

Wantai SARS-CoV-2 Diagnostics

WANTAI SARS-CoV-2 Ab Rapid Test

Rapid Test for Detection of Total Antibodies to SARS-CoV-2

FOR SERUM / PLASMA / WHOLE BLOOD SPECIMEN

INSTRUCTIONS FOR USE

Catalog No.:

WJ-2701, WJ-2710, WJ-2750

INTENDED USE

WANTAI SARS-CoV-2 Ab Rapid Test is a single use, rapid device for qualitative detection of total antibodies against 2019 novel coronavirus (SARS-CoV-2) in human serum, plasma or whole blood specimens. The kit is intended for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease 2019 (COVID-19).

SUMMARY

Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure and death.

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The 2019 novel coronavirus, formerly known as 2019-nCoV and now known as SARS-CoV-2, is a new strain of coronavirus that was first identified during an outbreak in Wuhan, China which started in December 2019.

PRINCIPLE OF THE ASSAY

WANTAI SARS-CoV-2 Ab Rapid Test employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens corresponding to SARS-CoV-2 are dry-immobilized at

the end of nitrocellulose membrane strip. SARS-CoV-2 antigens are bound at the Test Zone (T) and antibodies are bound at the Control Zone (C). When the specimen is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in specimen, SARS-CoV-2 antibody will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by the SARS-CoV-2 antibody generating a visible red line. If there is no SARS-CoV-2 antibody in specimen, no red line is formed in the Test Zone (T). The gold conjugate will continue to migrate alone until it is captured in the Control Zone (C) by the antibodies aggregating in a red line, which indicates the validity of the test.

COMPONENTS

Components	WJ-2701	WJ-2710	WJ-2750
Test Cassette	x1	X10	X50
Diluent Buffer	x1 vial	x1 vial	x5 vial

Test Cassette:

WANTAI SARS-CoV-2 Ab Rapid Test in white plastic cassette packed in foil pouch. Single use only.

Diluent Buffer (Code "0", [DIL | SPE]):

3ml per vial. The Diluent Buffer can be stored at room temperature.

Stable for 12 months after opening.

Others:

- Instructions for use

Materials required but not provided:

Clock or timer, specimen collection container, centrifuge, biohazard waste container, safety lancets and alcohol pads. **Do not use the lancet if the cap is already pulled off.**

SPECIMEN COLLECTION

- Human serum, plasma or whole blood samples are used for this test. Plasma or whole blood samples containing EDTA, sodium citrate or heparin can be used for this test. Whole blood samples can be venous whole blood, or fingertip blood.
- Samples containing suspended fibrin or aggregates and severe hemolysis (hemoglobin content greater than 400mg/L) cannot be detected, but jaundice (bilirubin content less than 1.71mmol/L) and hyperlipemia (triglyceride content less than 170mmol/L) can be detected.

- Serum and plasma samples can be refrigerated at 2-8°C for one week; In case of long-term storage, it shall be frozen below -15°C, and repeated freezing and thawing shall not exceed 3 times. Samples should be balanced to room temperature (15 minutes), mix the specimen before testing.
- It is recommended to test the whole blood specimen immediately after blood collection. Do not use the specimen after long-term storage.

STORAGE AND STABILITY

WANTAI SARS-CoV-2 Ab Rapid Test can be stored at room temperature (2-30°C, do not freeze!) for **12 months** from the date of manufacture.

PRECAUTIONS AND SAFETY

WANTAI SARS-CoV-2 Ab Rapid Test is for *In Vitro Use Only* [IVD]

FOR PROFESSIONAL USE ONLY

- This reagent is only used for in vitro testing, and the operation should be carried out in strict accordance with the instructions. Make sure that the test is not expired (EXP Date indicated on the kit box). The detection card cannot be reused.
- Do not use the samples that have been placed for too long, bacteria and peculiar smell, so as to avoid non-specific reactions caused by contamination of samples and bacteria.
- Due to the different intensity of the positive samples, the red strip of the test line (T) can show the color depth. During the specified observation time, even a very weak ribbon, regardless of its color, should be judged as a positive result.
- All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal. The desiccant in aluminum foil bag cannot be taken internally.
- At room temperature, the test card should be used within 30 minutes after it is taken out of the package to avoid prolonged exposure to humid air (humidity > 60%), which may affect the test result. If the kit is

