Finecare™ 2019-nCoV Antigen Test

Catalog No. W286

INTENDED USE

The Finecare™ 2019-nCoV Antigen Test is a fluorescence immunoassay used along with Finecare™ FIA Meters (Model No.: FS-113, FS-114, FS-205) for qualitative detection of novel coronaviruses (2019-nCoV) antigen extracted from the nasopharyngeal swab or oropharyngeal swab specimen. Clinically, the test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV.

The test provides preliminary test results. Negative results cannot exclude 2019-nCoV infection and they cannot be used as the sole basis for treatment or other management decision.

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

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The Finecare™ 2019-nCoV Antigen Test is based on fluorescence immunoassay technology for the detection of 2019-nCoV antigen extracted from the nasopharyngeal swab or oropharyngeal swab specimen.

When the extracted specimen is added into the sample well of the Test Cartridge, the fluorescence-labeled detector 2019-nCoV antibodies bind to 2019-nCoV antigens in extracted specimen and form immune complexes. As the complexes migrate on the nitrocellulose matrix by capillary action, the 2019-nCoV complexes can be captured by 2019-nCoV antibodies that have been immobilized on Test Region. Thus the more 2019-nCoV antigens in the extracted specimen, the higher signal value scanned by Finecare™ FIA Meters, the stronger positive degree of the specimen. This indicates a positive result.

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 Antigen 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℃), 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 Extraction 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 the 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 patient 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 instruments should be used away from vibration and magnetic field. During normal usage, the instruments 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. The Finecare™ 2019-nCoV Antigen Test should not be used as absolute evidence for 2019-nCoV infection. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
18. If you have questions or suggestions during the use of this reagent, please contact the manufacturer.

MAIN COMPONENTS

Materials Provided

1. 25 individual Sealed Pouches, each containing:
   - 1 Test Cartridge
   - 1 Desiccant Pouch
2. 1 ID Chip
3. 25 Sample Extraction Tubes
4. 25 Drippers
5. 25 Disposable Swabs CE 0197 MDD 93/42/EEC
6. 2 Extraction Buffer (2*7 mL)
7. Leaflet with Instructions for Use

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. Viral Transport Media(VTM)
3. Tongue Depressor
4. Timer
5. Personal protective equipment, such as medical gloves, medical mask, goggles and lab coat.
6. 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 2019-nCoV antibodies, anti-chicken IgY polyclonal antibodies; Conjugate pad contains 2019-nCoV antibodies 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℃ 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 nasopharyngeal swab or oropharyngeal swab specimen.

1. According to standard nasopharyngeal swab or oropharyngeal swab specimen collection procedure.
2. Nasopharyngeal swab specimen collection: Tilt patient's head back about 70 degrees to straighten nasal passage. Insert swab into nostril (Swab should reach depth equal to distance from nostrils to outer opening of the ear). Rotate the swab several times and leave swab in place for several seconds to absorb secretions. Slowly remove swab.
3. Oropharyngeal swab specimen collection: Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
4. It is recommended that the specimen is tested at the time of specimen collection. If the specimens are not tested immediately, they should be stored in a dry, disinfected tube and tightly sealed (Place tip of swab into a tube and snap/cut off the applicator stick). They may be stored at 2~8℃ for up to 8 hours, or they may be stored at -70℃ for a long time.
5. If the Viral Transport Media (VTM) is needed for transporting samples, the dilution ratio for samples should be controlled at minimum level, since large diluent volume could result in false negative. If possible, the diluent volume should not exceed 1 mL (however, the tip of the swab must be immersed in the liquid). Taking influenza virus as a reference, the nasopharyngeal swab or oropharyngeal swab in the VTM can stay stable for up to 72 hours at 2~8℃.

TEST PROCEDURE

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

Step1: Preparation.
Allow the Test Cartridge, Extraction Buffer and specimen to equilibrate to room temperature (10~30 ℃) prior to testing.
Ensure that the lot number of the Test Cartridge matches ID Chip as well as the Extraction Buffer. Insert ID Chip into Finecare™ FIA Meters.

- **Swab Test Procedure (Nasopharyngeal / Oropharyngeal)**

Step2.1: Sampling and Mixing
Transfer **400 μL** (about **10 drops**) Extraction Buffer to the Sample Extraction Tube vertically.
Insert the swab which has collected secretions into the Extraction Buffer and rotate about 10 times to dissolve the specimen in the solution as much as possible.
Squeeze the swab tip to keep the liquid in the tube as much as possible. Dispose of the used swab in the biohazard waste.

Step3.1: Loading
Cover the Dripper. Add **80 μL** (about **3~4 drops**) processed specimen to the sample well of the Test Cartridge.

Transfer 400 μL (about 10 drops) extraction buffer | Rotate about 10 times | Squeeze the swab tip | Cover the dripper | Add 80 μL (about 3~4 drops) to the sample well

- ***Viral Transport Media (VTM) Test Procedure***

Note: *Only Ardentbiomed GSP1110 series VTM and Zijian Biomed V10-S-25 VTM have been validated with the assay.*

Step2.2: Sampling and Mixing
Mix the specimen received in VTM by vortexing the tubes for 5 seconds.

Step3.2: Loading
Draw **80 μL** (about **3~4 drops**) of VTM specimen with a transfer pipette and add into the sample well of the Test Cartridge.

Step4: 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.

Step5: Reading results
Results are displayed on main screen or be printed by press "Print".

Step6: Withdraw
Discard the used Test Cartridge according to local regulations and procedures after released from the instrument.

