SARS-CoV-2 Rapid Antibody Test 2.0

REF		SYSTEM
9901-NCOV-03C	25	visual reading

English

Intended use

The SARS-CoV-2 Rapid Antibody Test 2.0 is a rapid chromatographic immunoassay intended for the qualitative in vitro detection of IgG antibodies to SARS-CoV-2 spike protein present in human serum, plasma or whole blood. The test is intended for use as an aid in the determination of an adaptive immune reaction to SARS-CoV-2, indicating recent or prior infection or vaccination. The SARS-CoV-2 Rapid Antibody Test 2.0 is intended for professional use in laboratory and near-patient testing environments. Not for self-testing.

Summary

Upon infection with SARS-CoV-2, the host mounts an immune response against the virus, typically including production of specific antibodies against viral antigens. There is significant inter-individual difference in the levels and chronological appearance of antibodies in COVID-19 patients, but median seroconversion has been observed at approximately 2 weeks (at day 12-14 for IgG).[1,2,3]

Antibody lateral flow assay can play an important role in understanding viral epidemiology in the general population and identifying individuals who are apparently naive and thus presumably susceptible to the virus.

Test principle

The SARS-CoV-2 Rapid Antibody Test 2.0 has 2 pre-coated lines, "C" control line and "T" test line for the device on the surface of the nitrocellulose membrane. The control line and test line in the result window are not visible before applying any specimens. Chicken IgY is coated on the control line region and mono-clonal anti-human IgG antibody is coated on the "T" test line region. Anti-chicken IgY antibodies conjugated with colloidal gold particles are used as detectors for "C" control line. During the test, SARS-CoV-2 spike protein specific antibodies in the specimen interact with recombinant SARS-CoV-2 spike protein conjugated with colloidal gold particles making antibody-antigen gold particles complex. This complex migrates on the membrane via capillary action until the "T" test line, where it will be captured by the monoclonal anti-human IgG antibody. A colored test line would be visible in the result window if SARS-CoV-2 spike protein specific antibodies are present in the specimen. If SARS-CoV-2 spike protein specific antibodies are not present in the specimen, 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 buffer of the control line is working.

Reagents

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

Precautions and warnings

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.

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

Warning

H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H360D	May damage the unborn child.
H412	Harmful to aquatic life with long lasting effects.

Prevention:

P201	Obtain special instructions before use.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313	IF exposed or concerned: Get medical advice/attention.

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.

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 2.0.

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 an Easy sample collector, collect the 20 µL of capillary whole blood to completely fill the collector tip.
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 5 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
- Easy sample collector (20 µL)
- 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 2.0.

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 from the easy sample collector bag, collect 20 µL of capillary whole blood.
4. Adding of sample: Apply the collected capillary whole blood to the specimen well of the test device by placing the bottom end of the capillary tube on the specimen well and pressing down lightly.
5. Dropping of buffer: Add 3 drops (90 µL) from the buffer bottle vertically into the specimen well of the test device. Do not touch the surface of the specimen well with the tip of the bottle.
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 line will appear in the top section of the result window to show that the test is working properly. This line is the control line (C).
2. If the IgG antibody test is positive, a colored line will appear in the lower section of the result window. This line is the test line of IgG (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.

- 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 available separately (SARS-CoV-2 IgG Antibody Control, Cat. No. 99COVC40) 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.

Limitations

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
2. The test procedure should be conducted in ambient temperature and pressure.
3. Results of these tests should be appropriately recorded in a test report.
4. This test detects the presence of SARS-CoV-2 IgG in the sample.
5. This test is a qualitative IgG test, hence it does NOT give a quantitative IgG value.
6. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.
7. The performance of this test has been established only for 15 or more days after symptom onset. SARS-CoV-2 IgG antibodies may be below detectable levels at less than 15 days after symptom onset.
8. This test should not be used to diagnose acute SARS-CoV-2 infection.
9. 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. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other results.
10. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
11. Positive results may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for an alternative serology test to confirm an adaptive immune response.
12. Positive test results do not rule out co-infections with other pathogens.
13. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
14. 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.
15. Negative test results are not intended to rule out other coronavirus infections.
16. A negative result may occur if the concentration of antibody in a sample is below the detection limit of the test, or if the antibodies are not present during the stage of disease in which a sample is collected, or if the virus has undergone amino acid mutation(s) in the epitope recognized by the antibody utilized in the test, or if the sample was collected or transported improperly. Also, certain patients with confirmed infection do not develop SARS-CoV-2 antibodies. 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.
17. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
18. Not for the screening of donated blood.

