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

REF WJ-2750 (cassette version)

INTENDED USE

WANTAI SARS-CoV-2 Ab Rapid Test detects total antibody as indicative of an immune response to SARS-CoV-2 in patients suspected of previous SARS-CoV-2 infection, or for the detection of seroconversion in patients following known recent SARS-CoV-2 infection. The test may also be used to aid in the diagnosis of acute or past SARS-CoV-2 infection in conjunction with other tests and clinical information. The prevalence of SARS-CoV-2 infection in the area where testing has occurred should be considered when interpreting positive test results. The test should not be used as the sole basis for diagnosis.

In the United States, the testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate and high complexity tests. Results are for the detection of SARS-CoV-2 antibodies. Positive results could occur after infection and can be indicative of acute or recent infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. A CLIA categorization of this device would be consistent with other automated immunoassay in vitro diagnostics of moderate complexity.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the basis for patient management decisions. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

At this time, it is unknown for how long antibodies to SARS-CoV-2 virus may persist following infection.

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 2019-2020 pandemic.

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 antigen 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-2750
Test Cassette	x50
Diluent Buffer	x5vials

Test Cassette:
Test cassettes are packed in foil pouches with desiccant. Each foil pouch contains 1 cassette. Single use only.

Diluent Buffer (Code "0", DIL SPE):
3ml per vial. Buffer solution containing surfactant. 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

1. Human serum, plasma or whole blood specimens are used for this test. Plasma or whole blood specimens containing EDTA, sodium citrate or heparin can be used for this test. Whole blood specimens can be venous whole blood, or fingertip blood.
2. Specimens 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.
3. Serum and plasma specimens 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. Specimens should be balanced to room temperature, mix the specimen before testing.
4. 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

1. 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 test cassette cannot be reused.
2. Do not use the specimens that have been placed for too long, bacteria and peculiar smell, so as to avoid non-specific reactions caused by contamination of specimens and bacteria.
3. Due to the different antibody levels of the positive samples, the test line (T) may show the different color intensity. During the indicated reading time, regardless of color intensity, even very weak color, should be judged as reactive.
4. All the waste and specimens should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal. The desiccant in aluminum foil pouch cannot be taken internally.
5. At room temperature, the test cassette 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 pouch for use.
6. During the test, the test cassette should be laid flat on the table, so as not to cause the lateral flow speed of specimen to be faster (or slower) and affect the test result.
7. Always interpret the results under good light conditions to avoid misreading of the test results. The result read after 20 minutes is invalid.

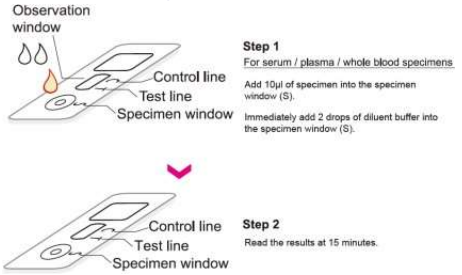
ASSAY PROCEDURE

Cassette version:

Place the cassette on flat surface. Before opening, allow the test cassette to reach room temperature. Use it immediately (within 30 minutes) after opening.

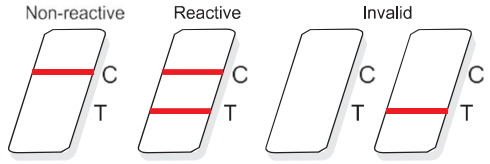
1. **For whole blood / serum / plasma specimens:** Add **10μl** of specimen into the specimen window (S). Immediately add **two drops** of diluent buffer into the specimen window.
2. Read the results at 15 minutes after specimen and buffer loading, but no later than 20 minutes.

Procedure diagram for cassette version



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 next to the Control Zone (C), 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

1. Sensitivity and specificity: clinical validation study of WANTAI SARS-CoV-2 Ab Rapid Test was conducted in 2020 in Beijing, Zhejiang and Yunnan of China. 132 specimens from confirmed COVID-19 cases and 271 specimens from the excluded COVID-19 cases and healthy individuals were tested. The kit demonstrated the sensitivity of 94.70% (125/132) and the specificity of 98.89% (268/271).

