SARS-CoV-2 Rapid Antibody Test

Put the answers in your hands

The world is looking for rapid answers.

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is an enveloped, single-stranded RNA virus of the family Coronaviridae.[1]

COVID-19 has evolved quickly to a global health threat. Within six months, the world has changed. Millions of lives have been directly affected, economies have shut down, global travel has ceased and the future has become more uncertain.

When our greatest threat is uncertainty, our greatest asset is knowledge.

Covid-19: What we know.[2-8]

Transmission
Person-to-person via respiratory secretions and aerosols

Incubation
Range of 2 – 14 days
(median – 5 days)

Main symptoms
Fever, respiratory symptoms, abdominal pain, diarrhea, loss of smell/taste, vomiting, headache, myalgia

Clinical presentation
Asymptomatic infection, ranges from mild illness to pneumonia or fatal disease

Clinical progression
Can cause severe respiratory disease, especially in 65+ and multi-morbid patients

Case fatality rate*
Reported mortality rates vary from 0.8 – 15.5 % (average 6.5 %)

** CFR is unreliable during an outbreak*

Providing answers in times of need.

If we look at the disease progression, there are two main phases, the first one is called the viral response phase. In this phase, the virus itself causes the disease symptoms by infecting cells and lysing those cells during proliferation. The second phase moves into the host inflammatory response phase, which is characterized by the body responding to the infection. In roughly 5 % of the cases it can lead to hyperinflammation. This is in the end what causes the severe hyperinflammation which causes the severe symptoms and can eventually lead to death.[2-5]

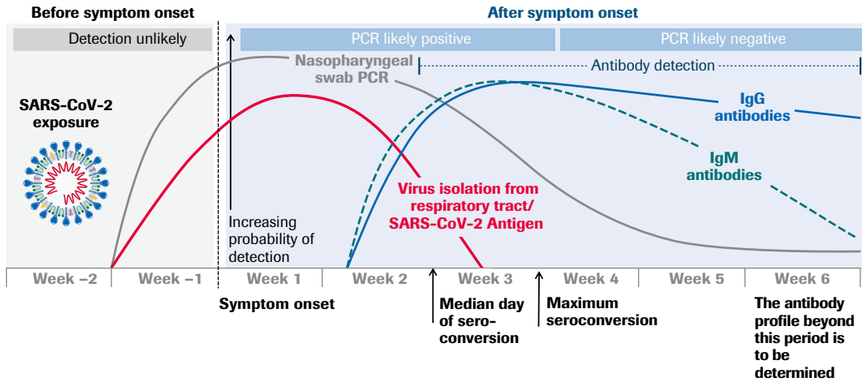
Markers of SARS-CoV-2 infection[9,10]
In the early phase of ongoing infectivity, the markers are the viral ribonucleic acid or RNA, which can be detected by PCR tests, and antigens of the virus which can be detected by serological or oropharyngeal tests. These markers disappear over time, and the immune reaction starts, marked by the appearance of both IgG and IgM antibodies.

Identifying antibodies with Serological tests[7,11]
Serological assays and tests, which detect antibodies against SARS-CoV-2, can help identify individuals who were previously infected by the virus, and help to assess the extent of exposure within a population. Information gathered through these tests can help in deciding on the application, enforcement or the relaxation of containment measures.

The IgG and IgM response detection[11,13]
All tests look for one or both subgroup of antibodies to SARS-CoV-2, the virus that causes COVID-19: IgM and IgG. Unlike in other diseases data so far show a high variability of IgM and IgG appearance. They often start both being detectable within the first week after symptom onset and maximum seroconversion occurs after 2 to 3 weeks.[9]

Antibody tests must provide good **sensitivity** to allow detection of also low antibody titers. They must also be highly **specific** to SARS-CoV-2 to avoid false positives and the erroneous assumption of convalescence and putative immunity.[10]

Estimated course of markers in SARS-CoV-2 infection[11]



Rapid testing. Rapid answers.

The global impact of the COVID-19 pandemic continues to rise and pushes healthcare workers, hospitals and clinics to the limit. Decentralized testing at the point of care can play a key role to provide healthcare professionals with the tools they need to scale up testing for patient management and to better understand characteristics of the SARS-CoV-2 virus. Trustworthy and decentralized testing is going to play an essential part in this next phase of the pandemic response.

