

Wantai SARS-CoV-2 Diagnostics

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

Self Test for Detection of SARS-CoV-2 Antigen

For anterior nasal swab and saliva

INSTRUCTIONS FOR USE

REF WJ-2901, WJ-2905, WJ-2910, WJ-2925

1/5/10/25

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 anterior nasal swab and saliva specimens. The test is intended for self-testing by layperson. Children and adolescents under the age of 18 must be supported by parents or eligible adults.

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-2901	WJ-2905	WJ-2910	WJ-2925
Test Cassette	x1	x5	x10	x25
Extraction Vial (0.5mL)	x1	x5	x10	x25
Disposable Sterile Swab	x1	x5	x10	x25
Plastic Sealable Bag	x1	x5	x10	x25
Instructions For Use & Operation Guide	x1	x1	x1	x1

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: 0.5mL per vial containing borate buffer and surfactant for the specimen extraction.

Disposable Sterile Swab: CE 0197 MDD 93/42/EEC, 

Materials required but not provided: Timer.

SPECIMEN COLLECTION

Specimen Requirements: anterior nasal swab and saliva specimens. 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.

Specimen Collection Procedure:

Anterior nasal swab:

- Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.
- Insert the entire absorbent tip of the swab into your nostril.
- Slowly rotate the swab in a circular path against the inside of your nostril at least 4 times for a total of 15 seconds. Be sure to collect any nasal drainage that may be present on the swab.
- Gently remove the swab.
- Using the same swab, repeat steps 2-4 in your other nostril.



Saliva specimen:

- Remove the swab from the container, being careful not to touch the soft end, which is the absorbent tip.
- Insert the entire absorbent tip of the swab into your mouth.
- Use the swab to slowly wipe the oral upper palate and the inside of the left and right cheeks. Be sure to collect any saliva that may be present on the swab.
- Gently remove the swab.



Specimen Storage and Transportation: The specimen should be tested immediately after collection.

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* 

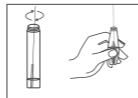
1. This kit is intended for use for self-testing by untrained individuals, the operation should be carried out in strict accordance with the instructions. Make sure that the test is not expired (EXP Date indicated on the kit box). The test cassette cannot be reused.

- All the waste and specimens should be treated in case of transmitting disease and must be properly disposed –place all the components in the plastic sealable bag provided, seal the bag and throw it into the trash bin.
- 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.
- Do not eat, use oral or nasal spray products (such as toothpaste, mouthwash or drug spray) for at least 30 minutes before the anterior nasal swab or saliva sample is collected, otherwise the test may show incorrect results.
- 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.
- During the testing, the test cassette should be laid flat on the table and away from wind. This is to avoid inconsistency in the lateral flow migration of specimen once it is added into the test cassette.
- Blood or mucoid substances presented in the specimen, or too sticky specimens may interfere with the test reaction, resulting in incorrect results.
- Read the test result at 15 minutes after the specimen loading, but no more than 30 minutes.
- In some cases, the C-line color intensity may appear weaker, this is a normal phenomenon. The test run is considered invalid only when there is a complete lack of color development at the C-line.
- Always interpret the results under good light conditions to avoid misreading of the test results.
- Do not modify the procedure.
- This test kit is intended for anterior nasal swab and saliva specimens. Do not use the swab for nasopharyngeal and oropharyngeal specimens for self testing.

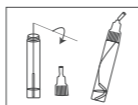
ASSAY PROCEDURE

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

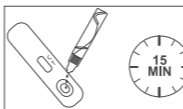
- Schritt 1** Unscrew the cap of the extraction vial. Place the swab collected into the extraction vial with the buffer, rotate the swab vigorously to mix well with the buffer, squeeze the swab against the inside of the vial to release the liquid from the swab.



- Schritt 2** Snap off the end of the swab at the break line and leave the swab head in the vial. Screw tightly the cap of the vial. Break the cap of the extraction vial.



- Schritt 3** Take out the test cassette from the foil pouch, place it on flat surface. Squeeze the vial to add three (3) drops of extracted sample from the extraction vial into the sample well of the test cassette. Read the test result at 15 minutes after the specimen loading, but no more than 30 minutes.



- Schritt 4** Place all the components in the plastic sealable bag provided, seal the bag and throw it away.



