Wantai SARS-CoV-2 Diagnostics

WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold)

Rapid Test for Detection of SARS-CoV-2 Antigen

For nasopharyngeal (NP) and oropharyngeal (OP) swab specimens

INSTRUCTIONS FOR USE

REF WJ-2910, WJ-2950

INTENDED USE

The WANTAI SARS-COV-2 Ag Rapid Test (Colloidal Gold) is a lateral flow immunochromatographic assay intended for qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasopharyngeal (NP) and oropharyngeal (OP) swab specimens directly collected, or collected in viral transport media (VTM).

SARS-CoV-2 antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient's history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with nucleic acid assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with 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 the recent COVID-19 pandemic.

PRINCIPLE OF THE ASSAY

The WANTAI SARS-COV-2 Ag Rapid Test (Colloidal Gold) employs lateral flow immunochromatography combined with double antibody sandwich method in a cassette format.

Antibodies to SARS-COV-2 are coated at the test line on the nitrocellulose membrane, and colloidal gold conjugated antibodies to SARS-COV-2 are dry-immobilized at the colloidal gold pad. During the testing, if SARS-COV-2 nucleocapsid antigen present in specimen, particles of "coated antibody - antigen - colloidal gold conjugated antibody" will be formed, and these particles aggregate at the Test Zone (T) to form a red line. If there is no SARS-CoV-2 nucleocapsid antigen in specimen, no red line will be formed at the Test Zone (T). Secondary antibodies coated at the control line on the nitrocellulose membrane can capture the colloidal gold conjugated antibody to form a red line at the Control Zone (C), which indicates the validity of the test.

COMPONENTS

Components	WJ-2910	WJ-2950
Test Cassette	x10	x50
Extraction Vial	x10	x50
Swab Extraction Buffer	6mL x1 vial	6mL x5 vials
VTM Extraction Buffer	6mL x1 vial	6mL x1 vial
Disposable Sterile Swab	x10	x50

Test Cassette: Test cassettes are packed in foil pouches with desiccant. Each foil pouch contains 1 cassette. Single use only. Anti-SARS-CoV-2 antibody (anti-N protein) is coated on NC membrane of the cassette.

Extraction Vial: Empty vial for the specimen extraction.

Swab Extraction Buffer: Borate buffer, surfactant.

VTM Extraction Buffer: Borate buffer, surfactant.

Others: Instructions for use

Materials required but not provided:
Timer, pipettor and tips, tube rack for specimens, any necessary personal protective equipment, and microbial swabs.

SPECIMEN COLLECTION

Specimen Requirements: Acceptable specimens for testing with this kit include direct nasopharyngeal and oropharyngeal swab specimens, or swab specimens collected in VTM (without inactivator such as guanidine hydrochloride).

It is essential that correct specimen collection and preparation methods be followed. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after seven days of symptoms were more likely to produce negative results when compared to an RT-PCR test. Inadequate specimen collection, improper specimen handling and/or transport may yield false negative results.

Sample Collection:
1. Nasopharyngeal and oropharyngeal swab: The swab should be a special purpose microbial swab (do not use common swabs). The head of the swab should be of medical grade artificial fiber, the material of the shaft should be plastic.
1.1 Nasopharyngeal swab: Use a microbial swab to collect samples in the nasal area. Softly rotate and push the swab, insert the head of the microbial swab deep into the nasopharyngeal at the root of the nasal cavity, rotate a few times to obtain an abundant sample. See image 1.

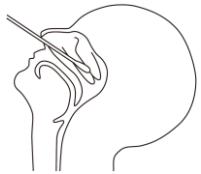


Image 1: Nasopharyngeal sampling

1.2 Oropharyngeal swab: Use a microbial swab to wipe the posterior pharyngeal wall and tonsil on both sides with moderate force. Avoid touching the tongue.
2. Specimen processing: After collecting the specimen, insert the microbial swab into the swab extraction buffer from this kit or other viral transport media.

