RUO This kit is intended for research use only. NOT for diagnostic and therapeutic purposes.

Easy! Rapid! Detection of novel coronavirus antibodies (IgG) in blood samples.

Feb. 2021 Ver2.4

CELLSPECT

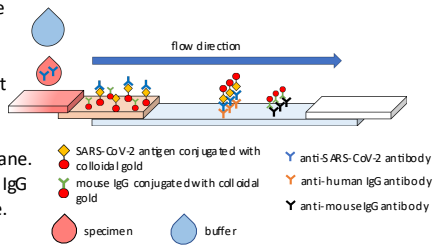
QuaResearch COVID-19 IgG LF 【Instructions for Use】

Significance of Measurement

This kit is intended for a research use in detecting human IgG antibodies against nucleocapsid protein of SARS-CoV-2 as the causative virus of COVID-19. There are two different methods to detect a virus infection, one is detecting virus itself like PCR methods and another is detecting antibodies (IgG, IgM, IgA, etc.) produced after virus infection. An immune response to COVID-19 is unclear, however, it was reported that IgM had not always produced in all patients. On the other hand, IgG had been detected in 60 - 80% of the patients in 10 days, and in most of the patients in 14 days after symptom onset. Further research and analysis are required for an immune reaction against SARS-CoV-2, though many cases are reported that amount of IgG against SARS-CoV-2 had been kept in 30 days after symptom onset.

Measuring Principles

1. The IgG antibodies against SARS-CoV-2 in the specimen, if exist, bind to the recombinant SARS-CoV-2 antigen protein conjugated with red colloidal gold which is immobilized in test stick.
2. This complex of IgG antibody and colloidal gold is flowed toward the end of the membrane.
3. The complex is trapped with the anti-human IgG antibodies fixed on the middle of membrane. Then it is recognized as red test line on test window of the test stick.
4. Uncomplexed colloidal gold is not trapped with the anti-human IgG antibodies fixed on the middle of membrane. In case of absence of IgG antibodies against SARS-CoV-2 in the specimen, no test line is observed in the test window.



Cautions

Please read before use

- This product is not an *in vitro* diagnostic medical device. Cannot be used for diagnostic or therapeutic purposes.
- This product is designed for laboratory research only.
- Be sure to read the instructions for use before use.
- Store in a cool and dark place at 2 - 25°C.
- The sampler is made of thin plastic. Handle with care as it is fragile.
- Use within the expiration date.
- Proper Infection control measures should be provided by individuals.

For safe disposal

All waste in this test procedure, this product, its solutions, and by-products that should be disposed in accordance with environmental protection and waste disposal regulations, relevant local laws and regulations.

Test Procedure

▼ Instruction Video Ver.2

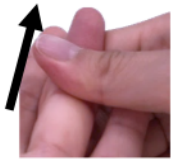
Check before Use

1 Open the package and take out the items inside.

Also open the buffer bottle cap
Use test stick in 15 minutes after open the package

Needed but not supplied materials:

2 Disinfect a blood collection site on your finger with disinfectant wipe and perform skin puncture to draw blood using a lancet.



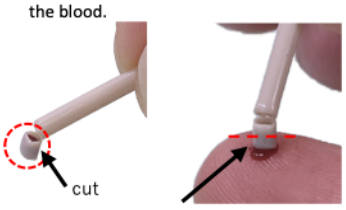
The action of opening and closing your hand and/or massaging your finger will help to enhance blood circulation in your finger.

Please follow the instructions of the chosen lancet product.

3 Press fingertip lightly to make a ball of rice grain-sized blood.

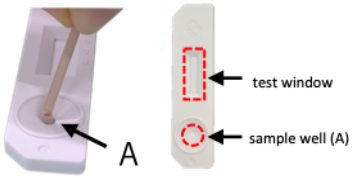
Bleeding speed depends on the lancet you use. Sample your blood from proper size of the drop. The sampler sometimes does not work properly when blood drop's size is too small.