The Roche SARS-CoV-2 Rapid Antibody Test is a rapid chromatographic immunoassay intended for qualitative detection of IgG and IgM antibodies specific to SARS-CoV-2 in human serum, plasma and whole blood.[14]

Reliable detection of IgG and IgM antibodies specific to SARS-CoV-2
Intended for use by healthcare professionals, the test has been designed to deliver reliable performance for rapid antibody testing in near patient settings such as clinics and physician offices. At times when the market is flooded with rapid tests of varying performances, the level of accuracy of the Roche SARS-CoV-2 Rapid Antibody Test gives you the confidence you need.

Fast results in 10 – 15 minutes
Fast results in just 10 – 15 minutes enable testing and decision-making on the spot. Therefore, a follow up visit to discuss results is not needed.

Easy handling
One finger prick is all it takes. In settings where access to central lab testing is limited or an alternative to a venous blood draw is needed, the SARS-CoV-2 Rapid Antibody test can be a vital tool. With the ready to use test kit there is no need for any special instruments, and as no refrigeration of the kit is needed, it can be stored easily with a long shelf life of up to 24 months.[14]

- **Reliable detection of IgG and IgM antibodies specific to SARS-CoV-2**
- **Fast results in 10 – 15 minutes**
- **Easy handling**
- **Hassle-free capillary sample from the fingertip (20 µL)**
- **Ready to use test kit without the need for instruments***
- **Long shelf-life of up to 24 months without refrigeration**

*Lancets are not included in test kit and need to be ordered separately.

Delivering reliable results at point of care

Specify
98.65 %

Sensitivity
99.03 %
>14 days after symptom onset.

The Roche SARS-CoV-2 Rapid Antibody Test shows high correlation with the Elecsys® Anti-SARS-CoV-2 and provides confidence where lab access is not available.[15]

EDTA PLASMA: RAPID AB VS. ELECSYS®

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

PPA (Positive Percent Agreement): 96.0 %, NPA (Negative Percent Agreement): 96.4 %

RAPID AB: WHOLE BLOOD VS. EDTA PLASMA

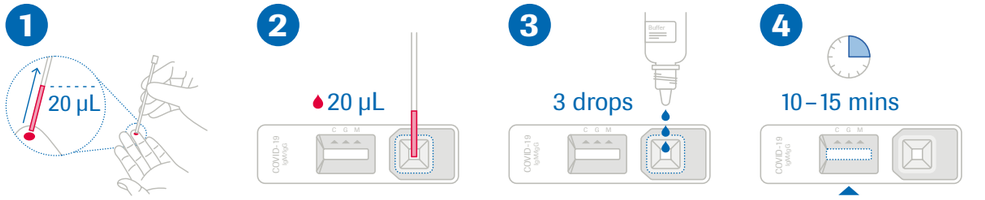
	Plasma positive	Plasma negative
Whole Blood positive	104	1
Whole Blood negative	2	268

PPA: 98.1 %, NPA: 99.63 %, OPA (Overall Percent Agreement): 99.2 %

Putting the answer in your hands.

Performing the Roche SARS-CoV-2 Rapid Antibody Test is intuitive and can be implemented in existing processes without the need of additional resources. Since this finger prick testing is less invasive, can be more comfortable compared to regular testing with frequent venous blood draws. No special training is needed. It only takes four simple steps to get the result within 10 – 15 minutes.[14]

The handling of finger-prick testing



Obtain blood from the finger

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.

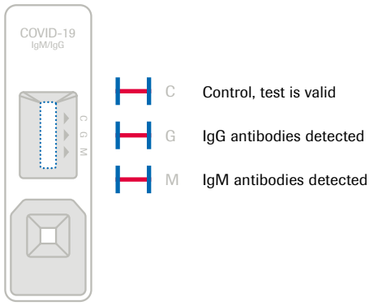
Read the result

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

When time is of the essence, one finger prick is all it takes.

Understanding the answers in your hands.