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.

Positive 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.

Negative 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 positive result obtained with the WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold) alone cannot be the final diagnosis of COVID-19. Individuals who test positive with the WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold) should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, do not rule out SARS-CoV-2 infection 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 an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

PERFORMANCE DATA

1. Analytical sensitivity: the WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold) limit of detection (LoD) has been established for different analytical units.

Limit of Detection (LoD) / unit of measurement	LoD
pg/mL (China National Reference (code: GBW(E)091097))	25
TCID50/mL	137
copies/mL (swab)	147
copies/mL (VTM)	2090

2. Diagnostic sensitivity and specificity: During clinical studies conducted with this test, total of 480 nasopharyngeal and 762 anterior nasal swabs which included 390 RT-PCR confirmed positive and 852 RT-PCR confirmed negative samples were tested, and total of 482 saliva specimens which included 146 RT-PCR confirmed positive and 336 RT-PCR confirmed negative samples were tested. In addition, self-testing by a layperson study was conducted and the test results by laymen were compared to the test results from the professional use of the test.

The sensitivity of the test for all specimen types was 90.11% (483/536) and the specificity was 99.24% (1179/1188). Detailed clinical performances of the test are summarized below:

- On nasopharyngeal swabs, the sensitivity was 91.91% (125/136) and the specificity was 98.55% (339/344).
- On anterior nasal swabs, the sensitivity was 89.76% (228/254) and the specificity was 99.61% (506/508).
- On saliva specimens, the sensitivity was 89.04% (130/146) and the specificity was 99.40% (334/336).
- As a self-test, the positive and the negative agreements in results between self testing and professional use testing for anterior nasal swabs were 98.99% (98/99) and 100% (313/313) respectively, and for saliva specimens these were 97.87% (92/94) and 100% (156/156) respectively.

3. Cross-reactivity: Cross reactivity of the WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold) was evaluated by testing the following panel in the table below. Each of the samples was tested in triplicate. No cross reactivity was seen except for SARS-coronavirus and MERS-coronavirus.

Potential Cross-Reactant	Concentration
Human coronavirus 229E	Not available
Human coronavirus OC43	Not available
Human coronavirus HKU1	Not available
Human coronavirus NL63	Not available
SARS-coronavirus (N antigen)	0.044 mg/ml
MERS-coronavirus (N antigen)	0.16 mg/ml
Adenovirus	>10 ⁶ TCID ₅₀ /ml
Human Metapneumovirus (hMPV)	Not available
Parainfluenza virus	>10 ⁶ TCID ₅₀ /ml
Influenza A	>10 ⁶ PFU/ml
Influenza B	>10 ⁶ PFU/ml
Enterovirus	>10 ⁶ PFU/ml
Respiratory syncytial virus	>10 ⁶ PFU/ml
Rhinovirus	>10 ⁶ PFU/ml
Chlamydia pneumoniae	Not available
Haemophilus influenzae	>10 ⁶ CFU/ml
Mycobacterium tuberculosis	Not available
Streptococcus pneumoniae	>10 ⁶ CFU/ml
Mycoplasma pneumoniae	>10 ⁶ CFU/ml
Pooled human nasal wash - to represent diverse microbial flora in the human respiratory tract	Not available

4. The following substances have been tested and found negative with the WANTAI SARS-CoV-2 Ag Rapid Test (Colloidal Gold): Whole blood (2% v/v), Mucin (1mg/mL), Hemoglobin (100mg/L), Bilirubin (0.68mmol/L), Triglycerides (13mmol/L), Rheumatoid factor (70IU/mL), Azithromycin (500µg/mL), Cefixime (50µg/mL), Aspirin (0.15mg/mL), Mentholatum (1mg/mL), Chewing gum (5mg/mL), OTC Throat drop (lemonmint) (10mg/mL), OTC Throat drop (forest blossom) (Ricola) (10mg/mL), OTC Fluticasone Propionate Nasal Spray (0.11µg/mL), Biotin (1mg/mL).

5. 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


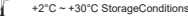














- The test is intended for anterior nasal swab and saliva specimens only. Using another sample collection device or method may cause false results.
- Test performance depends on the amount of virus in the sample and may or may not correlate with viral culture results performed on the same sample.
- A 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.