4 Hold the sampler vertically, put the sampler tip on the puncture site, from right above the blood drop to collect the blood.



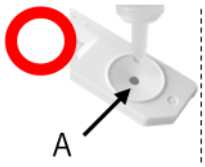
The blood volume is approximately 10 µL from the tip of the sampler to the cut. At least half full of blood is required for testing.

5 Immediately, hold the sampler vertically, attach the sampler tip with blood sample gently right above to the sample well (A) of the test stick. Keep the attachment until all blood absorbed into the test stick.



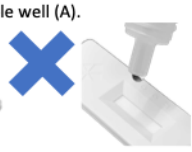
Apply the blood to the stick before coagulation. The coagulation makes it difficult to run this test.

6 Immediately, apply two drops of buffer to the sample well (A).

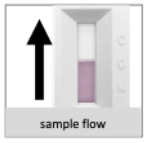


DO NOT make the nozzle touch the sample well (A)

DO NOT apply the buffer to the test window



The color of the sheet in the test window will begin to change in ten seconds after applying the buffer. If you see no change , you may be short of buffer. In this case, apply 1 - 2 more drops of buffer to the sample well (A) and make sure that the color of the sheet in the test window begins to change.



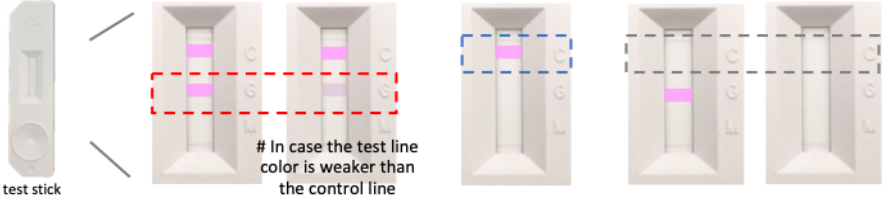
7 Wait until the colored line(s) appear(s). Read the test result in 15 min.

Labels on the test window

C : control line
indicating the test conducted successfully
G : IgG test line
indicating detection of IgG against SARS-Cov-2
M : not for this product

If you can not find the control line in the test window, the test you ran is failing for some reason.

Test example (Imagery)



The illustration is an image of the product. Product appearance is subject to change without notice.

Cellspect Co.,Ltd

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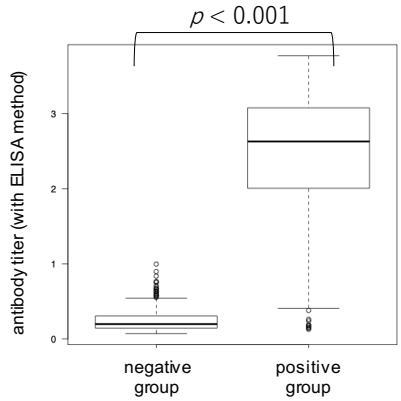
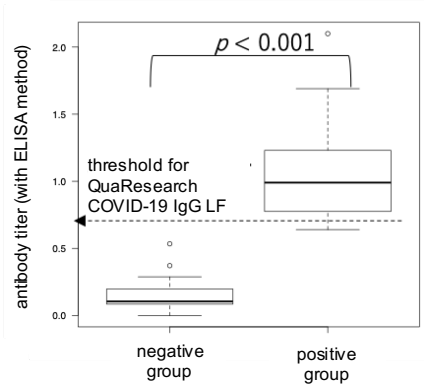
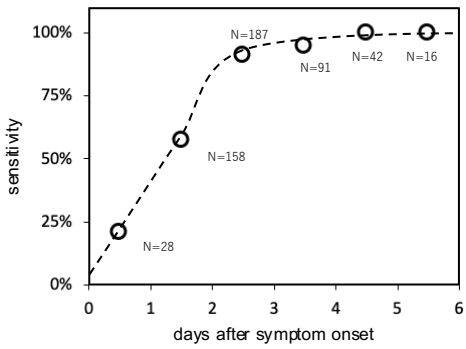
Scientific Information (Antibody Titer with ELISA Method)

