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SARS-CoV-2 Rapid Antibody Test

Point-of-care testing for the qualitative detection of SARS-CoV-2 antibodies

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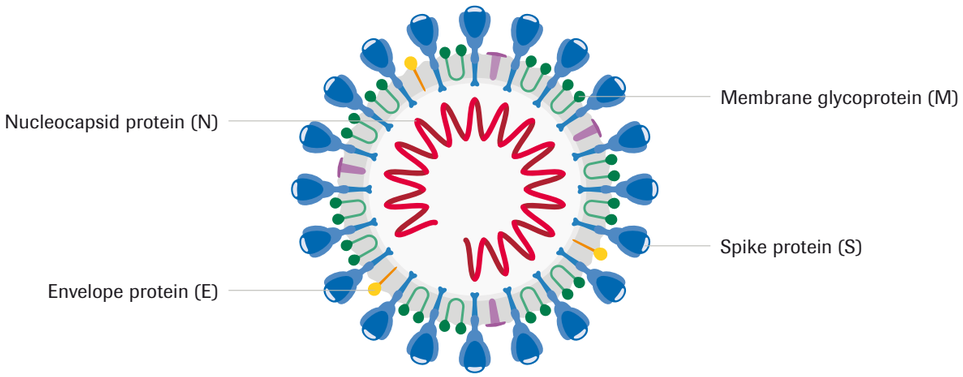
The SARS-CoV-2 Rapid Antibody Test is a CE marked lateral flow rapid chromatographic immunoassay intended for qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma or whole blood. Similar to laboratory instruments, it detects antibodies that an exposed host has produced in response to exposure to the virus by providing a qualitative result of "yes" or "no" with regards to the presence of IgG and/or IgM antibodies.

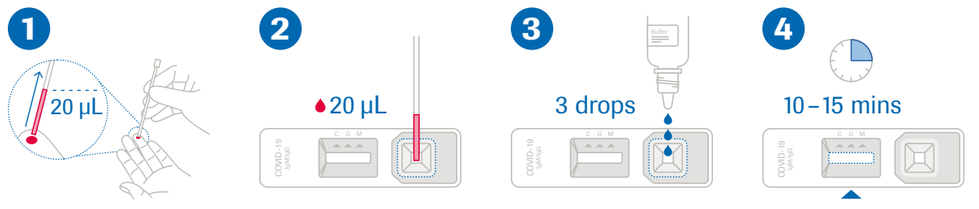
The SARS-CoV-2 Rapid Antibody Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating prior infection. It can be performed with a small capillary blood sample (20 µL) from the fingertip or a venous blood vial. This is equivalent to about one or two drops of blood.

Structure of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)[1-3]



Performing a test with a blood sample from the fingertip

Three simple steps and the result will be ready in 10 – 15 minutes



Take finger stick blood
Using a capillary tube, collect 20 µL of capillary whole blood as indicated by the black line of the capillary tube.

