/v)), Sodium Cromoglycate (20 mg/mL), Olopatadine Hydrochloride (10 mg/mL)
Oral anaesthetic:
Anbesol (Benzocaine 20 %), (5 % (v/v))
Throat lozenges:
Strepsils (flurbiprofen 8.75 mg) (5 % (w/v, 50 mg/mL)), Throat candy (mint) (5 % (w/v, 50 mg/mL))
Others:
Mucin: bovine submaxillary gland, type I-S (100 µg/mL), Biotin (100 µg/mL)
b) Endogenous factor:
Autoimmune disease:
Human anti-mouse antibody (802 ng/mL) (375 ng/mL) (317 ng/mL) (69 ng/mL) (727.5 ng/mL), Rheumatoid factor (3480 IU/mL)
Serum protein:
Whole blood (human), EDTA anticoagulated (10 % (w/w)), Human serum albumin (60 mg/mL)

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.

f) For VTM's described in section a), Preparing a sample from viral transport media.

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.

References

1 World Health Organization (WHO), https://www.who.int/emergencies/diseases/novel-coronavirus-2019.
2 Lavezzo E, Franchin E, Ciavarella C et al. Suppression of a SARS-CoV-2 outbreak in the Italian municipality of Vo. Nature 2020584(7821):425-429, PMID: 32604404.
3 van Beek J, Zsofia I, Boelsums T et al. From more testing to smart testing: data-guided SARS-CoV-2 testing choices, https://doi.org/10.1101/2020.10.13.20211524.
4 Jaafar R, Aherfi S, Wurtz N et al. Correlation between 3790 qPCR positives samples and positive cell cultures including 1941 SARS-CoV-2 isolates. Clin Infect Dis. 2020:1491 PMID: 32986798.

Symbols
The manufacturer uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

GTIN	Global Trade Item Number
UDI	Unique Device Identifier
SYSTEM	Systems on which reagents can be used

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

CE

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