SARS-CoV-2 Antibody Test (Lateral Flow Method)

Catalog No.: W195

INTENDED USE

Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic 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 to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 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

On December 31, 2019, several cases of pneumonia in Wuhan City, Hubei Province of China were reported to the World Health Organization (WHO). The novel virus, now known as SARS-CoV-2 (previously known as 2019-nCoV), a RNA virus of the beta coronavirus family, has since spread across China and to other countries and territories. The WHO has 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 handing 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. Do not touch the reaction area of test strip.
7. Do not use test kit beyond the expiration date.
8. Do not use the kit if the pouch is punctured or not well sealed.
9. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
10. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
11. 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

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 2ºC~30ºC in the sealed pouch up to the expiration date printed on the package. Do not freeze.
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.

SPECIMEN COLLECTION AND PREPARATION

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

For whole blood:

1. Using standard phlebotomy 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 2ºC～8ºC for up to 7 days. Prior to testing, mix the blood by gentle inversion several times, do not freeze or heat whole blood specimens.

For Serum and Plasma:

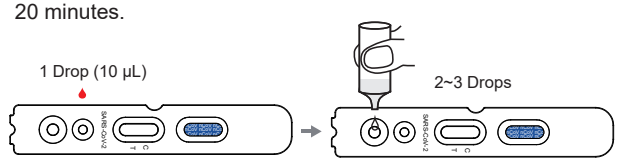
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (containing EDTA, Heparin or Citrated sodium). Other anticoagulants have not been validated and may give 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 houres 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 2ºC～8ºC for up to 3 days prior to testing. Serum or plasma specimens may be stored at -20ºC 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 (10ºC ~30ºC) 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. Transfer 1 drop (10 μL) of whole blood or serum or plasma specimen to the sample well (small well) and then add 2~3 drops (80 μL) 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.

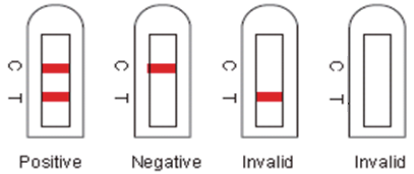
Negative Result

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 or the test may have deteriorated. 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

1. This reagent is designed to detect antibodies against SARS-CoV-2 in human whole blood, plasma, serum sample.
2. This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies.
3. 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.
4. The test result of this reagent are for clinical reference only, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
5. 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.
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 SARS-CoV-2 antibodies is below the detection limit of the test.
   3) Variations in viral genes may cause changes in antibody determinants.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity

596 clinical case samples which include 361 confirmed case samples* and 235 confirmed excluded case samples*, were obtained for testing, and then compared the test results between Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) and the confirmed case samples. The results of sensitivity and specificity between the two method are show below.

Reagents		Clinical cases		Total
		Confirmed case samples	Excluded case samples	
Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	Positive	312	1	313
	Negative	49	234	283
Total		361	235	596

* Confirmed cases were the patients diagnosed according to the treatment plan.
* Confirmed excluded cares were identified by negative PCR results.

Results analysis:
Sensitivity: 86.43% (95%CI: 82.51%~89.58%)
Specificity: 99.57% (95%CI: 97.63%~99.92%)
Total consistent: 91.61% (95%CI: 89.10%~93.58%)

B. Cross-reactivity

Specimens which tested positive with following various agents from patients were investigated with Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method). The results showed no cross reactivity.

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

C. Interferences

The test result of Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) do 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
Mouse IgG	1000 μg/mL

D. Precision

1. Within run precision was determined by using 10 replicates of three different specimens containing different concentrations of antibody. The negative and positive values were correctly identified 100% of the time.
2. Between run precision was determined by using the three different specimens containing different concentrations of antibody in 3 different lots of test devices. Again negative and positive results were correctly identified 100% of the time.

BIBLIOGRAPHY

[1] 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.
[2] Chen Wang, Peter W Horby, Frederick G Hayden, George F Gao. (2020). A novel coronavirus outbreak of global health concern. The Lancet, 395(10223), 470-473.
[3] Chaolin Huang, Yeming, et al. (2020). Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet, 395(10223), 497-506.
[4] 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.
[5] 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
Tests per Kit	Manufacturing Date	Keep Dry
LOT Batch Number	Manufacturer	Keep away from Sunlight
Store between 2～30ºC	Do not reuse	REF Catalog #
EC REP Authorized Representative		

CE