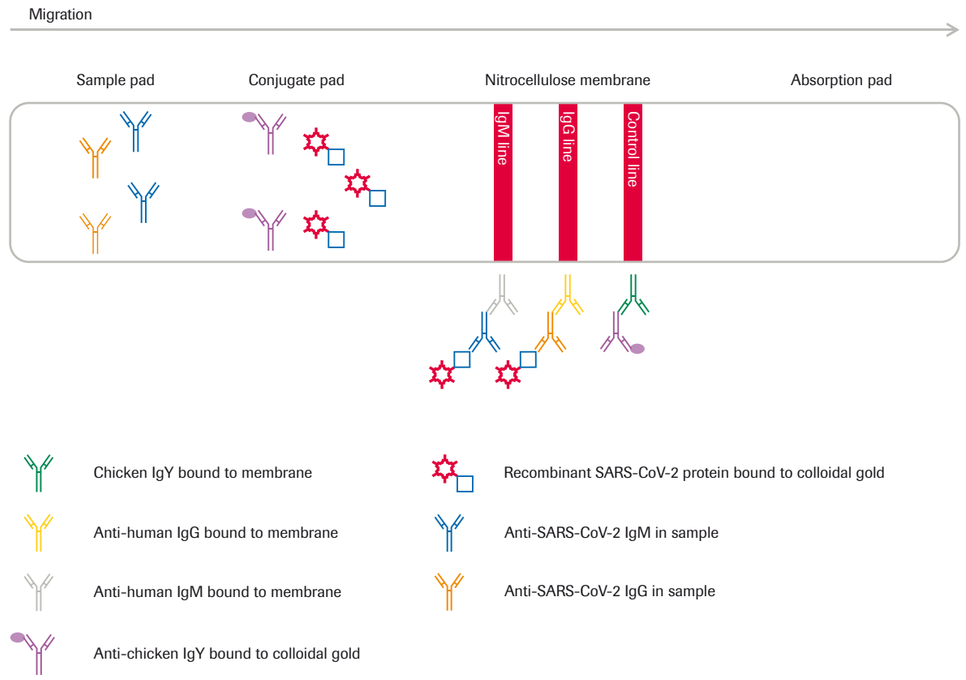
Apply blood to well
Add the collected capillary whole blood to the specimen well of the test device.

Add buffer solution
Add 3 drops (90 µL) of buffer vertically into the specimen well of the test device.

Read the result

Do not read test result after 15 minutes. It may give a false result.

Test principle



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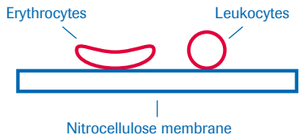
Test procedure

Following the application of a whole blood sample, the test result will be available after 10 – 15 minutes. During this period a sequence of 4 steps is carried out to produce a test result.

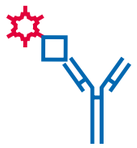
Step 1

A special fleece is used to separate the solid components of the blood from the liquid phase, the plasma. The remaining plasma and buffer solution can flow through the membrane of the test strip.



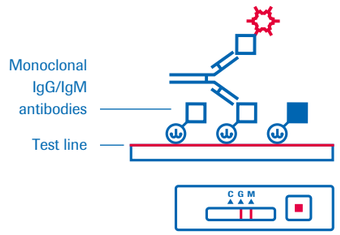
Step 2

SARS-CoV-2 IgM and IgG antibodies in the sample interact with antigens carrying gold particles. The result: an antibody-antigen-gold-particle complex.



Step 3

The complexes formed migrate to the “M” and “G” test lines. If IgM and/or IgG antibodies are present in the sample, the corresponding complexes bind specifically to the corresponding test line. The gold particles provide the visible coloration of the test line.

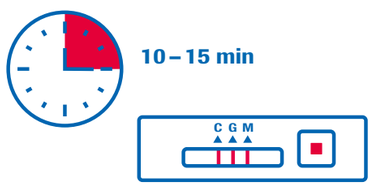


Step 4

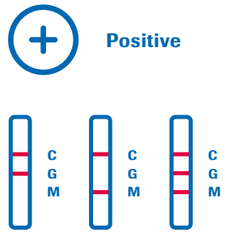
The third line that appears is the control line. It is used to control the process. It appears when the test procedure has been properly performed and the test reagents of the control line are working.

After the whole process is completed, the test result can be read at 10 to 15 minutes. It is positive if the control line and at least one test line “M” or “G” has formed.

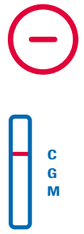
Do not read the test before 10 minutes or after 15 minutes as this may result in false results.



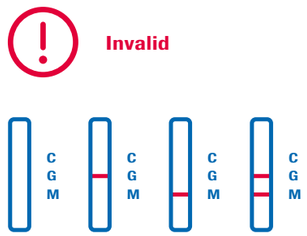
Results interpretation



Positive
Individual has had an adaptive immune response to SARS-CoV-2, indicating prior infection. Confirmation of positive results should be considered using additional laboratory tests, and considering the patient’s recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, if necessary for patient management.