Clinical evaluation

Post-infection antibody detection

Performance characteristics for the SARS-CoV-2 Rapid Antibody Test 2.0 for rapid detection of anti-SARS-CoV-2 antibodies were established in a retrospective, single center, randomized, single-blinded study conducted at a trial site in South-Korea during the SARS-CoV-2 pandemic. A total of 99 retrospective samples were tested using the SARS-CoV-2 Rapid Antibody Test 2.0. These samples consisted of serum from PCR-confirmed positive (24 patients) or negative (75 patients) patients. The absence of anti-SARS-CoV-2 antibodies in the PCR-negative patients was confirmed using 2 commercialized anti-SARS-CoV-2 antibody tests. The performance of the SARS-CoV-2 Rapid Antibody Test 2.0 was compared to a commercialized RT-PCR.

The SARS-CoV-2 Rapid Antibody Test 2.0 showed a PPA of 95.83 % compared to PCR in samples taken 15 or more days after symptom onset in SARS-CoV-2 PCR-positive patients. The SARS-CoV-2 Rapid Antibody Test 2.0 showed a NPA of 100 % compared to PCR in samples from SARS-CoV-2 PCR-negative patients taken on the same day as the PCR sample.

		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Rapid Antibody Test 2.0	Positive	23	0	23
	Negative	1	75	76
Total		24	75	99

All samples for SARS-CoV-2 IgG measurement in PCR-positive patients were collected at 15 or more days after symptom onset.

Positive percent agreement: 95.83 % (23/24), (95 % CI: 78.88 % - 99.89 %)

Negative percent agreement: 100 % (75/75), (95 % CI: 95.20 % - 100 %)

Post-vaccine antibody detection

This was a retrospective, single-center, single-blinded study conducted at a trial site in South-Korea during the SARS-CoV-2 pandemic. The presence of anti-SARS-CoV-2 antibodies was measured using the SARS-CoV-2 Rapid Antibody Test 2.0 in paired samples from the same patient before vaccination and after a first and a second SARS-CoV-2 vaccination. Only subjects with no detectable antibodies before vaccination were included. In a further group of subjects, the presence of anti-SARS-CoV-2 antibodies was measured using the SARS-CoV-2 Rapid Antibody Test 2.0 after a booster SARS-CoV-2 vaccination.
The SARS-CoV-2 Rapid Antibody Test 2.0 detected anti-SARS-CoV-2 antibodies in 91.25 % of the subjects after a first, a second or a booster SARS-CoV-2 vaccination.

	Number of samples around 4 weeks after 1st vaccination* Cohort 1	Number of samples 3-4 weeks after 2nd vaccination Cohort 2	Number of samples after booster vaccination Cohort 3	Total
ChAdOx1 (Astra-Zeneca)	13/20	20/20	5/5	38/45
BNT162b2 (Pfizer/ BioNTech)	19/20	20/20	5/5	44/45
mRNA-1273 (Moderna)	20/20	20/20	N/A	40/40
Ad26.COV2.S (Johnson & Johnson)	10/15	14/15	N/A	24/30
Total	75	75	10	160
PPA	82.67 % (62/75) 95 % CI: 72.19 - 90.43 %	98.67 % (74/75) 95 % CI: 92.79 - 99.97 %	100 % (10/10) 95 % CI: 69.15 - 100 %	91.25 % (146/160) 95 % CI: 85.75 - 95.13 %

* After first vaccination, the samples in which antibody presence was assessed using the SARS-CoV-2 Rapid Antibody Test 2.0 were collected ≥ 28 days after vaccination in 35 (46 %) subjects, 25 days after vaccination in 20 (27 %) subjects and between 20 and 21 days after vaccination in 20 (27 %) subjects.