RESULT INTERPRETATION

The Finecare™ FIA Meters calculates the test result automatically and displays 'Positive' / 'Negative' with ancillary value, cut off index (COI).

COI	Result
< 1.0	Negative
≥ 1.0	Positive

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).

Note:
1. The magnitude of the measured result above the cut off is not indicative of the total amount of antigen present in the sample.
2. The measured 2019-nCoV value can vary depending on the testing procedure used and the applied standard. Results obtained from a single sample using tests from different manufacturers can therefore differ. Results of assays from different manufacturers should not be used interchangeably.

QUALITY CONTROL

1. Internal Quality Control: each Finecare™ 2019-nCoV Antigen Test contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient 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.
2. External Quality Control: 2019-nCoV Antigen Control manufactured by Wondfo is recommended for Finecare™ 2019-nCoV Antigen Test.
3. Quality control material should be used to confirm the reliability and the validity of Finecare™ 2019-nCoV Antigen Test.
4. Quality control test should be performed both to verify proper operation of instrument and to exclude any possible performance change in storage.

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect 2019-nCoV antigen in human nasopharyngeal or oropharyngeal swab specimen.
2. This test is a qualitative assay. It is not designed to determine the quantitative concentration of 2019-nCoV antigens.
3. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or unsuitable VTM will affect the test result.
4. The test results of this reagent are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered based on their symptoms / signs, medical history, other laboratory examinations and treatment response.
5. Limited by the method of Antigen detection reagents, for negative test results, it is recommended to use nucleic acid diagnosis or virus culture identification methods for review and confirmation.
6. Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:

1) Improper sample collection, improper sample transfer or handing, the virus titer in the sample is too low.
2) The level of 2019-nCoV antigen is below the detection limit of the test.
3) Variations in viral genes may cause changes in antigens determinants.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity
A total of 537 samples retrospectively collected from 2019-nCoV PCR positive and negative individuals (184 positive and 353 negative) were tested with the Finecare™ 2019-nCoV Antigen Test.

Reagents		PCR		Total
		Positive	Negative	
Finecare™ 2019-nCoV Antigen Test	Positive	181	2	183
	Negative	3	351	354
Total		184	353	537
Sensitivity		98.37% (95.31%~99.66%)		
Specificity		99.43% (97.97%~99.93%)		
PPV		98.91% (96.11%~99.87%)		
NPV		99.15% (97.54%~99.82%)		
Total agreement		99.07% (97.84%~99.70%)		

1. Performance data was calculated from a study of individuals suspected of exposure to COVID-19 or who have presented with symptoms in the last 7 days, and the samples of Ct values ≤30.
2. Positive agreement of the Finecare™ 2019-nCoV Antigen Test was higher with samples of Ct values ≤33 with a sensitivity of 94.90%.

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

Common coronavirus (NL63, 229E, OC43) antigen	EB virus antigen
Influenza A H1N1 antigen	Measles virus antigen
Influenza A H3N2 antigen	Human Cytomegalovirus antigen
Influenza B Yamagata antigen	Rotavirus antigen
Influenza B Victoria antigen	Norovirus antigen
Respiratory syncytial virus A/B antigen	mumps virus antigen
Rhinovirus-A/-B antigen	Varicella-zoster virus antigen
Adenovirus-1/-2/-3/-4/-5/-7/55 antigen	Mycoplasma pneumoniae antigen
Enterovirus A/B/C/D antigen	Chlamydia pneumonia antigen

C. Interferences
The test results of Finecare™ 2019-nCoV Antigen Test were not interfered with the following substances:

Type	Substance
Allergic Symptoms	Histamine Dihydrochloride
Antiviral Drugs	Interferon alpha
	Zanamivir
	Ribavirin
	Oseltamivir
	Palamivir
	Lopenavir
	Ritonavir
	Abidor
Antibiotics	Levofloxacin
	Azithromycin
	Ceftriaxone
	Meropenem
Systemic Antibacterial Drugs	Tobramycin

D. Hook effect
There was no hook effect at 7.5×10^5 $TCID_{50}$/mL of 2019-nCoV which was isolated from a COVID-19 confirmed patient.

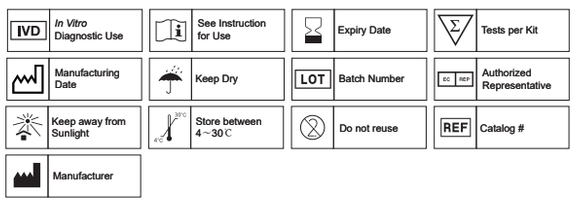
E.Precision
1. Within-run precision was determined by testing 10 replicates of negative and positive specimens. The negative agreement rate and the positive agreement rate was 100%.
2. Between-run precision was determined by testing three different specimens including positive and negative in 3 different lots of test devices. The negative agreement rate and the positive agreement rate was 100%.

F.Limit of Detection
The LoD of this test was 1.02×10^2 $TCID_{50}$/mL.

BIBLIOGRAPHY

[1] Chen H , Wurm T , Britton P , et al. Interaction of the Coronavirus Nucleoprotein with Nucleolar Antigens and the Host Cell[J]. Journal of Virology, 2002, 76(10).

INDEX OF SYMBOLS



Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District, 510663,Guangzhou, P.R.China
Tel: +86-20-32296083 400-888-5268(Toll Free)
Fax: +86-20-32296063
E-mail: Finecare@wondfo.com.cn
Website: www.wondfo.com.cn

EC REP
Qarad BV
Cipalstraat 3
2440 Geel , Belgium

Rev. A3 Rel.: 2021/1/16