SARS-CoV-2 Antigen rapid test kit -PRO

(Colloidal Gold)

Instructions for Use (IFU)

【PRODUCT NAME】

SARS-CoV-2 Antigen rapid test kit -PRO (Colloidal Gold)

【PACKAGE AND SPECIFICATION】

1Test/box (1Test/pouch ×1 pouch), 20 Tests/box (1Test/pouch ×20 pouches)

【INTENDED USE】

For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal, oropharyngeal, and nasopharyngeal swab specimen directly from individuals who are suspected of COVID-19 after onset of symptoms. This test is compatible with SARS-COV-2 variants which have mutation on spike protein, such as 20I/501Y.V1 and 20H/501Y.V2. This test is provided for use by clinical laboratories or to healthcare workers for point-of-care testing. Not for children under the age of 3.

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 generally detectable in upper respiratory 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-PRO uses an immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory 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	20x Tests/Kit	1x Test /Kit	Main Components
Test Device	20 Tests/box (1Test/ pouch × 20 pouches)	1Test/box (1Test/ pouch ×1 pouch)	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	20x Packs	1x Pack	Silica Gel
Extraction Tube with Buffer	350 μL /bottle x20 bottles	350 μL /bottle x1 bottle	Detergent Solution
Sampling Swab	20x pcs	1x pc	/

Materials required but not provided with the kit: Timer

【STORAGE AND STABILITY】

1. Store at 2~30°C 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

This product is compatible with nasal, oropharyngeal, and nasopharyngeal swab specimens. Correct specimen collection and preparation methods must be followed. 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; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

2. Specimen Transport and Storage

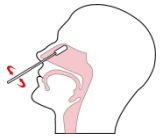
Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Correct specimen collection and preparation methods must be followed.

3. Specimen Sampling Procedure

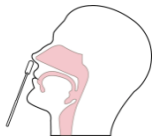
Please select one of the following specimen sampling procedure to collect either nasal, oropharyngeal, or nasopharyngeal specimen.

3.a Option 1 – Nasal Swab Specimen Collection

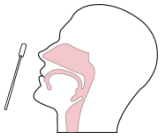
Step 1 Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times firmly along the mucosa inside the nostril to ensure that both mucus and cells are collected.



Step 2. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.



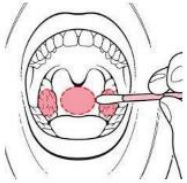
Step 3. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the kit.



3.b Option 2 - Oropharyngeal Specimen Collection

Step 1: Position the head back slightly, open the mouth wide to expose the tonsils and back of the throat.

Step 2: Use a sampling swab to collect specimen by rubbing the swab up and down against the back of the throat (red area in the image) for 10-15 seconds, avoiding the tongue and cheeks.



Step 3: Remove the swab while avoiding touching the tongue and cheeks.

3.c Option 3 - Nasopharyngeal specimen collection

Step 1: Position the head slightly back.

Step 2: Gently insert the swab into the nostril. Keep the swab near the septum floor of the nose while gently pushing the swab into the post nasopharynx until resistance is met.

Step 3: When the swab is in place, rotate in a circular motion gently against the nasopharyngeal mucosa for 10 – 15 seconds then gently remove swab.

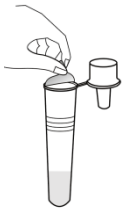
4.DOs and DON’Ts of Sample Collection

1. Do collect samples as soon as possible after the onset of symptoms.
2. Do test samples immediately.
3. Use only swabs provided with the kit.
4. Do not place the swab back into the swab packaging sleeve after specimen collection.

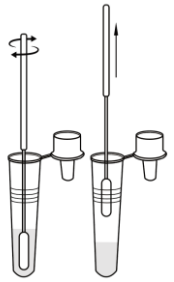
【TEST PROCEDURE】

1. The test kit, the specimen must be at room temperature (15~30°C) for before testing. The kit is only intended for nasal, oropharyngeal, or nasopharyngeal swab specimens that are collected and tested directly (i.e., swabs that have **NOT** been placed in transport media). The kit includes a pre-diluted processing reagent in a ready to use buffer bottle. This kit **IS NOT INTENDED** for testing liquid samples such as a wash or aspirate samples or swabs in transport media as results can be compromised by over dilution.

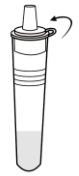
•Step 1:
Peel off the sealing film of extraction tube.



