

INTENDED USE

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immuno-chromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG/IgM antibody in human whole blood, serum or plasma sample. The test is only to be used in conjunction with nucleic acid method in the diagnosis of suspected cases.

The test is not intended to be used for general population screening and only provides preliminary test results. Positive results need further confirmation and negative results cannot exclude the possibility of SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

The test is only for clinical use and emergency storage during pneumonia epidemic caused by SARS-CoV-2. It cannot be used as regular IVD product for clinical purpose. Test result is only for clinical reference. The test result should be interpreted by the physician along with other clinical findings and other laboratory test results.

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

SUMMARY

On December 31, 2019, several cases of pneumonia were reported to the World Health Organization (WHO). The novel coronavirus, now known as SARS-CoV-2 (previously known as 2019-nCoV), a RNA virus of the beta coronavirus family, has spread all over the world. The WHO named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (abbreviated "COVID-19").

PRINCIPLE

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is based on the principle of capture immunoassay for determination of SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum and plasma. When the specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antigen-dye conjugate and flows across the pre-coated membrane.

When the SARS-CoV-2 antibodies level in the specimen is at or above the target cutoff (the detection limit of the test), the antibodies bound to the antigen-dye conjugate are captured by anti-human IgG antibody and anti-human μ chain antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antibody level in the specimen is zero or below the target cutoff, there is not a visible colored band in the Test Region (T) of the device. This indicates a negative result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTION

1. This kit is for *in vitro* diagnostic use only.

2. 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.
3. Wear appropriate personal protective equipment (e.g. gowns, gloves, eye protection) when handling the contents of this kit.
4. Proper specimen collection, storage and transport are critical to the performance of this test.
5. Discard after first use. The test cannot be used more than once.
6. Avoid excessively high temperature in the experiment environment. Test cards and detection buffer stored at low temperature need to be returned to room temperature before opening to avoid moisture absorption.
7. Do not touch the reaction area of test strip.
8. Do not use test kit beyond the expiration date.
9. Do not use the kit if the pouch is punctured or not well sealed.
10. Testing should be applied by professional trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
11. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
12. DISPOSAL OF THE DIAGNOSTIC: All specimens and the used-kit has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

MATERIAL

Material Provided

1. 20 Individual sealed pouches, each pouch contains:
 - 1 x Test cassette
 - 1 x Desiccant pouch
2. 20 disposable droppers
3. Detection buffer (1*6 mL)
4. Instructions for use

Reactive ingredients of main components

The test cassette consists of test strip and plastic cassette. The test strip includes: nitrocellulose membrane, sample pad, conjugated pad, absorbent paper and PVC board. Nitrocellulose membrane is coated with anti- μ chain antibody/anti-human IgG antibody and anti-rabbit IgG polyclonal antibody; Conjugate pad is containing recombination SARS-CoV-2 antigen and rabbit IgG.

Material Required but Not Provided

1. Specimen collection containers
2. Centrifuge (for serum/plasma sample)
3. Timer
4. Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.
5. Appropriate biohazard waste container and disinfectants.

STORAGE AND STABILITY

1. Store at 2~30°C in the sealed pouch up to the expiration date printed on the package. Do not freeze. The validity period of this product is tentatively 6 months.
2. The test cassette should be used within 1 hour after taking out from the foil envelope. Buffer solution should be re-capped in time after use.
3. Keep away from sunlight, moisture and heat.

4. Kit contents are stable until the expiration date printed on the outer box.
5. The production date is printed on the outer box.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with venous 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, Heparin or Citrated sodium). **Other anticoagulants have not been validated and may give incorrect result.**
2. It is recommended that whole blood specimen is tested at the time of specimen collection. If the specimens are not tested immediately, they may be stored at 2°C~8°C for up to 3 days. Prior to testing, mix the blood by gentle inversion several times, do not freeze or heat whole blood specimens.

For Serum and Plasma:

1. According to standard venous blood collection procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). **Other anticoagulants have not been validated and may give incorrect result.**
2. Centrifuge whole blood and separate the plasma from red blood cell as soon as possible to avoid hemolysis.
3. Test should be performed within 8 hours after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum or plasma specimens may be stored at 2°C~8°C for up to 7 days prior to testing. Serum or plasma specimens may be stored at -20°C for up to 9 days.

Note: 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

Please read the instruction for use carefully before performing the test.

1. Allow the device, buffer and specimen to equilibrate to room temperature prior to testing.
2. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
3. Add 10 μ L of venous whole blood or serum or plasma specimen to the sample well (small well) and then add 2-3 drops (80 μ L) of buffer solution to the buffer well (large well).
4. As the test begins to work, you will see purple color move across the result window in the center of the test device.
5. Wait for 15 minutes and read the results. Do not read results after 20 minutes.



Note: the rightmost window on the cassette shows the product abbreviation "nCoV" to identify this product.