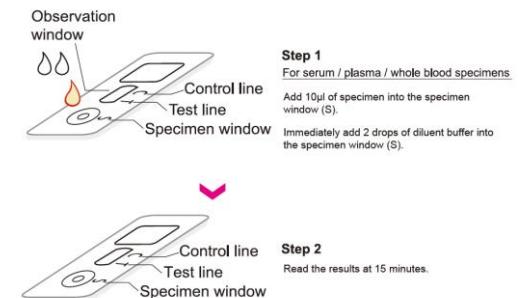
- stored at 2-8°C, the reagent should be balanced to room temperature (30 minutes) before the experiment, then open the aluminum foil bag for use.
- During the test, the test card should be laid flat on the table, so as not to cause the sample chromatography speed to be faster (or slower) and affect the test result.
 - Always interpret the results under good light conditions to avoid misreading of the test results.

ASSAY PROCEDURE

Place the cassette on flat surface. Before opening, allow the test cassette to reach room temperature. Use it immediately (within 15 minutes) after opening.

- For whole blood / serum / plasma specimens:** Open the pouch and add **10µl** of specimen into the specimen window (S). Immediately add **two drops** of diluent buffer into the specimen window.
- Read the results at 15 minutes after specimen and buffer loading.

PROCEDURE DIAGRAM



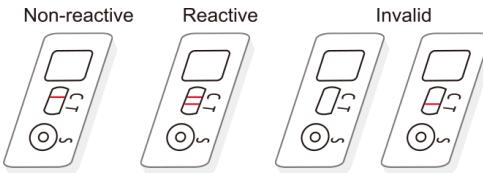
RESULTS

Quality Control: One red line will always appear next to the Control Zone (C) indicating the validity of the test.

Invalid test run: If no red line appears, the test is invalid - discard the test and repeat with new specimen and new cassette.

Reactive Results: One red line appears next to the Test Zone (T) which indicates that antibodies to SARS-CoV-2 have been detected through using this test.

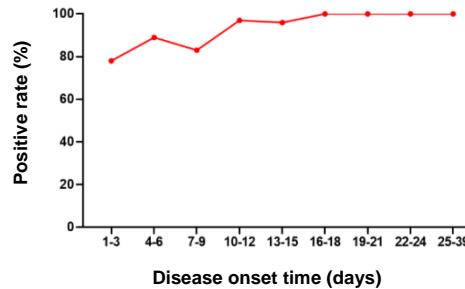
Non-reactive Results: No red line appears next to the Test Zone (T) which indicates that no antibodies to SARS-CoV-2 have been detected with this test. However, this does not exclude the possibility from infection with SARS-CoV-2.



The reactive result obtained with WANTAI SARS-CoV-2 Ab Rapid Test alone cannot be the final diagnosis of COVID-19. Any reactive results must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of all reactive specimens with other tests is required to confirm any reactive result.

PERFORMANCE DATA

- Sensitivity and specificity: clinical validation study of WANTAI SARS-CoV-2 Ab Rapid Test was conducted in 2020 in Shenzhen, China. 137 specimens from confirmed COVID-19 patients and 209 specimens from healthy individuals were tested. The kit demonstrated the sensitivity of 95.6% (131/137) and the specificity of 95.2% (199/209).
- Samples were collected from COVID-19 confirmed cases with clinical symptoms, laboratory abnormalities or pulmonary imaging manifestations. No tests have been performed on specimens from latent infections or patients in the incubation period. It was observed that the detection rate of the kit was closely related to the time of disease onset, the kit showed higher positive detection rate in specimens from patients with delayed onset. Therefore, the interpretation of the test results should consider the specimen's collection time.



LIMITATIONS

- Positive results must be confirmed with another available method and interpreted in conjunction with the patient's clinical information.
- Negative test results of this reagent do not rule out the possibility of SARS-CoV-2 infection. Patients with impaired immune function or receiving immunosuppressive therapy have limited serological antibody levels. Antibodies in samples are destroyed or inactivated; and the limitation of the reaction principle of immunochromatography; It is recommended that the patient should be reexamined within 7 to 14 days. During reexamination, the samples collected last time should be tested in parallel to confirm whether there is serological Yang rotation or significant increase in titer.
- This reagent cannot be used as a quantitative reagent.
- This reagent is only used for the detection of human serum, plasma or whole blood samples.

CE MARKING SYMBOLS:

IVD	In Vitro Diagnostic Medical Device		+2°C~+30°C Storage Conditions
	Use By		
	Content Sufficient For <n> Tests	LOT	Batch
	Instructions For Use		
	CE Marking – IVDD 98/79/EC	EC REP	EU Authorized Representative
	Catalog Number		
			Manufacturer

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