Non-parametric statistical analysis in antibody titers 15 - 21 days after symptom onset





Relationship between sensitivity of ELISA method and the days after symptom onset



ROC analysis as IgG antibody marker (ELISA method)
sensitivity: 88%, specificity: 99%
positive percent value: 99%, negative percent value: 97%
false-positive rate: 0.2%, false-negative rate: 12%
area under the curve: 0.96
(95% confidence interval: 0.941 - 0.987)

		positive group	negative group	total
IgG titer	positive	128	1	129
	negative	18	494	512
	total	146	495	641

Properties of QuaResearch IgG LF
sensitivity: 87%, specificity: 100%
positive percent value: 100%, negative percent value: 92%
false-positive rate: 0%, false-negative rate: 13%

		positive group	negative group	total
QuaResearch IgG LF	positive	20	0	20
	negative	3	36	39
	total	23	36	59

Please check the followings before use

[Specimen Sampling]
- Apply the collected specimen to the sample well of the test stick immediately.
- Needed but not supplied materials:
  lancet (finger prick), adhesive plaster, disinfectant wipe, hemostatic gauze.

[Operation]
- Perform this test in accordance with the procedure indicated in this manual.
- Do NOT apply buffer before the specimen application.
- This kit is designed for blood testing, but not for other type of specimen.
- This kit is available only for the designated purpose.
- Use the buffer provided with the test stick.

[Others]
- Do not use this product for diagnostic and therapeutic treatment, as it is not an *in vitro* diagnostic medical device.
- Users of this product are at their own risk and we are not responsible for any damage or inconvenience caused by it.
- Keep away from unrelated persons.

Specification

Product Name	:	QuaResearch COVID-19 IgG LF
CAT Code	:	ERCGLF101 (10test/kit)
Measurement Principle	:	Immunochromatography
Specimen	:	Whole blood, serum, plasma
Specimen Volume	:	10 µL
Measurement Time	:	15 minutes
Storage Temperature	:	2 - 25°C
Expiration Date	:	12 months after manufacture date

Kit Contents

【10 tests/kit】

Test Stick	:	10
Sampler	:	10
Buffer	:	10
Safety Data Sheet	:	1
Instructions for Use	:	1

[Reference]
1.) Kei-ichi Hiramatsu, Standard Microbiology, 11th Edition, Igaku-Shoin (2012)
2.) Anu Haveri , "Serological and molecular findings during SARS-CoV-2 infection: the first case study in Finland," January to February 2020, Eurosurveillance. Volume 25, Issue 11, 19, Mar 2020.
3.) Wanbing Liu, "Evaluation of Nucleocapsid and Spike Protein-based ELISAs for detecting antibodies against SARS-CoV-2", J Clin Microbiol. 2020 Mar 30.
4.) Li Guo, "Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19)", Clin Infect Dis. 2020 Mar 21.
5.) Juanjuan Zhao, "Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019", Clin Infect Dis. 2020 Mar 21.
6.) Grzelak et al, "SARS-CoV-2 Serological Analysis of COVID-19 Hospitalized Patients, Pauci-Symptomatic Individuals and Blood Donors". (Infectious Diseases (except HIV/AIDS), 24 April 2020)
7.) Liu et al, "Evaluation of Nucleocapsid and Spike Protein-Based ELISAs for Detecting Antibodies against SARS-CoV-2", Journal of Clinical Microbiology, 2020, JCM.00461-20, jcm;JCM.00461-20v1
8.) Sun et al, "Kinetics of SARS-CoV-2 Specific IgM and IgG Responses in COVID-19 Patients", Emerging Microbes & Infections, 9.1 (2020), 940–48

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Reception time: 9:00-17:00
(Except weekends and holidays)

※ We support the utilization and research with this product, but not for purposes other than intended.
In case you find any SARS-CoV-2 positive specimen in your research, please handle it properly according to the regulations of your facilities and competent authorities.