RESULT INTERPRETATION

Positive Result

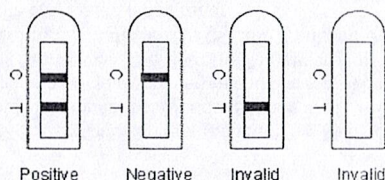
Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antibodies in the specimen.

Negative Result

Colored band appear at control line (C) only. It indicates that the concentration of the SARS-CoV-2 antibodies is zero or below the detection limit of the test.

Invalid Result

No visible colored band appear at control line after performing the test. The directions may not have been followed correctly. Pay particular attention to whether the sample volume is sufficient. It is recommended that the specimen be re-tested.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

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

LIMITATIONS OF PROCEDURE

- This reagent is designed to detect antibodies against SARS-CoV-2 in human whole blood, plasma, serum sample.
- The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.
- This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies. If you need to test the quantitative concentration, please use the relevant professional instruments.
- The test result of this reagent are for clinical reference only and should not be used as the sole basis 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.
- Limited by the method of antibody detection reagents, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
- Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:
 - Improper sample collection, improper sample transfer or handing, the virus titer in the sample is too low;
 - The level of SARS-CoV-2 antibodies is below the detection limit of the test.
 - Variations in viral genes may cause changes in antibody determinants.

PERFORMANCE CHARACTERISTICS

A.Sensitivity and Specificity

Whole blood/plasma/serum specimens from 596 patients, which included 361 confirmed as COVID-19 positive and 235 confirmed as COVID-19 negative, were obtained for testing. Of the 361 confirmed COVID-19 positive patients, 312 were tested positive with the Wondfo SARS-CoV-2 Antibody Test. Of the 235 confirmed COVID-19 negative patients, 234 were tested negative.

Reagents		Clinical diagnosis*		Total
		Confirmed COVID-19 positive	Confirmed COVID-19 negative	
Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	Positive	312	1	313
	Negative	49	234	283
Total		361	235	596

* The clinical diagnosis decisions were based on the criteria in the COVID-19 diagnosis and Treatment Guideline.

Sensitivity: 86.43% (95%CI: 82.51%~89.58%)

Specificity: 99.57% (95%CI: 97.63%~99.92%)

Overall agreement: 91.61% (95%CI: 89.10%~93.58%)

Moreover, 172 clinical samples which include 91 confirmed COVID-19 positive samples and 81 confirmed COVID-19 negative samples were obtained for testing, and then compared the test results between homologous whole blood sample test results with serum/plasma sample test results. The positive percent agreement of the whole blood sample is 93.41% (95%CI: 86.35%~96.94%), the negative percent agreement of the whole blood sample is 100.00% (95%CI: 95.47%~100.00%), the overall agreement is 96.51% (95%CI: 92.60%~98.39%).

After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of the epidemic situation. We will further collect clinical data to confirm the clinical performance of the product after the product is launched.

B.Cross-reactivity

Cross-reactivity of the Wondfo SARS-CoV-2 Antibody Test was evaluated using specimens containing the antibodies listed below. The results showed no cross reactivity with the following:

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

C.Interference

The test result of Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) are not be interfered with the substance at the following concentration:

Substance	Concentration
Bilirubin	250 μmol/L
Hemoglobin	9 g/L
Triglyceride	15 mmol/L
Rheumatoid factors	80 IU/mL
Antinuclear antibody (ANA) titer	1:240
Anti-mitochondrial antibody (AMA)	80 U/mL
HAMA	1000 μg/mL

The test result of Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) are not be interfered with these drugs: Histamine hydrochloride, interferon alpha, zanamivir, ribavirin, oseltamivir, paramivir, lopinavir, ritonavir, abidor, levofloxacin, azithromycin, ceftriax Pine, meropenem, tobramycin.

D.Hook effect

Within the titer range of clinically positive samples of SARS-CoV-2 antibodies, there is no hook effect in the test results of this product.

E.Precision

- Within run precision was determined by testing separately two positive specimens in 10 times. The agreement rate was 100%.
- 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 were 100%.

BIBLIOGRAPHY

- Na Zhu, Ph.D., Dingyu Zhang, M.D., Wenling Wang, Ph.D., et al. (2020). A Novel Coronavirus from Patients with Pneumonia in China, 2019. The New England Journal of Medicine.
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- Chaolin Huang, Yeming, et al. (2020). Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet, 395(10223), 497-506.
- Nanshan Chen, Min Zhou, Xuan Dong, et al. (2020). Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. The Lancet, 395(10223), 507-513.
- World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance. 12 January, 2020.

INDEX OF SYMBOL

IVD In Vitro Diagnostic Use	See Instruction for Use	Expiry Date	Manufacturer
Tests per Kit	Manufacturing Date	Keep Dry	Do not reuse
LOT Batch Number	Authorized Representative	Keep away from Sunlight	Catalog #
Store between 2°C~30°C			

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