SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Instructions for Use

【PRODUCT NAME】

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

【PACKAGE AND SPECIFICATION】

20 Tests/box (1Test/bag ×20 Bags) ,40 Tests/box (1Test/bag ×40 Bags)

【INTENDED USE】

For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in oral fluid directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days after onset of symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, not for at-home testing.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M), and nucleocapsid (N).

The antigen is detectable in oral fluid samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a 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, which 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 a patient'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.

For in vitro diagnostic use only. For professional use only

【TEST PRINCIPLE】

JOYSBIO Biotechnology's SARS-CoV-2 Antigen Rapid Test Kit uses an immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in oral fluid samples from patients with signs and symptoms of infection who are suspected of COVID-19.

Key components: the anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with anti-nucleocapsid protein antibody, and goat anti-chicken IgY antibody.

When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to colloidal gold in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A color band will show up when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the device.

【COMPONENT】

Materials provided:

COMPONENT	20Tests/Kit	40Tests/Kit	Main components
Test card	20 Tests/Kit (1Test/bag ×20 Bags)	40 Tests/Kit (1Test/bag ×40 Bags)	The anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with anti-nucleocapsid protein antibody and goat anti-chicken IgY antibody.
Desiccant	20 packs	40 packs	Silica Gel
Buffer	350 μL /bottle×40 bottles	350 μL /bottle×80 bottles	Detergent solution
Extraction tube	20 single-use reaction tubes, each with 1x nozzle cap	40 single-use reaction tubes, each with 1x nozzle cap	/
Specimen collection bag	20 sterile, single-use specimen collection bags	40 sterile, single-use specimen collection bags	/
Dropper	20 single-use Droppers	40 single-use Droppers	/

Materials required but not provided with the kit: N/A

SARS-CoV-2 (+)	1 each – individually wrapped for single-use	Non-infectious, recombinant viral protein antigen with less than 0.1% Proclin 300.
SARS-CoV-2 (–)	1 each – individually wrapped for single-use	Buffer with less than 0.1% Proclin 300.

【STORAGE AND STABILITY】

1. Store at 2~30℃ in the sealed pouch up to the expiration date and the validity is tentatively 24 months. **Do not freeze**.
2. The test cassette should be used within 1 hour after taking out from the aluminum foil bag.
3. Keep away from sunlight, moisture, and heat.

【SPECIMEN COLLECTION AND HANDLING】

1. Specimen Collection and Preparation

The oral fluid specimen should be collected using the collection bag provided with the kit. Correct specimen collection and preparation methods must be followed. No other collection devices should be used with this assay. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result.

2. Specimen Transport and Storage

Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection.

3. Oral Fluid Specimen Collection

a. Before collecting oral fluid relax your cheeks and gently massage cheeks with fingers for 15-30 seconds, Place the tongue against the upper and lower jaws and roots to enrich the oral fluid.

b. Gently spit oral fluid into the collection bag.The sample is now ready for processing using the kit.

4.DOs and DON'Ts of Sample Collection

a.Do collect samples as soon as possible after the onset of symptoms.

b.Do test samples immediately.

c.Use only collection bags provided with the kit.

d. The sample is best collected after getting up early in the morning

e. Do not eat or drink within 1 hour before sampling.

f.Do not place the collection bags back into the collection bags packaging sleeve after specimen collection.

5. Precautions

a. For in vitro diagnostic use.

b. This test has been authorized only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.

c. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.

d. Proper sample collection, storage and transport are essential for correct results.

e. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.

f. Do not use kit past its expiration date.

g. Do not mix components from different kit lots.

h. Do not reuse the used test card.

i. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.

j. Do not store specimens in viral transport media for specimen storage.

k. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

l. Solutions used to make the positive control specimen are non-infectious. However, patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.

m. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.

n. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically and add drops slowly.

o. Collection bags in the kit are approved for use with the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold). **Do not use other collection bags.**

p. The Extraction Reagent packaged in this kit contains saline, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.

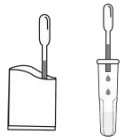
【TEST PROCEDURE】

1.The test kit, the specimen must be at room temperature (15~30℃) for before testing. The kit is only intended for oral fluid specimens that are collected and tested directly (i.e., oral fluid that have **NOT** been placed in transport media).

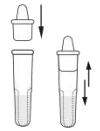
2.Freshly collected specimens should be processed within 1 hour.