- A positive test result does not rule out co-infections with other pathogens. Positive test result do not differentiate between SARS-CoV and SARS-CoV-2.
- Failure to follow the procedure may adversely affect test performance and/or invalidate the test result.

REFERENCES

- Lauer, S.A., et al. The incubation period of Coronavirus disease 2019 (COVID-19) from confirmed cases: estimation and application. doi: <https://doi.org/10.7326/M20-0504>
- 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>
- <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>

CE MARKING SYMBOLS

 In Vitro Diagnostic Medical Device	
 Use By	 Batch
 Content Sufficient For <=> Tests	 Instructions For Use
 CE Marking - IVDD 98/79/EC	 EU Authorized Representative
 Catalog Number	 Manufacture Date
 Single Use	 Manufacturer
 Keep Dry	 Sterile (radiation)
 Keep Away From Direct Sunlight	 Do Not Use If Package Is Damaged

 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: wtxepor@ystwt.com

 QIPAR BV
Cipalstraat 3, 2440 Geel, Belgium

 2854

WANTAI SARS-CoV-2

Ag Rapid Test (Colloidal Gold)

(Anterior Nasal Swab and Saliva Specimens)
Intended for Self-testing by Layperson

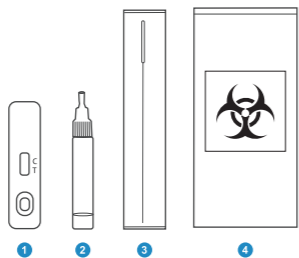
Operation Guide

Preparation

- Read carefully the Instructions for Use before you conduct the test.
- Take all the components out and place them on the table.

Test components :

- 1 - Test Cassette
 - 2 - Extraction Vial (0.5mL)
 - 3 - Disposable Sterile Swab
 - 4 - Plastic Sealable Bag
- Instructions For Use & Operation Guide



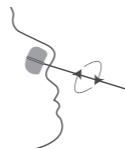
You may scan the QR code to watch the operation video.



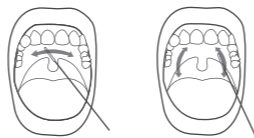
Step 1. Collect Specimen

- Open the swab pouch.
- You may choose between two specimen types for collection:

Anterior nasal swab specimens: Insert the entire absorbent tip of the swab into your nostril and slowly rotate in a circular path against the inside of both of your nostrils. Rotate 4 times for total of 15 seconds.



Or,
saliva specimens: Insert the entire absorbent tip of the swab into your mouth and slowly wipe the oral, upper palate and the inside of the left and right cheeks (be sure to collect any saliva that may be present on the swab).

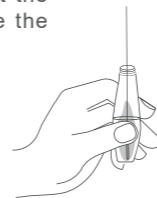


Step 2. Extracting specimens

- Unscrew the cap of the extraction vial.
- Place the swab collected into the extraction vial with the buffer, rotate the swab vigorously to mix well with the buffer.

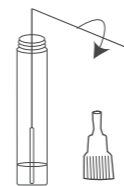


- Squeeze the swab against the inside of the vial to release the liquid from the swab.



Step 3. Remove the swab

- Snap off the end of the swab at the break line and leave the swab head inside the vial.

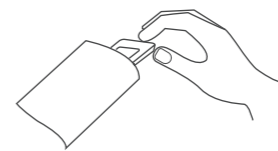


- Screw tightly the cap of the vial. Break the cap of the extraction vial.

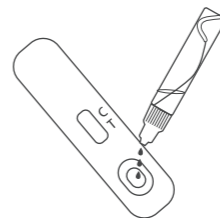


Step 4. Testing

- Open the cassette pouch and place the cassette on a flat surface.

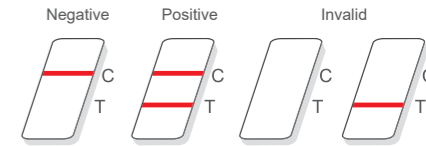


- Squeeze the vial to add three (3) drops of sample from the extraction vial into the sample well of the test cassette. Wait for 15 minutes.



Step 5. Read the results

- Read the test result at 15 minutes, but no more than 30 minutes



Disposal

- Place all the components in the provided plastic sealable bag. Seal the bag and throw it away.