Negative
No antibodies to SARS-CoV-2 detected. Negative results do not preclude prior SARS-CoV-2 infection. Antibody titers in the blood can be present but at a lower concentration than the analytical detection limit. The individual may also not have developed antibodies, especially early after infection or due to insufficient or suppressed immune system.



Invalid
Result not valid. Do not use this test result and consider retesting.

If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. 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 result.

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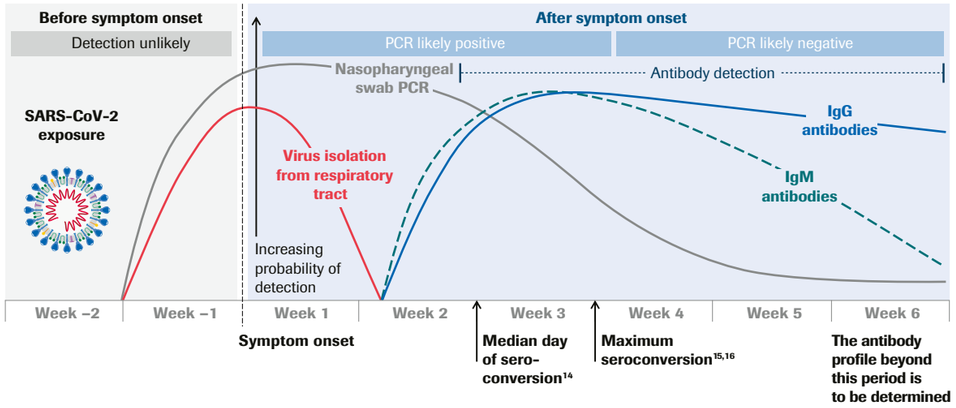
What can a SARS-CoV-2 Antibody test tell us?
An antibody test determines whether antibodies to SARS-CoV-2, which might include neutralising antibodies, are present in the blood of an individual. This means that an individual has been exposed to the virus and hence reacted with an immune response by creating antibodies.[4,5]

Individuals infected with coronaviruses (incl. the new coronavirus SARS-CoV-2) typically generate antibodies, which can help to neutralise and might thus be associated with some level of protection for a period of months to years.[6-9] A neutralising antibody response has been demonstrated in SARS-CoV-2 infected patients from day 10 – 15 after the onset of the disease and remained thereafter.[10] However, the full time period for which antibodies remain is not yet known[10] and the levels of neutralising antibodies in COVID-19 patients are variable. Some data shows that 20 – 30 % of patients failed to develop high antibody titers.[11,12]

Estimated course of markers in SARS-CoV-2 Infection[13]



What is current evidence on the correlation of a positive antibody response and immunity?
According to the WHO, as of 26 June 2020, no study has evaluated whether the presence of antibodies to SARS-CoV-2 confers immunity to subsequent infection by this virus in humans.[17] Thus it cannot be said with certainty that the detected antibodies are neutralising in nature and therefore offer immunity. The exact time period for which a SARS-CoV-2 infected individual, who has developed neutralising antibodies, remains immune to a new infection has not been determined yet.[17]

ASSAY CHARACTERISTICS[18]