•Step 1:
Twist off the top of the buffer bottle, slowly dispense all of the 2 bottles of buffer into the extraction Tube.
NOTE: If the volume of buffer is excessive or insufficient,an Inaccurate test result may occur .

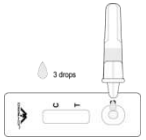
•Step 2:
Hold the dropper vertically and draw oral fluid from collection bag and transfer 3 drops of oral fluid into the extraction tube.



•Step 3:
Mix thoroughly by swirling or flicking the bottom of the tube. Place the extraction tube(s) in a rack in the designated area of the workspace.



•Step 4:
Tear off the foil pouch, take out the test cassette and place the test kit on a clean and level surface. Label the test device and one extraction tube for each specimen or control to be tested.



•Step 5
Gently squeeze the ridged body of the tube, dispensing **three (3) drops** of the processed specimen into the sample well.

•Step 6
Read the test results between **15 and 20 minutes.** Do not read the results after **20 minutes.**

NOTE: **Do not use tubes or tips from any other product, or from other manufacturers.**

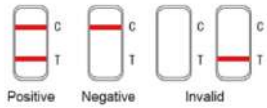
【INTERPRETATION OF TEST RESULTS】

1.POSITIVE: Two lines appear. A colored line should be in the control line region (C), a colored line appears in the test line region (T). Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

2.NEGATIVE: Only one colored control line appears. Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results be confirmed by a molecular testing method, if necessary, for patient management.

3.INVALID: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

4.Result determination time: The result should be judged within **15~20 minutes** after the sample is added into the sample well, and the result displayed after **20 minutes** is invalid.



(The picture is for reference only)

【LIMITATIONS OF TEST METHOD】

1. This product is only suitable for a qualitative test and auxiliary diagnosis.
2. The test results are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, physical signs, medical history, other laboratory tests, therapeutic reaction, and epidemiological information.
3. Users should test specimens as quickly as possible after specimen collection.
4. Positive test results do not rule out co-infections with other pathogens.
5. Results from the test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
6. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly;

therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.
7. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to an RT-PCR assay.
8. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
9. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from oral fluid specimens only.
10. The kit performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
11. Negative test results are not intended to rule in other non-SARS-CoV-2 viral or bacterial infections.
12. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false-positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False-negative test results are more likely when the prevalence of disease caused by SARS-CoV-2 is high.
13. This kit has been evaluated for use with human specimen material only.
14. Monoclonal antibodies may fail to detect or detect with less sensitivity, SA
RS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
15. The performance of this test has not been evaluated for use in patients without signs and symptoms of infection and performance may differ in asymptomatic individuals.
16. The sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to an RT-PCR SARS-CoV-2 assay.
17. Negative results should be treated as presumptive and confirmed with an molecular assay, if necessary, for clinical management, including infection control.
18.Specimen stability recommendations are based upon stability data from influenza testing and performance may be different from SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within one hour after specimen collection.
19. The validity of the kit has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

【PERFORMANCE CHARACTERISTICS】

1. Clinical Performance

The performance of the kit was established with 362 oral fluid prospectively collected and enrolled from individual symptomatic patients who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases.
Oral fluid were collected and handled as described in the instruction of the kit. All specimens were selected and then sequentially tested in a blinded fashion. The performance of the kit was compared to results of a commercialized molecular assay.
The kit showed 95.10% of sensitivity and 100% of specificity.

Table 1. Clinical Study Results from symptom onset

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	97	0	97
negative	5	260	265
Subtotal	102	260	362

Positive Percent Agreement (PPA)= 97/102(95.10%)
（95%CI:88.9%~98.4%）
Negative Percent Agreement (NPA)= 260/260(100%)
（95%CI:98.6%~100%）
Accuracy=(97+260)/362×100%=98.62%
Kappa=2×25220/ 52250=0.97＞0.5

2. Assay Cross-Reactivity

Cross-Reactivity: There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus.

