SARS-CoV-2 Rapid Antibody Test

REF		SYSTEM
9901-NCOV-02C	40	visual reading

English
Intended use
The SARS-CoV-2 Rapid Antibody Test is a rapid chromatographic immunoassay intended for the qualitative in vitro detection of antibodies to SARS-CoV-2 in human serum, plasma or whole blood. The SARS-CoV-2 Rapid Antibody Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection.
The SARS-CoV-2 Rapid Antibody Test is intended for professional use in laboratory and point-of-care environments.

Summary
Coronaviruses are single-stranded positive-sense RNA viruses with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets and humans. They 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). The test results are for clinical reference only and cannot be used alone as a basis for confirming or excluding cases.

Test principle
The SARS-CoV-2 Rapid Antibody Test has three pre-coated lines, "C" control line, "G" and "M" test line for the device on the surface of the nitrocellulose membrane. The control line and two test lines in the result window are not visible before applying any samples. Monoclonal chicken IgY antibody is coated on the control line region and monoclonal anti-human IgG antibody and monoclonal anti-human IgM antibody are coated on the "G" and "M" test line region. And anti-chicken IgY antibody conjugated with colloidal gold particles are used as detectors for "C" control line. During the test, SARS-CoV-2 specific antibodies in the sample interact with recombinant SARS-CoV-2 protein conjugated with colloidal gold particles making antibody-antigen gold particle complex. This complex migrates on the membrane via capillary action until the "M" and "G" test line, where it will be captured by the monoclonal anti-human IgG antibody or monoclonal anti-human IgM antibody. A colored test line would be visible in the result window if SARS-CoV-2 specific antibodies are present in the sample. The intensity of the colored test line will vary depending upon the amount SARS-CoV-2 antibodies present in the sample. If SARS-CoV-2 specific antibodies are not present in the sample, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

Reagents
- Monoclonal anti-human IgM
- Monoclonal anti-human IgG
- Chicken IgY
- Monoclonal anti-SARS-CoV-2 nucleocapsid protein
- Recombinant SARS-CoV-2 nucleocapsid protein gold conjugate
- Recombinant SARS-CoV-2 spike protein gold conjugate
- Monoclonal anti-chicken IgY

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.
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 eye protection/ face protection.

Response:

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

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.
Contact phone: all countries: +49-621-7590
- 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.
- Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

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 room temperature, 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. The test must be used within 1 hour once the pouch has been opened.

Sample collection and preparation
Carefully read these instructions and also the enclosed Quick Reference Guide (with illustrations) before using the SARS-CoV-2 Rapid Antibody Test.

Serum
1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as Sodium heparin, K2-EDTA, Sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum sample of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8 °C/36-46 °F, the sample can be used for testing within 1 week after collection. Using the sample in the long-term keeping more than 1 week can cause non-specific reaction.
3. They should be brought to room temperature prior to use.

Plasma
1. Collect the venous blood into the commercially available anti-coagulant tube such as Sodium heparin, K2-EDTA, Sodium citrate by venipuncture and centrifuge blood to get plasma sample.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8 °C/36-46 °F, the sample can be used for testing within 1 week after collection. Using the sample in the long-term keeping more than 1 week can cause non-specific reaction.
3. They should be brought to room temperature prior to use.

Whole blood
- **Capillary whole blood**

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Refer to the instructions for use that come with the lancing device. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Using a capillary tube, collect the 20 µl of capillary whole blood to the black line of the capillary tube.
5. The capillary whole blood must be tested immediately after collection.

- **Venous whole blood**

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as Sodium heparin, K2-EDTA , Sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8 °C/36-46 °F, the sample can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood samples.

⚠ Use separate disposable materials for each sample in order to avoid cross-contamination which can cause erroneous results.

Materials provided
Test device (individually in a foil pouch with desiccant)
Buffer bottle
Capillary tube (20 µl)
Film (can be attached to the test device when performing outdoor testing)
Instructions for Use
Quick Reference Guide

Materials required (but not provided)
Single use disposable lancing device (e.g. Accu-Chek Safe-T-Pro Plus)
General laboratory equipment (e.g., sample transfer pipette for venous blood or alcohol wipes for the fingerstick)
Timer

Test procedure
Carefully read these instructions and also the enclosed Quick Reference Guide (with illustrations) before using the SARS-CoV-2 Rapid Antibody Test.

Preparing for a test
1. Check the expiry date at the back of the foil pouch. Do not use the test device, if expiry date has passed.
2. Open the foil pouch and remove the test device and the desiccant package.
3. Check both the test device and the desiccant in the foil pouch. 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.