Wantai SARS-CoV-2 Ab Rapid Test evaluation centers

Clinical institution	Confirmed (Cases)	Excluded (Cases)	Total
Military Medical Sciences Academy	12	0	12
Kumming Hospital	39	195	234
Zhejiang University	81	76	157
Total	132	271	403

Summary of clinical evaluation results

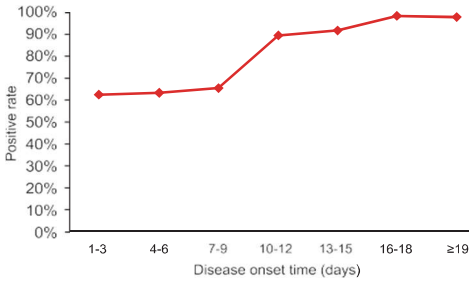
Cases		Confirmed/excluded SARS-CoV-2 results		Total
		Confirmed	Excluded	
Wantai	Positive	125	3	128
	Negative	7	268	275
Total		132	271	403

Summary of clinical performance

Performance	Results	95% CI
Sensitivity	94.70%	89.38%-97.84%
Specificity	98.89%	96.80%-99.77%
Overall agreement	97.52%	95.48%-98.80%

2. Specimens 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.

Days from symptom onset	Number of specimens from PCR-confirmed positive cases	Number of specimens positive with Wantai test	PPA
1-3	16	10	62.50%
4-6	41	26	63.41%
7-9	63	41	65.08%
10-12	77	69	89.61%
13-15	71	65	91.55%
16-18	60	59	98.33%
≥19	87	85	97.70%



3. Study was conducted to evaluate the reactivity of the test with potentially cross-reactive specimens containing antibodies against the following viruses and autoimmune conditions.

Specimen	No.	Lot #1		Lot #2		Lot #3		Specificity
		+	-	+	-	+	-	
Flu A	8	0	8	0	8	0	8	100%
Flu B	6	0	6	0	6	0	6	100%
HCV	6	0	6	0	6	0	6	100%
HBV	6	0	6	0	6	0	6	100%
ANA	5	0	5	0	5	0	5	100%
RSV	8	0	8	0	8	0	8	100%
Rhinovirus	6	0	6	0	6	0	6	100%

Specimen	No.	+	-	Specificity
alpha COV 229E	5	0	5	100%
alpha COV NL63	5	0	5	100%
beta COV OC43	7	0	7	100%
beta COV HKU1	4	0	4	100%

LIMITATIONS

1. Reactive results must be confirmed with another available method and interpreted in conjunction with the patient's clinical information.
2. Non-reactive results do not exclude the possibility of SARS-CoV-2 infection. Non-reactive results may be caused due to patients with impaired immune function or receiving immunosuppressive therapy have limited serological antibody levels, or antibodies in specimens are destroyed or inactivated, and the limitation of the reaction principle of immunochromatography; It is recommended that the patient should be retested within 7 to 14 days. During retest, the specimens collected last time should be tested in parallel to confirm whether there is seroconversion or significant increase in titer.
3. This test cannot be used for quantitative test.
4. This test is only used for the detection of human serum, plasma or whole blood specimens.

REFERENCES

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CE MARKING SYMBOLS

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

Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.
No.31 Kexueyuan Road, Changping District, Beijing
102206, China
Tel: +86-10-59528888, Fax: +86-10-89705849
Website: www.ystwt.com Email: wtexport@ystwt.com

EC REP **Qarad b.v.b.a.**
Cipalstraat 3, B-
2440 Geel, Belgium
Email:
qarad@qarad.com

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Distributed by

Human

Human Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21 65205 Wiesbaden Germany
Telefon +49 6122 9988 0 Telefax +49 6122 9988 100
E-Mail: human@human.de