•Step 2:
After sampling, insert the swab into the bottom of the extraction tube. Please roll the swab for five turns, and then move the swab up and down in the buffer for a minimum of 20 seconds (do not spill the solution). Remove the swab while simultaneously push against the side of the extraction tube to extract the liquid from the swab.

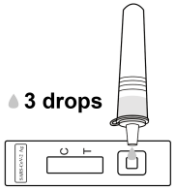


•Step 3:
Please close the cap onto the extraction tube with the processed sample. Mix it thoroughly by twisting the tube or flicking its bottom.



•Step 4:
Tear off the foil pouch, take out the test strip/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:
Remove the nozzle cap of extraction tube. *Gently squeeze the ridged body of the tube, dispensing **three (3) drops** of the processed specimen into the sample well.* Cap the nozzle cap back to extraction tube after use.



•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 (T) region. 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.

！ Important information in the event of a positive test result:

You are obliged to immediately go into domestic isolation (isolation). Likewise, the members of your household should isolate themselves immediately.

Only leave your apartment or house in the event of a medical or other emergency.

Have a PCR test carried out to confirm suspicion of SARS-CoV-2 infection. Talk to your doctor about further measures for you and your contact persons.

Contact the responsible health department.

Let your employer know that you have had a positive test result.

Note the quarantine rules!

Observe the most important rules of conduct and hygiene to protect your household members from infection:

-Distance (if possible, stay in a separate room)

-Hygiene,

-Wearing suitable protective masks,

-Regular ventilation.

Inform the persons you contacted in the past 14 days about your possible infection. Write down your contact persons! If you have any complaints, seek medical advice immediately.

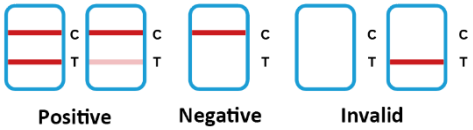
Please note that the legal bases and instructions of the respective responsible government, or the district or city, or the responsible health department apply.

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)

5. Precautions

a. For use in in vitro diagnostics.
b. This test is only approved for the detection of SARS-CoV-2 antigen, not for other viruses or pathogens.
c. Treat all specimens as potentially infectious. Use general precautions when handling specimens, this kit, and its contents.
d. Correct specimen collection, storage and transport are important for correct results.
e. Leave the test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
f. Do not use the kit after the expiration date.
g. Do not mix components from different kit lots.
h. Do not reuse the used test card.
i. Inadequate or improper sample collection, storage, and transport can lead to incorrect test results.
j. Do not store specimens in viral transport media for specimen storage.
k. All components of this kit should be disposed of as biological hazardous waste in accordance with federal, state and local regulations.
l. The solutions used to prepare the positive control sample are not infectious. However, patient samples, controls, and test cards should be treated as if they could transmit disease. Observe the specified precautionary measures against microbial hazards during use and disposal.
m. Wear appropriate personal protective equipment and gloves when performing any test and handling patient samples. Change gloves between handling samples suspected of having COVID-19.
n. INVALID RESULTS can occur when an insufficient volume of extraction buffer is added to the test card. To ensure adequate volume is dispensed, hold the bottle upright and slowly add the three drops.
o. The accessories in the kit are approved for use with the novel coronavirus antigen (colloidal gold) test kit. Do not use any other accessories.
p. The extraction reagent packaged in this kit contains saline, detergents, and preservatives that inactivate cells and virus particles. The samples eluted in this solution are not suitable for culture.

【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 nasal swab 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, SARS-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 respiratory 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 FDA authorized 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 determined on 334 nasal swab specimens of patients suspected of COVID-19, which during the daily clinical practice at Heilongjiang Provincial Hospital. For each of the 334 patients, a nasopharyngeal swab was taken for molecular diagnosis using RT-PCR and a nasal swab for the antigen rapid test. The samples were taken by qualified personnel. The nasal swabs were taken using the double nasal hole method and processed as described in the kit instructions. The kit showed a diagnostic sensitivity of 98,18% and a diagnostic specificity of 99,55% compared to RT-PCR results.

