Finecare™

2019-nCoV RBD Antibody Test

INTENDED USE

The Finecare™ 2019-nCoV RBD Antibody Test is a fluorescence immunoassay used along with Finecare™ FIA Meters (Model No.: FS-113, FS-114, FS-205) for qualitative and semi-quantitative detection of spike receptor-binding domain (RBD) antibodies of novel coronaviruses (2019-nCoV) in human fingerstick whole blood, venipuncture whole blood, serum or plasma specimen.

The 2019-nCoV RBD antibodies are protective antibody produced by the human body after inoculation with 2019-nCoV vaccine or infection with 2019-nCoV. The test is intended as an aid to assess the adaptive humoral immune response to the 2019-nCoV RBD protein.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

The 2019-nCoV belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible.

The current research has found that the 2019-nCoV binds to their host cell receptor, angiotensin-converting enzyme 2 (ACE2) through RBD from the spike protein (S protein), and undergoes a process of cell membrane fusion. Then the virus enters the cell through endocytosis, replicates and infects the body.

Antibodies against 2019-nCoV with strong neutralizing capacity, especially potent if directed against the RBD, have been identified. Numerous vaccines for COVID-19 are in development, many of which focus on eliciting an immune response to the RBD.

PRINCIPLE

The Finecare™ 2019-nCoV RBD Antibody Test is based on fluorescence immunoassay technology, specifically the sandwich immunodetection method.

Add the specimen to detection buffer and mix well. When the specimen is added into the sample well of the Test Cartridge, the fluorescence-labeled detector 2019-nCoV RBD protein bind to RBD antibodies in blood specimen and form immune complexes. As the complexes migrate on the nitrocellulose membrane by capillary action, the 2019-nCoV RBD antibodies can be captured by another RBD protein that have been immobilized on test strip. Thus the more the 2019-nCoV RBD Antibody in 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.

PRECAUTION

1. This product is a single-use *in vitro* diagnostic reagent, do not reuse, do not use expired products.
2. Sealed pouch contains desiccant pouch, which is for storage purposes only, and is not used in test procedures.
3. The Finecare™ 2019-nCoV RBD Antibody Test is only operated in Finecare™ FIA Meters (Model No.: FS-113, FS-114, FS-205) manufactured by Wondfo Company.
4. Testing should be performed at room temperature(10~30 °C), and applied by professionally trained staff working in certified laboratories or clinic at which the sample(s) is taken by qualified medical personnel.
5. The Test Cartridge should remain in its original sealed pouch until use. Do not use a damaged Test Cartridge or damaged ID Chip.
6. Reagents with different lot numbers cannot be mixed. Please make sure that the Test Cartridge, the ID Chip and the Detection Buffer are with the same lot before use.
7. Disappearance of the blue line on the window of the test will indicate the test device has been used. Do not reuse such device.
8. Wear appropriate personal protective equipment (e.g. medical gloves, medical mask, goggles and lab coat) when handing the contents of this kit.
9. Proper specimen collection, storage and transport are critical to the performance of this test.
10. All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of testing samples and used kit contents. And follow biosafety level 2 or higher guidelines.
11. DISPOSAL OF THE DIAGNOSTIC: All specimens and the used-kits have the infectious risk, and must be discarded after first use. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.
12. Do not insert a Test Cartridge that is wet with other liquids into the instrument, as this will contaminate or damage the instrument.
13. Do not touch the reaction area of test strip.
14. Do not touch the insertion end of the ID Chip.
15. The Test Cartridge and instrument should be used away from vibration and magnetic field. During normal usage, the instrument may introduce minute vibration, which should be regarded normal.
16. Bring the test device to room temperature before opening a seal. Test should be performed in the required environment.
17. If you have questions or suggestions during the use of this reagent, please contact the manufacturer.

MAIN COMPONENTS

Materials Provided

REF	Sealed pouches*	ID Chip	Pipette Tips	Tubes of Detection Buffer	Sterile Lancet**	Alcohol Pad	Capillary Sampler***	IFU
W290P0001	5	1	5	5	/	/	/	1
W290P0002	5	1	5	5	5	5	5	1
W290P0003	10	1	10	10	/	/	/	1
W290P0004	10	1	10	10	10	10	10	1
W290P0005	20	1	20	20	/	/	/	1
W290P0006	20	1	20	20	20	20	20	1
W290P0007	25	1	25	25	/	/	/	1
W290P0008	25	1	25	25	25	25	25	1
W290P0009	40	1	40	40	/	/	/	1
W290P0010	40	1	40	40	40	40	40	1

Note:

*each sealed pouches containing: 1 Test Cartridge and 1 Desiccant Pouch

**CE information of Sterile Lancet: CE 0123 MDD 93/42/EEC

***capillary sampler is for fingerstick blood specimen only.

Materials Required But Not Provided

1. Finecare™ FIA Meters (choose one of below):
   Finecare™ FIA Meter Plus, Model No.: FS-113
   Finecare™ FIA Meter II Plus SE, Model No.: FS-114
   Finecare™ FIA Meter III Plus, Model No.: FS-205
2. Transfer Pipette Set
3. Specimen Collection Containers
4. Centrifuge (for serum/plasma specimen only)
5. Timer
6. Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat.
7. Appropriate biohazard waste container and disinfectants.