Reading and understanding results of the Roche SARS-CoV-2 Rapid Antibody Test is simple. A colored line indicates the detection of IgG and IgM antibodies specific to SARS-CoV-2. The control line determines whether the test is valid. You can read the result in just 10 – 15 minutes.[14]

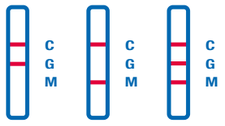


C Control, test is valid

G IgG antibodies detected

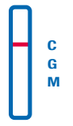
M IgM antibodies detected

Positive



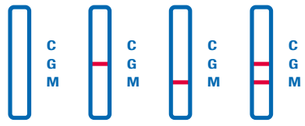
3 different positive results are possible. All showing an adaptive immune response to SARS-CoV-2, indicating prior infection.

Negative



No antibodies to SARS-CoV-2 detected.

Invalid



Result not valid. Repeat the test.

Product Information sheet

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

*Not included in the kit, but recommended by Roche.

References

1 https://www.who.int/health-topics/coronavirus#tab=tab_3.
2 Nanshan Chen*, Min Zhou*, Xuan Dong*, Jieming Qu*, Fengyun Gong, Yang Han, Yang Qiu, Jingli Wang, Yi (v1.0). Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *Lancet. 395,* 507-13.
3 Holshue et al-Holshue, M.L. et al. (2020). First Case of 2019 Novel Coronavirus in the United States. N (v1.0). *N Engl J Med. 382,* 929-36.
4 Huang, C., Wang, Y., Li, X. et al. (-Huang, C., Wang, Y., Li, X. et al. (2020). Clinical features of (v1.0) patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet 395,* 497-506.
5 Wang, D., Hu, B., Hu, C. et al.-Wang, D., Hu, B., Hu, C. et al. (2020). Clinical characteristics of (v1.0) 138 Hospitalized Patients With 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA 323,* 1061-1069.
6 Centers for Disease Control and Prevention. Coronavirus Disease 2019 (COVID-19)–Evaluating and Reporting Persons Under Investigation (PUI). https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html. Accessed March 4, 2020.
7 Joseph T Wu*, Kathy Leung*, Gabriel M Leung-Wu J.T. et al (2020). Nowcasting and forecasting the poten (v1.0) domestic and international spread of the 2019-nCoV outbreak originating in Wuhan, China: a modelling study. *Lancet 395,* 689-97.
8 COVID-19 #CoronaVirus Data-Pack from Information is Beautiful. https://informationisbeautiful.net/visualizations/covid-19-coronavirus-infographic-datapack.
9 Sethuraman, N., Jeremiah, S.S., Ryo, A.-Sethuraman, N., Jeremiah, S.S., Ryo, A. Interpreting Diagnostic Tests for (v1.0) SARS-CoV-2. (v1.0). *JAMA.* Published online May 06, 2020. doi:10.1001/jama.2020.8259.
10 Patel R et al-Patel R et al. (2020). Report from the American Society for Microbiology COVID-19 International (v1.0) Summit, 23 March 2020: Value of Diagnostic Testing for SARS–CoV-2/COVID-19. (v1.0). mBio Mar 2020, 11 (2) e00722-20; DOI: 10.1128/mBio.00722-20.
11 Sethuraman, N. et al. Jama Network-Interpreting Diagnostic Tests for SARS-2020. Literature (v1.0). *JAMA.* Published online May 06, 2020. doi:10.1001/jama.2020.8259.
12 Liu, W., Liu, L., Kou, G. et al.-Liu, W., Liu, L., Kou, G. et al. (2020). Evaluation of Nucleocapsid (v1.0) and Spike Protein-based ELISAs for detecting antibodies against SARS-CoV-2 [published online ahead of print, 2020 Mar 30]. *J Clin Microbiol.* pii: JCM.00461-20. doi: 10.1128/JCM.00461-20.
13 Tan, W., Lu, Y., Zhang, J. et al.-medRxiv. preprint doi: https://doi.org/10.1101/2020.03.24.20042382 (v1.0).
14 Method Sheet SARS-CoV-2 Rapid Antibody Test (2020).
15 Findeisen, Stiegler, Lopez-Calle, Schneider, Urlaub, Hayer, Zemmrich-MVZ Labor Dr. Limbach und Kolle (v1.0). Clinical Performance Evaluation of a SARS-CoV-2 Rapid Antibody Test for Determining Past Exposure to SARS-CoV-2, submitted to MEDRXIV/2020/180687.

Published by
Roche Diagnostics International Ltd
6343 Rotkreuz, Switzerland

diagnostics.roche.com