Analytical performance

Limit of detection:

Type	Specimen Type	Concentration at the detection limit
Humanized IgG anti-COVID-19 antibody	EDTA Plasma Serum Whole blood	23 ng/mL
Commercial COVID-19 IgG positive specimen TRINA BIOREACTIVES 21368	Serum	SN Titer 1:2.5
Working Standard (NIBSC Anti-SARS-CoV-2 Antibody Diagnostic Calibrant) 20/162	Plasma	Unit: 7.81 IU/mL
WHO Reference Panel (First WHO International Reference Panel for anti-SARS-CoV-2 Immunoglobulin 20/268) 20/148	Plasma	NeutAb: 6.6 IU/mL Anti-RBD IgG: 6.4 BAU/mL Anti-S1 IgG: 7.7 BAU/mL Anti-Spike IgG: 7.5 BAU/mL Anti-N IgG: 9.2 BAU/mL

Cross-reactivity:

No cross-reactivity was observed for the following IgG and IgM specimens:
Anti-Influenza A IgG, Anti-Influenza B IgG, Anti-HCV IgG (Hepatitis C Virus), Anti-HBV IgG, Anti-Haemophilus Influenzae IgG, Anti-229E (Alpha coronavirus) IgG, Anti-NL63 (Alpha coronavirus) IgG, Anti-OC43 (Beta coronavirus) IgG, Anti-HKU1 (Beta coronavirus) IgG, ANA IgG, Anti-Respiratory syncytial virus IgG, Anti-HIV IgG;
Anti-Influenza A IgM, Anti-Influenza B IgM, Anti-HCV IgM (Hepatitis C Virus), Anti-HBV IgM, Anti-Haemophilus Influenzae IgM, Anti-229E (Alpha coronavirus) IgM, Anti-NL63 (Alpha coronavirus) IgM, Anti-OC43 (Beta coronavirus) IgM, Anti-HKU1 (Beta coronavirus) IgM, ANA IgM, Anti-Respiratory syncytial virus IgM, Anti-HIV IgM.

The SARS-CoV-2 Rapid Antibody Test 2.0 may cross-react with antibodies against SARS-CoV.

High-dose hook effect:

Pooled serum of vaccinated donors was used. There was no hook effect up to the stock titer of 4526 BAU/mL for pooled serum of donors vaccinated with Moderna or 19442 BAU/mL for pooled serum of donors vaccinated with Pfizer.

Interference study:

All tested interfering materials do not affect sensitivity and specificity of the SARS-CoV-2 Rapid Antibody Test 2.0 (test concentrations according to CLSI EP07-A2).[4] The SARS-CoV-2 Rapid Antibody Test 2.0 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 µM
Tinidazole	1 mg/mL	Niclosamide	1 mg/mL
Praziquantel	1 mg/mL	Rifampicin	80 µM
Isoniazid	300 µM	Acetaminophen	200 µM
Acetylsalicylic acid	4 mM	Ibuprofen	3 mM
L-ascorbic acid	350 µM	Erythromycin	82 µM
Ciprofloxacin	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 µM
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	1794 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

Matrix equivalency:

The matrix and anticoagulants do not affect the detection of SARS-CoV-2 IgG 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 tubes without anti-coagulants).

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 Long Q-X, Liu B-Z, Deng H-J, et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nat Med 2020;26:845-848.

2 Lou B, Li T-D, Zheng S-F, et al. Serology characteristics of SARS-CoV-2 infection after exposure and post-symptom onset. Eur Respir J 2020;56:2000763.

3 Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients with novel coronavirus disease 2019. Clin Infect Dis 2020;71:2027-2034.

4 CLSI EP07-A2 / Vol. 25 No. 27, Interference Testing in Clinical Chemistry.

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

Distributor

CE

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