Performing a test with capillary whole blood
1. Clean a fingertip by wiping with an alcohol swab.
2. Refer to the instructions for use that come with the lancing device. Squeeze the end of the fingertip and pierce with a sterile lancet.
3. Collecting of sample: Using a capillary tube, collect the 20 µl of capillary whole blood to the black line of the capillary tube.
4. Adding of sample: Apply the collected capillary whole blood to the sample well of the test device.
5. Dropping of buffer: Add 3 drops (90 µl) of buffer vertically into the sample well of the test device. Add the buffer immediately after applying the sample.
6. Reading time: Read the test result at 10-15 minutes.

⚠ Risk of incorrect results. Do not read test results after 15 minutes. It may give false results.

Performing a test with serum, plasma, or venous whole blood
1. Collecting of sample: Using a micropipette, collect the 10 µl of serum, plasma or 20 µl of venous whole blood with micropipette.
2. Adding of sample: Add the collected serum, plasma or venous whole blood to the sample well of the test device.
3. Dropping of buffer: Add 3 drops (90 µl) of buffer vertically into the sample well of the test device. Add the buffer immediately after applying the sample.
4. Reading time: Read the test result at 10-15 minutes.

⚠ Risk of incorrect results. Do not read test results after 15 minutes. It may give false results.

Understanding results
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 the control line (C).
2. Colored bands will appear in the lower section of the result window. These bands are the test lines 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.

- 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.

QC
1. Positive and negative controls are optional contents (SARS-CoV-2 Antibody Control Cat No. 99COVC20) and these controls can be provided as a means on additional QC to demonstrate a positive or negative reaction.
2. Quality controls should be treated and tested the same as patient samples.
3. It is recommended that positive and negative controls be run:
   - once for each new lot
   - once for each untrained operator
   - as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

Notification for SARS-CoV-2 Antibody Tests
1. 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.
2. 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.
3. Not for the screening of donated blood.
4. The test procedure should be conducted in ambient temperature and pressure.
5. Results of these tests should be appropriately recorded in a test report.
6. The SARS-CoV-2 Rapid Antibody Test should not be used to diagnose acute SARS-CoV-2 infection.

Limitations
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 sample 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. Neither the quantitative value nor the ratio anti-SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
5. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
6. A negative result may occur if the concentration of antibody 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 an molecular assay or ELISA.
7. Positive test results do not rule out co-infections with other pathogens.
8. Negative test results are not intended to rule out other coronavirus infection.
9. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other results.

Specific performance data

Clinical evaluation
Performance characteristics for the SARS-CoV-2 Rapid Antibody Test for rapid detection of anti-SARS-CoV-2 antibodies were established in retrospective, multi institutes, randomized, single-blinded study conducted at a trial site in Korea during the 2020 SARS-CoV-2 pandemic situation. A total of 379 retrospective samples were tested using the SARS-CoV-2 Rapid Antibody Test. These samples consisted of serum from PCR positive or negative confirmed patients. The performance of the SARS-CoV-2 Rapid Antibody Test was compared to a commercialized molecular assay. Although the SARS-CoV-2 Rapid Antibody Test allows to test for IgM and IgG separately, due to the differing inter-patient time response to the virus, any individual with positive result for the IgM or the IgG test should be read as a positive for anti-SARS-CoV-2 antibodies. The combined test result (positive for IgM and/or IgG or negative for IgM and/or IgG) was used to calculate the total test sensitivity and specificity.

• Test sensitivity
The seroconversion time of IgM and IgG antibodies varies from person to person, but it was estimated to be around 7-14 days after onset of symptoms.[1,2] The SARS-CoV-2 Rapid Antibody Test showed a sensitivity of **92.59 %** compared to PCR in samples taken 7-14 days after symptom onset in SARS-CoV-2 PCR positive patients.

7-14 days after symptom onset		**PCR**		
		Positive	**Negative**	**Total**
SARS-CoV-2 Rapid Antibody Test	Positive	50	0	50
	Negative	4	0	4
	Total	54	0	54
Sensitivity		**92.59 % (50/54, 95 % CI, 82.11 % -97.94 %)**		

The SARS-CoV-2 Rapid Antibody Test showed a sensitivity of **99.03 %** compared to PCR in samples taken > 14 days after symptom onset in SARS-CoV-2 PCR positive patients.

> 14 days after symptom onset		**PCR**		
		Positive	**Negative**	**Total**
SARS-CoV-2 Rapid Antibody Test	Positive	102	0	102
	Negative	1	0	1
	Total	103	0	103
Sensitivity		**99.03 % (102/103, 95 % CI, 94.71 % -99.98 %)**		

• Test specificity
The SARS-CoV-2 Rapid Antibody Test showed a specificity of **98.65 %** compared to PCR in samples from SARS-CoV-2 PCR negative patients.