Table 2: Cross-reactivity Results

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
Influenza A	1.6 x 10^5 $TCID_{50}$/mL	NO
Influenza B	1.6 x 10^5 $TCID_{50}$/mL	NO
Human coronavirus HKU1	1.6 x10^5 $TCID_{50}$/mL	NO
Human coronavirus OC43	1.6 x10^5 $TCID_{50}$/mL	NO
Haemophilus influenzae	2.2x 10^5 $TCID_{50}$/mL	NO
MERS-coronavirus	2.1 x 10^5 $TCID_{50}$/mL	NO
SARS-coronavirus	3.2 x 10^5 PFU/mL	YES
Adenovirus C1	1.5 x 10^5 $TCID_{50}$/mL	NO
Adenovirus 71	1.5 x 10^5 $TCID_{50}$/mL	NO
Candida albicans	4.2 x 10^5 CFU/mL	NO
Respiratory syncytial virus	5.1 x 10^5 $TCID_{50}$/mL	NO
Enterovirus	5.4 x 10^5 $TCID_{50}$/mL	NO
Malaria	2.2 x 10^6 CFU/mL	NO
Dengue	1.2 x 10^5 $TCID_{50}$/mL	NO
Human coronavirus NL63	1.7x 10^5 $TCID_{50}$/mL	NO
Human coronavirus 229E	2.2 x 10^5 $TCID_{50}$/mL	NO
Streptococcus pneumoniae	1.1 x 10^6 CFU/mL	NO
Pneumocystis jirovecii	1.0 x 10^5 $TCID_{50}$/mL	NO
Legionella pneumophila	1.4 x 10^6 CFU/mL	NO
Chlamydia pneumoniae	1.1 x 10^6 IFU/mL	NO
Human Metapneumovirus (hMPV)	1.1 x $10^5$$TCID_{50}$/mL	NO
Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/mL	NO
Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL	NO
Parainfluenza virus 3	3.5 x 10^5 $TCID_{50}$/mL	NO
Parainfluenza virus 4	1.4 x 10^5 $TCID_{50}$/mL	NO
Rhinovirus	1.3 x 10^5 PFU/mL	NO
Mycoplasma pneumoniae	1.8 x 10^6 CFU/mL	NO
Bordetella pertussis	1.5 x 10^6 CFU/mL	NO
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL	NO
Pooled human nasal wash-representative of normal respiratory microbial flora	100%	NO
Streptococcus pyogenes	1.0 x 10^6 CFU/mL	NO

3.Potentially Endogenous Interfering Substances

SARS-CoV-2 Antigen samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity or false negativity was found with the following:

Interfering substances	concentration	Interfering substances	concentration
Whole Blood	5%	Dexamethasone	0.7mg/mL
Flunisolide	7.1ng/mL	Mucin	0.54%
CVS Nasal Drops (Phenylephrine)	17%v/v	Orange juice	100%
Rebetol	4.8 ug/mL	Afrin(Oxymetazoline)	14%v/v
Relenza	290 ng/mL	Mouthwash	2%
Tamiflu	1.1 ug/mL	Caffeine	1mg/mL
Tobryamycin	2.45 mg/mL	Mupirocin	12 mg/mL
Tea	33.7 mg/mL	Coca Cola	/
Milk	11.5%	Toothpaste	/

4.Limit of Detection (ANALYTICAL SENSITIVITY)

The LoD for the SARS-CoV-2 antigen rapid test kit is 3.2 x $10^2$$TCID_{50}$/mL.
The LoD for the SARS-CoV-2 antigen rapid test kit was established using limiting dilutions of cell-culture derived novel coronavirus. The material was supplied at a concentration of 1.3 x 10^6 $TCID_{50}$/mL. An initial range-finding study was performed testing devices using a 10-fold dilution series. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using this concentration, the LoD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

5.Hook Effect:

As part of the LoD study, the highest concentration of the sample (1.3 x 10^6 $TCID_{50}$/mL) was tested. There was no Hook effect detected.

【WARNINGS】

1.A negative result can occur if the SARS-CoV-2 virus present in the specimen is below the sensitivity of the kit.
2.Not for the screening of donated blood.
3.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
4.Dispose of all specimens and materials used to perform the test as biohazardous waste.
5.Handle the negative and positive controls in the same manner as patient specimens for operator protection.
6.Do not perform the test in a room with strong airflow, i.e. an electric fan or strong air-conditioning

【EXPLANATION OF LABELS】

IVD	In Vitro Diagnostic Use		See Instruction for Use	REF	Catalog #
LOT	Batch Number		Expiry Date		Manufacturing Date
	Do not reuse		Store between 2～30℃		Keep away from Sunlight
	Keep Dry		Manufacturer	EC REP	EU Authorized Representative
CE	CE Mark				

【BASIC INFORMATION】

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