Specimen Storage and Transportation: Specimens collected in VTM, which will be tested within 12 hours, can be stored at 2-8°C. For long-term storage, keep under -70°C. Avoid multiple freeze-thaw cycles (no more than 3 times). Before testing, balance the specimens at room temperature. The frozen samples should be mixed well before testing. Please note that if use VTM to collect specimens, the VTM must not contain inactivator such as guanidine hydrochloride, otherwise may cause the incorrect results.

STORAGE AND STABILITY

Store the kit at temperature 2°C to 30°C. Avoid direct sunlight. The kit components are stable until the expiration date printed on the outer box. Do not freeze.

PRECAUTIONS AND SAFETY

The WANTAI SARS-COV-2 Ag Rapid Test (Colloidal Gold) is for *In Vitro Use Only* IVD

FOR PROFESSIONAL USE ONLY

1. This kit 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. 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.
4. 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.
5. 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.
6. All laboratory personnel using the product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Reagents, specimens and cassettes must be at room temperature for testing. 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 reagents and cassettes should be balanced to room temperature before the testing.
8. During the testing, 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.
9. Blood or mucoid substances may interfere the test, resulting in incorrect results.
10. Read the test result at 20 minutes after the specimen loading, but no more than 30 minutes.
11. If the viscosity of newly collected swab specimen is too high, it may lead to abnormal flow and affect the performance. For this kind of specimen, increase the swab extraction buffer to twenty (20) drops.
12. Different swab may have different liquid absorption, which may cause the insufficiency of sample volume,

please squeeze the swab vigorously as much as possible. If the sample volume is still insufficient, increase the swab extraction buffer to twenty (20) drops.

13. Do not modify the test procedure.

ASSAY PROCEDURE

Check expiration date on outer box before using. Do not use any test past the expiration date on the label.

Direct Nasopharyngeal and Oropharyngeal Swab Test Procedure:

Step 1	Open the cap of the extraction vial. Add twelve (12) drops of swab extraction buffer.
Step 2	Place the swab into the extraction vial. Rotate the swab vigorously to mix well, squeeze the swab on the sides of the vial to release the liquid from the swab. Remove and properly discard the swab. Close the cap of the vial and push firmly onto the vial.
Step 3	Take out the test cassette from the foil pouch. Add four (4) drops of extracted sample from the extraction vial into the sample well of the test cassette. Read the test result at 20 minutes after the specimen loading, but no more than 30 minutes.

Nasopharyngeal and Oropharyngeal Swab in Viral Transport Media (VTM) Test Procedure:

Step 1	Open the cap of the extraction vial. Add three (3) drops of VTM extraction buffer.
Step 2	Collect 300μL of swab specimen with a calibrated pipettor from the VTM tube to add into the extraction vial, and mix well.
Step 3	Take out the test cassette from the foil pouch. Add four (4) drops of extracted sample from the extraction vial into the sample well of the test cassette. Read the test result at 20 minutes after the specimen loading, but no more than 30 minutes.

For the situation that the sample volume in VTM is not sufficient, Nasopharyngeal and Oropharyngeal Swab in Viral Transport Media (VTM) Test Procedure can be adjusted as follows:

Step 1	Open the cap of the extraction vial. Add 20μL of VTM extraction buffer with a calibrated pipettor.
Step 2	Collect 80μL of swab specimen with a calibrated pipettor from the VTM tube to add into the extraction vial, and mix well.
Step 3	Take out the test cassette from the foil pouch. Add 80μL of extracted sample with a calibrated pipettor from the extraction vial into the sample well of the test cassette. Read the test result at 20 minutes after the specimen loading, but no more than 30 minutes.

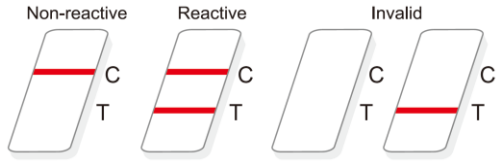
RESULTS

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.

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

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



The reactive result obtained with the WANTAI SARS-COV-2 Ag Rapid Test (Colloidal Gold) 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

The limit of detection (LoD) of 20 pg/mL for this test was established using limiting dilutions of the Nucleocapsid Protein China National Reference Material of Corona Virus Disease 2019 (code: GBW(E)091097).