		PCR		
		Positive	**Negative**	**Total**
SARS-CoV-2 Rapid Antibody Test	Positive	0	3	3
	Negative	0	219	219
	Total	0	222	222
Specificity		**98.65 % (219/222, 95 % CI, 96.10 %-99.72 %)**		

Analytical performance
Limit of detection: SN titer 1:40
Cross-reactivity:
No cross-reactivity for the specimen of HIV Seroconversion panel, Japanese Encephalitis positive, Zika virus positive, Chikungunya positive, Dengue IgM positive, Salmonella typhi IgM positive, Rubella IgM, CMV IgG/IgM, Tick borne encephalitis IgM positive, West Nile Virus positive, Treponema pallidum, HAV IgM positivie, HAV IgG positive, HBV Ab positive, HCV Ab positive, Influenza vaccine positive, Leishmania positive, Brucella IgM positive, Chagas positive, Toxoplasma positive, Filariasis positive, RSV positive, Haemophilis Influenza positive, Mycoplasma pneumonia IgM positive, Mycoplasma pneumonia IgG positive, Influenza A IgM positive, Influenza B IgM positive, Influenza A and B IgG+IgM positive, Tuberculosis positive, non-SARS-CoV of MERS CoV or coronaviruses HKU1, NL63, OC43 and 229E. But, the SARS-CoV-2 Rapid Antibody Test may cross-react with antibody against SARS-CoV.
Additional cross-reactivity test results:
In a separate evaluation, 18 samples from a cohort with common cold were tested with the SARS-CoV-2 Rapid Antibody Test for potential cross-reactivity. The samples were obtained before December 2019. All sample results were negative.
Interference study:
All tested interfering materials do not affect sensitivity and specificity of the SARS-CoV-2 Rapid Antibody Test (test concentrations according to CLSI EP07-A2).[3] The SARS-CoV-2 Rapid Antibody Test was not affected by interfering materials at the following concentrations:

Interfering substance	Interfering level	Interfering substance	Interfering level
Zanamivir (Influenza)	5 mg/mL	Oseltamivir (Influenza)	10 mg/mL
Artemether-lumefantrine (Malaria drug)	50 µM	Doxycycline hyclate (Malaria drug)	70 µM
Quinine (Malaria drug)	150 µM	Lamivudine (Retroviral medication)	1 mg/mL
Ribavirin (HCV drug)	1 mg/mL	Daclatasvir (HCV drug)	1 mg/mL
Tenofovir (HIV drug)	1 mg/mL	Metronidazole	701 µmol/L
Tinidazole	1 mg/mL	Niclosamide	1mg/mL
Praziquantel	1 mg/mL	Rifampicin	80 µmol/L
Isoniazid	300 µmol/L	Acetaminophen	200 µM
Acetylsalicylic acid	4 mM	Ibuprofen	3 mM
L-ascorbic acid	350 µM	Erythromycin (antibiotic)	82 µM
Ciprofloxacin (antibiotic)	31 µM	Kanamycin	130 µM
Ampicillin	160 µM	Caffeine	310 µM
Ethanol	90 mM	Biotin	1200 ng/mL
Triglycerides	90 mM	Cholesterol	100 µg/mL
Bilirubin (Unconjugated)	15 ng/mL	Bilirubin (Conjugated)	5 ng/mL
Hemoglobin	200 mg/mL	EDTA	3.4 µmol/L
Heparin	3000 U/L	Sodium citrate	3.8 % (w/v)
Human anti-mouse antibody	titer 802	Anti-Nuclear Antibody (ANA)	Commercial kit titer > 1:1280
Rheumatoid factor	3480 IU/mL	Elevated IgG	1.794 mg/dL
Elevated IgM	229 mg/dL	Human antibodies to E.coli	Commercial kit O.D 4.17
Human serum albumin	60 mg/mL	Serum total proteins	120 mg/mL

There was no interference with serum of pregnant women.

Matrix equivalency:
The matrix and anticoagulants do not affect the detection of SARS-CoV-2 IgG and IgM in contrived specimens of serum, plasma (Sodium heparin, K2-EDTA, Sodium citrate), venous whole blood (Sodium heparin, K2-EDTA, Sodium citrate), and capillary whole blood (collected in K2-EDTA-treated tubes).

References

1 Guo L et al. Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19). Clinical Infectious Disease. 2020.
2 Zhao J et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clinical Infectious Disease. 2020.
3 CLSI EP07-A2 / Vol. 25 No. 27, Interference Testing in Clinical Chemistry.

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