Test description	Rapid chromatographic immunoassay intended for qualitative detection of IgM and IgG antibodies to SARS-CoV-2.
Test type	Qualitative
Sample material	**Whole Blood** 20 µL of capillary blood collected aseptically with a capillary tube from the fingertip or a sodium heparin, K_2-EDTA or sodium citrate tube. **Plasma** 10 µL in Sodium heparin, K_2-EDTA, Sodium citrate. **Serum** Whole blood in plain tube, NOT containing anti-coagulants such as Sodium heparin, K_2-EDTA, Sodium citrate. Sample needs to settle for 30 minutes for blood coagulation and then to be centrifuged to get serum sample of supernatant.
Target antigen	Nucleocapsid (N) Spike (S)
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
Reading time	10 – 15 minutes
Storage temperature	2 – 30 °C / 36 – 86 °F
Shelf life	Up to 24 months (as of October 2020)
Stability (test, opened pouch)	1 hour once the pouch has been opened
Materials required	**Included in the kit** Test device Buffer bottle Capillary tube (20 µL) Film (for outdoor testing) **Not included in the kit** Lancing device General laboratory equipment (e.g. wipes)
Controls	Positive and negative controls are optional components (STANDARD COVID-19 IgM/IgG Control Cat No. 10COVC20). It is recommended that positive and negative controls be run once for each new lot, once for each untrained operator, and in accordance with local, county and government regulations or accreditation requirements.
Approved for donated blood	No

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CLINICAL SENSITIVITY[18]

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 %)**		

≥14 days after symptom onset

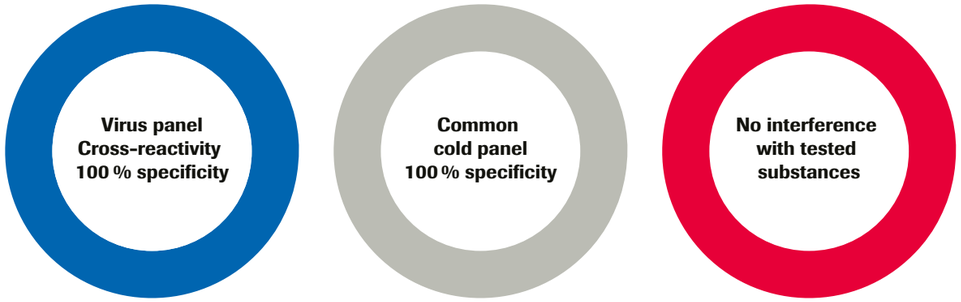
		PCR		
		Positive	**Negative**	**Total**
SARS-CoV-2 Rapid Antibody Test	Positive	102	0	102
	Negative	1	0	1
	Total	103	0	103
Sensitivity		**99.03 %** **(102/103, 95 % CI, 94.71 – 99.98 %)**		

CLINICAL SPECIFICITY

		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 %)**		

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.

Analytical performance[18]



No cross-reactivity for 30 human-pathogenic specimens, including influenza A and B IgM and IgG were found. Cross-reactivity for SARS-CoV-1, non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E has not been tested.

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.

In a study to evaluate 27 potential interfering substances neither endogenous (e.g. pregnancy) nor exogenous (e.g. anti-inflammatory or anti-malaria medications, antibiotics, anticoagulants) factors that were tested affected sensitivity and specificity of the SARS-CoV-2 Rapid Antibody Test.

Method Comparison and Matrix Equivalency[19]

SARS-CoV-2 Rapid AB Test vs. Elecsys® Anti-SARS-CoV-2

EDTA PLASMA: RAPID AB VS. ELECSYS®

	Elecsys® positive	**Elecsys® negative**
Rapid AB positive	96	10
Rapid AB negative	4	265

PPA: 96.0 %
NPA: 96.4 %

RAPID AB: WHOLE BLOOD VS. EDTA PLASMA

	Plasma positive	**Plasma negative**
Whole Blood positive	104	1
Whole Blood negative	2	268

PPA: 96.6 %
NPA: 98.1 %
OPA: 99.2 %

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Ordering Information

Test	Quantity per kit	Ref No	Cat No
SARS-CoV-2 Rapid Antibody Test English version	40	09216448190	99COV70GM-EN01

Controls	Quantity per kit	Ref No	Cat No
STANDARD™ COVID-19 IgM/IgG Control International version	10 IgM Positive 10 IgG Positive 10 IgM/IgG Negative	9319263190	10COVC20

Lancing devices	Quantity per kit	Ref No
Accu-Chek Safe T Pro Uno EU-Version	200	05888662150
Accu-Chek Safe T Pro Plus EU version	200	03603539150

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