Reactive Ingredients Of Main Components

The test cartridge consists of test strip and plastic cartridge. The test strip includes: nitrocellulose membrane, sample pad, conjugated pad, absorbent paper and PVC board. Nitrocellulose membrane is coated with RBD protein, anti-chicken IgY polyclonal antibodies; Conjugate pad contains RBD protein and chicken IgY polyclonal antibodies.

Note: To ensure the accuracy of test results, components in different lots cannot be mixed-used.

STORAGE AND STABILITY

1. Store at 4~30°C in the sealed pouch up to the expiration date printed on the package. Do not freeze.
2. The test device should be used within 1 hour after taking out from the foil envelope.
3. Keep away from sunlight, moisture and heat.
4. Kit contents are stable until the expiration date printed on the outer box.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with whole blood, serum and plasma.

For Venous Whole Blood:

1. According to standard venous blood collection procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant (containing EDTA or Heparin).
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged period.
3. If the specimens are not tested within 8 hours, they should be kept at 2~8 °C for up to 3 days.

For Fingerstick Whole Blood:

1. Clean the area to be lanced with an alcohol pad. Allow the finger to dry thoroughly.
2. Use a sterile lancet, puncture the skin just off the center of the finger pad. Apply gentle pressure beside the point of the puncture. Wipe away the first drop of blood. Allow a new drop of blood to form. If blood flow is inadequate, the subject's finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume.
3. Draw 20 µL of finger blood with the capillary sampler. Whole blood specimen collected by fingerstick should be tested immediately.

For Serum or Plasma:

1. According to standard phlebotomy procedure, collect a venipuncture whole blood specimen. If you need to collect plasma, please use a blood collection tube which contains suitable anticoagulant (EDTA or Heparin).
2. Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
3. Test should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged period.
4. If the specimens are not tested within 8 hours, they should be kept at 2~8 °C for up to 7 days. For storage more than 7 days, specimens should be kept below -20°C for up to 15 days.

Note:

1) Other anticoagulants have not been validated and may give incorrect result.

2) Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Severe hemolytic or heat-inactivated specimens are not recommended.

TEST PROCEDURE

For complete information and operating procedures, please refer to Finecare™ FIA Meters Operation Manual. Test should be performed at room temperature.

Step 1: Preparation

Allow the Test Cartridge and specimen to equilibrate to room temperature (10~30°C) prior to testing.

Ensure that the lot number of the Test Cartridge matches ID Chip. Insert ID Chip into Finecare™ FIA Meters.

Step 2: Sampling

1)For venous whole blood/ serum/ plasma specimen:

Draw **20 µL** of venous whole blood or serum or plasma with a transfer pipette and add into the detection buffer tube.

2) For fingerstick whole blood specimen:
Draw **20 μL** (no external force required, the capillary sampler will aspirate the blood sample by itself) from finger with a capillary sampler, then squeeze out the specimen to the detection buffer tube.

Step 3: Mixing
Close the lid of Detection Buffer tube and mix the sample mixture thoroughly by shaking it well.

4: Loading
Pipette **75 μL** of sample mixture and load it into the sample well of the Test Cartridge.

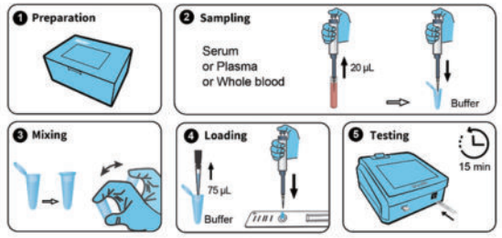
Step 5: Testing
There are two test modes for Finecare™ FIA Meters, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA Meters for details.

a) **For Standard Test Mode:** Insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well. Press "Test" to start testing. The reaction time of the Test Cartridge is 15 minutes.
b) **For Quick Test Modefor (FS-113, FS-114 only):** Set the timer and count down right after adding sample mixture into the sample well and wait for 15 minutes at room temperature. Then insert the Test Cartridge onto the Test Cartridge holder of Finecare™ FIA Meters. Press "Test" to start testing.

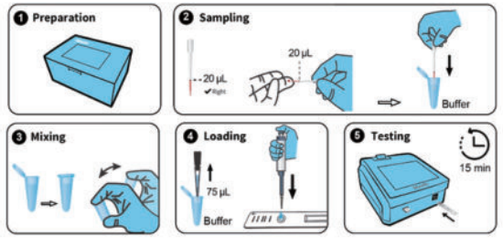
Step 6: Reading results
Results are displayed on main screen or be printed by press "Print".

Step 7: Withdraw
Discard the used Test Cartridge and other contents of the used kit according to local regulations and procedures after released from the instrument.

SOP for venous whole blood / serum/ plasma:



SOP for fingerstick whole blood:



RESULT INTERPRETATION

Finecare™ FIA Meters displays the test result automatically on the screen. The result will be displayed in Relative Fluorescence Unit (RFU, AU/mL).

