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- Trockeneiszuschlag
- Gefahrgutzuschlag
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Wantai SARS-CoV-2 Diagnostics

WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative)

Rapid Test for Semi-Quantitative Detection of IgG Antibody to SARS-CoV-2

FOR SERUM / PLASMA SPECIMEN

INSTRUCTIONS FOR USE

Catalog No.: WJ-3010, WJ-3050

INTENDED USE

The WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative) is a lateral flow assay for the semi-quantitative detection of IgG antibody against SARS-CoV-2 in human serum or plasma. The test is intended for use as an aid in detecting immune response level for individuals infected with SARS-CoV-2, indicating recent or prior infection, or individuals who have been vaccinated with COVID-19 vaccines. The quantitative results obtained with this kit are for clinical reference only, should not be used as the sole basis for vaccine immunization or treatment management.

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 the recent COVID-19 pandemic.

PRINCIPLE OF THE ASSAY

The WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative) employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated SPA proteins 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). The antigen used in the assay is the receptor-binding domain (RBD) of SARS-CoV-2 spike protein. When the specimen is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in specimen, SARS-CoV-2 IgG antibody will bind with the gold conjugated SPA proteins 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. The degree of color intensity of the red line is an indicator of the concentrations of the IgG antibodies in the specimen. If there is no SARS-CoV-2 IgG 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-3010	WJ-3050
Test Cassette	x10	x50
Specimen Dilution Tube	x10	X50

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

Specimen Dilution Tube (Code "0", DIL | SPE):
1.5ml per vial. Buffer solution containing surfactant.
The Specimen Dilution Tube can be stored at room temperature.

Others:
Color Chart, Instructions for use

Materials required but not provided:
Clock or timer, specimen collection container, centrifuge, biohazard waste container.

SPECIMEN COLLECTION

1. Human serum, plasma specimens are used for this test. Plasma specimens containing EDTA, sodium citrate or lithium heparin can be used for this test.
2. Specimens containing suspended fibrin or aggregates and severe hemolysis cannot be detected, but jaundice and hyperlipemia can be detected.
3. Original specimens cannot be used directly for testing, they must be diluted in the Specimen Dilution Tube provided in this kit before testing.
4. Serum and plasma specimens can be refrigerated at 2-8°C for 72 hours; 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.

STORAGE AND STABILITY

The WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative) can be stored at 2-30°C for 18 months from the date of manufacture.

PRECAUTIONS AND SAFETY

The WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative) 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. Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.
4. Bring all reagents to room temperature before use.
5. 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.
6. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.
7. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient samples. Wash hands thoroughly after handling specimens and kit reagents.
8. 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 before the experiment, then open the aluminum foil pouch for use.
9. 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.
10. Always interpret the results under good light conditions to avoid misreading of the test results. The result read after 20 minutes is invalid.
11. Read the instructions for use carefully before testing and perform the testing strictly accordance with the instruction for use.
12. Due to methodology or antibody specificity reasons, different products from different manufacturers may produce different test results for the same specimen. Therefore, the results obtained by different products cannot be directly compared, in order to avoid incorrect medical interpretation. It is suggested that laboratories specify the characteristics of the kit in the test report sending to the clinician.

ASSAY PROCEDURE

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. Add **15μL** of serum or plasma specimen into the **Specimen Dilution Tube**, and mix well.
2. Aspirate **80μL** of diluted specimen from the Specimen Dilution Tube into the test cassette's specimen window (S).
3. Read the results at 15 minutes after diluted specimen loading, but no later than 20 minutes.

RESULTS

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

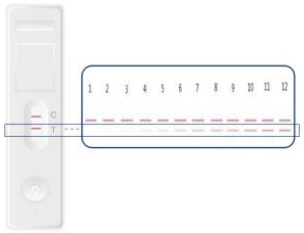
Invalid test run: If no red line appears next to the Control Zone (C), the test is invalid - discard the test and repeat with new specimen and new cassette.

One red line appears next to the Test Zone (T) and another line next to the Control Zone (C) which indicates that IgG antibody to SARS-CoV-2 has been detected through using this test.

The degree of color intensity of the red line at the Test Zone (T) can be used to estimate the concentrations of the IgG antibody in the specimen.

1. Use the provided Color Chart to compare, and record

the color intensity of the red line at Test Zone (T).



2. Estimate the IgG antibody concentrations in the specimen according to the blow table.

Color intensity	<3	3~6	6~9	>9
IgG antibody	<10GU/ml	10~60GU/ml	60~100GU/ml	>100GU/ml

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The semi-quantitative results obtained with this test should be used only as an indirect indicator for the patient's immune response against SARS-CoV-2. The estimated IgG concentrations do not necessarily indicate that the patient has antibody levels which offer protection against infection or re-infection with SARS-CoV-2.

PERFORMANCE DATA

Prospective clinical validation study of the WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative) was conducted at two sites in China in 2020. Serum and plasma specimens were evaluated from 351 subjects. Out of the 351 samples, 154 subjects were COVID-19 cases confirmed positive by an RT-PCR assay while 197 subjects were confirmed PCR negative. All patients who were confirmed positive exhibited clinical signs or symptoms of COVID-19.

Of the 154 positive samples, 125 were positive on the WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative), and of the 197 negative samples, 196 were negative. The kit demonstrated the Positive Percent Agreement (PPA) of 81.17% (125/154), the Negative Percent Agreement (NPA) of 99.49% (196/197). The kit demonstrated the Positive Percent Agreement (PPA) of 94.94% (75/79) for ≥15 days from onset of symptoms, as indicated in the tables below.

Cases		PCR Comparator SARS-CoV-2 results		Total
		Positive	Negative	
WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative)	Positive	125	1	126
	Negative	29	196	225
Total		154	197	351
PPA		81.17% (95%CI: 74.26%-86.56%)		
NPA		99.49% (95%CI: 97.18%-99.91%)		

Days from onset of symptoms	Total PCR Positive Samples	Number of Wantai Positive Result	PPA	95% CI
≤ 7	20	8	40.00%	21.88% - 61.34%
8 - 14	55	42	76.36%	63.65% - 85.63%
≥ 15	79	75	94.94%	87.69% - 98.01%
Total Subjects	154			

Retrospective analysis of the 75 positive samples (≥15 days from onset of symptoms) was conducted to measure the levels of IgG antibodies in the specimens. 100% of these specimens had IgG concentration of 100GU/ml.

To evaluate the potential cross-reactivity of the WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative) to antibodies to other viruses that may be present in the population, the following viruses and autoimmune conditions were assessed. No false positive results were observed with the WANTAI SARS-CoV-2 IgG Rapid Test (Semi-Quantitative).

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%

Precision: Two reproducibility reference samples CV1~CV2 were tested, the results were all colored, and the color intensity were same. CV1~CV2 were tested at intra-day, inter-day, by the different operators and at the different locations, the results were all colored, and the color intensity were same.

LIMITATIONS

1. Positive results must be confirmed with another available method and interpreted in conjunction with the patient's clinical information.
2. Negative 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 IgG antibody 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 is only used for the detection of human serum or plasma. Other types of specimens were not verified.

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4. Fan Wu, et al. Neutralizing antibody responses to SARS-CoV-2 in a COVID-19 recovered patient cohort and their implications.
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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 Marking – IVDD 98/79/EC

EC REP EU Authorized Representative

REF Catalog Number

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CE

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