Table 1. Clinical Study Results

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	108	1	109
negative	2	223	225
Subtotal	110	224	334

Positive Percent Agreement (PPA)= 108/110(98.18%)（95%CI:93.6%~99.8%）
Negative Percent Agreement (NPA)= 223/224(99.55%)
（95%CI:97.5%~100.0%）
Accuracy= (108+223)/334×100%=99.1%
Kappa= 2×24082/ 49166=0.98＞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-reactive substances	Concentration Tested	Cross-Reactivity (Yes/No)
Influenza A	1,6 x10^6 $TCID_{50}$/mL	NO
Influenza B	1,6 x10^6 $TCID_{50}$/mL	NO
Human coronavirus HKU1	1,6 x10^6 $TCID_{50}$/mL	NO
Human coronavirus OC43	1,6 x10^6 $TCID_{50}$/mL	NO
Haemophilus influenzae	2,2x 10^6 $TCID_{50}$/mL	NO
MERS-coronavirus	2,1x 10^6 $TCID_{50}$/mL	NO
SARS-coronavirus	3,2 x 10^6 PFU/mL	YES
Adenovirus C1	1,5 x10^6 $TCID_{50}$/mL	NO
Adenovirus 71	1,5 x10^6 $TCID_{50}$/mL	NO
Candida albicans	4,2 x 10^6 CFU/mL	NO
Respiratory syncytial virus	5,1 x 10^6 $TCID_{50}$/mL	NO
Enterovirus	5,4 x10^6 $TCID_{50}$/mL	NO
Malaria	2,2 x 10^6 CFU/mL	NO
Dengue	1,2 x10^6 $TCID_{50}$/mL	NO
Human coronavirus NL63	1,7 x10^6 $TCID_{50}$/mL	NO
Human coronavirus 229E	2,2 x10^6 $TCID_{50}$/mL	NO
Streptococcus pneumoniae	1,1 x 10^6 CFU/mL	NO
Pneumocystis jirovecii	1,0 x10^6 $TCID_{50}$/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 10^6 $TCID_{50}$/mL	NO
Parainfluenza virus 1	1,0 x 10^6 $TCID_{50}$/mL	NO
Parainfluenza virus 2	1,0 x 10^6 $TCID_{50}$/mL	NO
Parainfluenza virus 3	3,5 x 10^6 $TCID_{50}$/mL	NO
Parainfluenza virus 4	1,4 x 10^6 $TCID_{50}$/mL	NO
Rhinovirus	1,3 x 10^6 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 nasal swab 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%	Naso GEL(Nei Med)	6%v/v
Fluticasone	4%v/v	Mucin	0.54%
CVS Nasal Drops (Phenylephrine)	17%v/v	Ricola(Menthol)	1.6mg/mL
Tamiflu(Oseltamivir Phosphate)	6mg/ml	Afrin(Oxymetazoline)	14%v/v
Sucrets(Dyclonin/Menthol)	1.4 mg/mL	CVC Nasal Spray(Cromolyn	16%v/v
Chloraseptic(Menthol/Benzocaine)	1.8 mg/mL	Nasal Gel(Oxymetazoline)	9%v/v
Homeopathic(Alkalol)	1:10dilution	Mupirocin	12 mg/mL
Ore Throat Phenol Spray	16%v/v	Fisherman's Friend	1.3mg/ml
Tobramycin	5ug/mL	Zicam	4%v/v

4.Limit of Detection (ANALYTICAL SENSITIVITY)

The LoD for the SARS-CoV-2 Antigen rapid test kit –PRO is 1.2 x $10^2$$TCID_{50}$/mL.
The LoD for the SARS-CoV-2 Antigen rapid test kit-PRO was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 2.4 x 10^6 $TCID_{50}$/mL. In this study, designed to estimate the LoD of the assay when using a direct nasal swab, the starting material was spiked into a volume of virus dilution in saline. An initial range-finding study was performed testing devices in triplicate using a 10-fold dilution series. At each dilution, 50 µL samples were added to swabs and then tested using the procedure appropriate for patient nasal swab specimens. 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 (2.4 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
LOT	Batch Number		Expiry Date
	Do not reuse	2°C 30°C	Store between 2～30℃
	Keep Dry		Manufacturer
REF	Catalog #		Manufacturing Date
	Keep away from Sunlight	EC REP	EU Authorized Representative
CE	CE Mark		Biological risks

【BASIC INFORMATION】

JOYSBIO(Tianjin) Biotechnology Co., Ltd.
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Address: Koningin Julianaplein 10,1e Verd,2595AA, The Hague,Netherlands.

【DATUM DER GENEHMIGUNG UND ÄNDERUNG DER IFU】

4/23/2021