Value Results	Test Result Interpretation
Negative(<1 AU/mL)	2019-nCoV RBD antibodies are not detected
Positive(≥1 AU/mL)	2019-nCoV RBD antibodies are detected

Invalid Result: The instrument shows that the sample has not been added (when the signal is lower than the preset minimum signal) or the cartridge is inserted reversely (when the cartridge has no code or the code is incorrect).

QUALITY CONTROL

Each Finecare™ 2019-nCoV RBD Antibody Test contains internal control that satisfies routine quality control requirements. This internal control is performed each time a testing sample is tested. This control indicates that the Test Cartridge was inserted and read properly by Finecare™ FIA Meters. An invalid result from the internal control causes an error message on Finecare™ FIA Meters indicating that the test should be repeated.

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. This reagent is only used for *in vitro* diagnosis.
2. This reagent is only for testing human serum, plasma, and whole blood samples. The results of testing with other samples or solutions may be incorrect.
3. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of samples will affect the test results.
4. It is reasonable for the hematocrit of the whole blood specimen between 30% and 60%. The hematocrit of whole blood <30% or >60% may cause the incorrect results.
5. A negative test result may not completely rule out the possibility of an infection with 2019-nCoV. Serum or plasma samples from the very early (pre-seroconversion) phase can yield negative findings. Therefore, this test cannot be used to diagnose an acute infection. It has also been reported that certain patients with confirmed infection do not develop 2019-nCoV antibodies. Furthermore, waning of antibody titers has been reported in some individuals within a range of months after infection, a feature which has also been reported for other coronaviruses.
6. False negative results may occur if the titer of antibodies against the 2019-nCoV virus present in the specimen is below the detection limit of the test.
7. A positive result may not indicate previous 2019-nCoV infection. Consider other information including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
8. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A total of 246 samples retrospectively collected from 2019-nCoV PCR positive and negative individuals (63 positive and 183 negative) were tested with the Finecare™ 2019-nCoV RBD Antibody Test.
The sampling date of positive samples were both more than 7 days after diagnosis with PCR.

Reagents		PCR		Total
		Positive	Negative	
Finecare™ 2019-nCoV RBD Antibody Test	Positive	61	1	62
	Negative	2	182	184
Total		63	183	246

Sensitivity: 96.83 % (95 % CI: 89.00 %~99.61 %)
Specificity: 99.45 % (95%CI: 96.99 %~99.99 %)
Total agreement: 98.78 % (95%CI: 96.48 %~99.75 %)

Correlation of test results to serum neutralization capacity

The Finecare™ 2019-nCoV RBD Antibody Test was compared to The Pseudovirus Neutralization Assay. The following tables show the correlation between $NtAb_{50}$* of Pseudovirus Neutralization Assay and RFU of Finecare™ 2019-nCoV RBD Antibody Test.

Reagents		Pseudovirus Neutralization Assay			Total
		<1:20	1:20~1:160	>1:160	
Finecare™ 2019-nCoV RBD Antibody Test	<1 AU/mL	21	0	0	21
	1~20 AU/mL	1	8	0	9
	>20 AU/mL	0	0	26	26
Total		22	8	26	56

*$NtAb_{50}$= Antibody titers resulting in 50% virus neutralization:

Dilution Titer	Result	Test Result Interpretation
<1:20	Negative	Neutralizing antibodies for 2019-nCoV are not detected at 50% virus neutralization.
1:20~1:160	Low titer	Low Neutralizing antibodies for 2019-nCoV are detected at 50% viral neutralization.
>1:160	High titer	High neutralizing antibodies for 2019-nCoV are detected at 50% virus neutralization.

Cross-reactivity

Specimens which tested positive with following various agents from patients were investigated with Finecare™ 2019-nCoV RBD Antibody Test. The results showed no cross reactivity.

Parainfluenza virus antibodies	Treponema pallidum antibodies
Influenza A antibodies	HIV antibodies
Influenza B antibodies	EB virus antibodies
Chlamydia pneumonia antibodies	Measles virus antibodies
Mycoplasma pneumoniae antibodies	Cytomegalovirus antibodies
Adenovirus antibodies	Enterovirus type 71 antibodies
Respiratory syncytial virus antibodies	Mumps antibodies
Hepatitis B surface antibodies	Varicella-zoster virus antibodies
Hepatitis C virus antibodies	

Interferences

The test result of Finecare™ 2019-nCoV RBD Antibody Test was not interfered by the substance at the following concentration:

Substance	Concentration
Bilirubin	25 mg/dL
Hemoglobin	1 g/dL
Triglyceride	3000 mg/dL
Rheumatoid factors	100 IU/mL
Cholesterol	1000 mg/dL

Precision

Within-run Precision: CV ≤10%.
Between-run Precision: CV ≤10%.

BIBLIOGRAPHY

[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).

INDEX OF SYMBOLS

IVD *In Vitro* Diagnostic Use	See Instruction for Use	Expiry Date
Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	EC REP Authorized Representative	Keep away from Sunlight
Store between 4～30°C	Do not reuse	REF Catalog #
Manufacturer		

Guangzhou Wondfo Biotech Co., Ltd.
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Rev. A1
Rel.: 2021/01/06