The limit of detection (LoD) was 230 $TCID_{50}$/mL.

Clinical Performance: Total 148 samples included oropharyngeal swabs and nasopharyngeal swabs collected from 61 confirmed COVID-19 cases within 7 days of onset and 87 excluded COVID-19 cases (including 20 influenza A/B cases) were evaluated with this kit. The test results were compared with the test results by RT-PCR, the clinical performance is as follows:

Test results between this kit and the RT-PCR

WANTAI	RT-PCR		
	Positive	Negative	Total
Positive	57	0	57
Negative	4	87	91
Total	61	87	148
Positive Percent Agreement (PPA)	93.44% (95% CI: 84.32%-97.42%)		
Negative Percent Agreement (NPA)	100.00% (95% CI: 95.77%-100.00%)		

The results show that the positive percent agreement of the test was 93.44% (57/61) and the negative percent agreement was 100.00% (87/87), which indicates that the WANTAI SARS-COV-2 Ag Rapid Test (Colloidal Gold) has a good detection rate for cases of the early disease onset.

The cross-reactivity of the WANTAI SARS-COV-2 Ag Rapid Test (Colloidal Gold) was evaluated by testing of a panel of high prevalence respiratory pathogens.

No.	Pathogen	Results
N1	Staphylococcus aureus	Neg
N2	S.pneumoniae	Neg
N3	Measles virus	Neg
N4	Mumps virus	Neg
N5	Ad type 3	Neg
N6	Mycoplaa Pneumoniae	Neg
N7	Parainfluenza virus 2	Neg
N8	HMPV	Neg
N9	Human coronavirus OC43	Neg
N10	Human coronavirus 229E	Neg
N11	Bordetella parapertussia	Neg
N12	Influenza B virus (Victoria)	Neg
N13	Influenza B virus (Y series)	Neg
N14	Influenza A H1N1(2009)	Neg
N15	Influenza A H3N2 virus	Neg
N16	Avian influenza virus H7N9	Neg
N17	Avian influenza virus H5N1	Neg
N18	EB virus	Neg
N19	Enterovirus CA16	Neg
N20	Rhinovirus	Neg

The following substances have been tested and found non-reactive: whole blood (2% v/v), Mucin (1mg/mL), Azithromycin (500μg/mL), Gefixime (50μg/mL), Aspirin (0.15mg/mL), Mentholatum (1mg/mL), Chewing gum (50mg/mL), OTC Throat drop (lemonmint) (Ricola) (100mg/mL), OTC Throat drop (forest blossom) (Ricola) (100mg/mL), OTC Fluticasone Propionate Nasal Spray (0.11μg/mL), Biotin (1mg/mL).

LIMITATIONS

1. The test is used for the detection of SARS-CoV-2 nucleocapsid antigen from human nasopharyngeal swab and oropharyngeal swab.
2. Test performance depends on the amount of virus in the sample and may or may not correlate with viral culture results performed on the same sample.
3. A negative result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly. Sample collected after day 7 of illness are more likely to be negative. A negative test result does not eliminate the possibility of SARS-CoV-2 infection.
4. A positive test result does not rule out co-infections with other pathogens. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
5. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
6. Failure to follow the procedure may adversely affect test performance and/or invalidate the test result.
7. Specimens should be collected into VTM without inactivator such as guanidine hydrochloride. However, there are still circumstances that could affect testing results. Please evaluate VTM from different manufacturers before using it.

REFERENCES

1. Lauer, S.A., et. al. The incubation period of Coronavirus disease 2019 (COVID-19) from publicly reported confirmed cases: estimation and application.
doi: https://doi.org/10.7326/M20-0504
2. Bo Diao et. al. Diagnosis of Acute Respiratory Syndrome Coronavirus 2 Infection by Detection of Nucleocapsid Protein
doi: https://doi.org/10.1101/2020.03.07.20032524
3. https://www.who.int/emergencies/diseases/novel-coronavirus-2019

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

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 BV**
Cipalstraat 3, 2440 Geel, Belgium

CE

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