CORONATEST.DE

Name	[redacted]
DOB	
Sample	
Sample Type	**capillary blood**
Test Date	**2021-09-30**
Result	**Positive**

Report on SARS-CoV-2 antibody diagnostic - , 2021-09-30

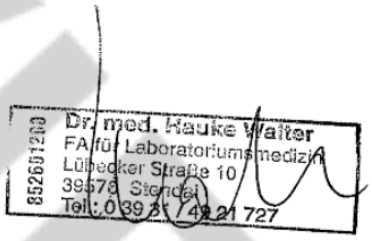
Dear [redacted]

The result of this antibody test is **positive. Specific antibodies** against the spike protein of SARS-CoV-2 could be detected in your sample.

Your value: 46AU/ml

If you have been vaccinated against SARS-CoV-2 (target antigen: spike), the **vaccination was successful**. If you have not been vaccinated, you likely have already been infected with the virus. According to current knowledge, you have **acquired immunity against SARS-CoV-2**. However, it is uncertain how long this immunity lasts. In very rare cases, a positive test result can occur even though no specific antibodies are present in the sample (so-called false-positive result).

Please observe all protective measures recommended by public health authorities to effectively prevent infections and further spreading of SARS-CoV-2.



Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Luogang District, 510663, Guangzhou, P.R. China
Tel: 86-20-32296083 Fax: 86-20-32296063
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Result report on Finecare 2019-nCoV RBD Antibody Test

Dear 【name】

We,

Guangzhou Wondfo Biotech Co., Ltd.

Would like to declare that the product "Finecare 2019-nCoV RBD Antibody Test" manufactured by Guangzhou Wondfo Biotech Co., Ltd. detects the antibodies specially targeted the receptor binding domain (RBD) on the spike protein of the 2019-nCoV virus in the human fingerstick whole blood, venipuncture whole blood, serum or plasma specimen. The quantitative results of the "Finecare 2019-nCoV RBD Antibody Test" are displayed as Relative Fluorescence Unit (RFU, AU/mL) or Binding Antibody Units per milliliter (BAU/mL) from Finecare™ FIA Meters.

The interpretation of the test results are as follows:

Positive（≥ 1 AU/mL or ≥ 20 BAU/mL）; **Negative** (< 1 AU/mL or <20 BAU/mL)

The range of test results is : 0.01 to 200 (AU/mL) or 0.2 to 4000（BAU/mL）

The test is intended to serve as an aid to assess the adaptive humoral immune response against RBD on the spike protein of the 2019-nCoV virus. The current research has found that the 2019-nCoV binds to human cell through RBD on the spike protein, and undergoes cell membrane fusion to enter the human cell and infect the human body. Therefore, the antibody targeted the RBD on the spike protein of the 2019-nCoV virus is mostly considered as protective antibody, as part of them can block the infection by binding to RBD specifically.

Many available vaccines for COVID-19 focus on eliciting an immune response against the RBD of the spike protein. If the person has been vaccinated with one of those vaccines, the positive test result of "Finecare 2019-nCoV RBD Antibody Test" indicates the vaccination was successful. Otherwise, if the person has not been vaccinated, the positive test result possibly indicates he/she has been infected by the virus. In both of above cases, it can be considered this person has acquire the adaptive immune response against the 2019-nCoV according to our current knowledge, but it is uncertain how long this immunity will last. Please pay attention to prevent the virus infection effectively. The negative result of "Finecare 2019-nCoV RBD Antibody Test" indicates the antibody against the RBD on the spike protein of the 2019-nCoV virus is not detected, it may mean the antibody not present in the specimen or the antibody present in the specimen but the level is below the detection limit of the test. In both of above cases, it does not necessarily indicate the person is not immunized, other information (*e.g.* vaccine type, immune cells level) should be taken into consideration.

Sincerely yours,

Guangzhou Wondfo Biotech Co., Ltd.

15th Sep. 2021

Guangzhou Wondfo Biotech Co., Ltd.
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Additional information

"Finecare 2019-nCoV RBD Antibody Test" is based on fluorescence immunoassay technology, specifically the sandwich immune-detection method. When the specimen is added into the sample well of the test cartridge, the anti-RBD antibodies in blood specimen bind to the fluorescence-labeled 2019-nCoV RBD protein on the test strip, and detected by the Finecare™ FIA Meters. Thus the more the anti-RBD antibodies in the blood, the higher the signal value scanned by Finecare™ FIA Meters, the stronger the positive degree of the specimen. The default results unit of this test is displayed as Relative Fluorescence Unit (RFU, AU/mL) from Finecare™ FIA Meters.

WHO and NIBSC launched the first international standard for COVID-19 antibodies (NIBSC code: 20/136) in December 2020. The standard unit for binding antibodies is BAU/mL (binding antibody units per milliliter). "Finecare 2019-nCoV RBD Antibody Test" has been standardized with the WHO Reference Panel (NIBSC code: 20/136). It can be considered that 1 AU/mL is approximately equal to 20 BAU/mL for "Finecare 2019-nCoV RBD Antibody Test", the verification data is as follows:

NIBSC Standard (BAU/mL)		10	20	50	100
Finecare Result (AU/mL)	F29015105 A	0.64	1.02	2.41	5.49
	F29015106 A	0.53	1.20	2.33	4.26
	F29015109 A	0.54	1.11	2.82	5.28

The neutralization assay is also used for verification of the "Finecare 2019-nCoV RBD Antibody Test". Compared with 33 samples from convalescent COVID-19 patients, the test shows high correlation with the neutralization assay.

Reagents		CPE*		Total
		Positive	Negative	
Finecare™ 2019-nCoV RBD Antibody Test	≥1 AU/mL or ≥20 BAU/mL	31	0	31
	<1 AU/mL or <20 BAU/mL	0	2	2
Total		31	2	33

*CPE= Cytopathic effect

Reference

[1] Ismail A A A. ANNALS EXPRESS: Serological tests for Covid-19 antibodies: limitations must be recognized [J]. Annals of Clinical Biochemistry, 2020, 57(4):000456322092705.

[2] Nie J , Wu X , Ma J , et al. Development of in vitro and in vivo rabies virus neutralization assays based on a high-titer pseudovirus system[J]. Rep,2017, 7:42769.

[3] Liu S , Song D , Bai H , et al. A safe and reliable neutralization assay based on pseudovirus to measure neutralizing antibody titer against
poliovirus[J]. Journal of Medical Virology, 2017, 89(12).