SARS-CoV-2 Antigen Rapid Test Kit(Colloidal Gold) Instructions for Use (IFU)
For self-testing IVD

Please scan the QR code for an instructional video and multi-language instructions.

Always read the instruction below thoroughly before use. You must follow the test directions carefully to get an accurate result.

【COMPONENT】

Component	1 Test/box	5 Tests/box	15 Tests/box	20 Tests/box
	REF#G03321	REF#G03322	REF#G03325	REF#G03326
Test device	1 Test/box (1 Test/pouch ×1 pouch)	5 Tests/box (1 Test/pouch ×5 pouches)	15 Tests/box (1 Test/pouch ×15 pouches)	20 Tests/box (1 Test/pouch ×20 pouches)
Desiccant	1 pack	5 packs	15 packs	20 packs
Buffer	1 single-use bottle with 350 µL extraction buffer	5 single-use bottles, each with 350 µL extraction buffer	15 single-use bottles, each with 350 µL extraction buffer	20 single-use bottles, each with 350 µL extraction buffer
Extraction tube	1 single-use reaction tube with 1x nozzle cap	5 single-use reaction tubes, each with 1x nozzle cap	15 single-use reaction tubes, each with 1x nozzle cap	20 single-use reaction tubes, each with 1x nozzle cap
Specimen sampling swab	1 sterile, single-use specimen sampling swab	5 sterile, single-use specimen sampling swabs	15 sterile, single-use specimen sampling swabs	20 sterile, single-use specimen sampling swabs
Biological garbage bag	1 single-use biological garbage bag	5 single-use biological garbage bags	15 single-use biological garbage bags	20 single-use biological garbage bags
Tube rack	/	/	1	1
Instructions for use	1 piece	1 piece	3 pieces	4 pieces

【PRODUCT COMPOSTION】

Component	Main components
Test card	The 4µg/test anti-nucleocapsid protein antibody and 1.2µg/test chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with 6µg/test anti-nucleocapsid protein antibody, and 6µg/test goat anti-chicken IgY antibody.
Buffer	99.8% Distilled Water , 0.1% Tris-HCl , 0.1% Proclin-300
Desiccant	Silica Gel

【TEST PROCESS】

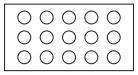
Step 1:

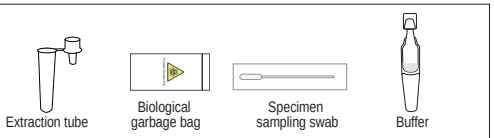
Wash and dry your hands. Allow the test cassette to equilibrate to room temperature prior to testing.

Check your test kit component. Pay attention that each test kit can only be used once.


Instructions for use


Test device


Tube rack
（15 and 20 Tests/box）



Note: The tube rack for 1 test/box and 5 tests/box is the round hole on the back of the packing box.

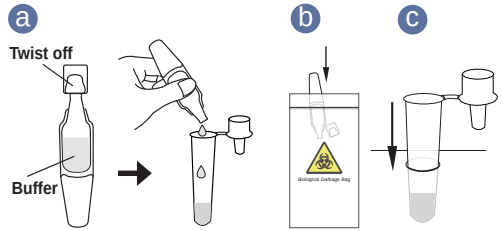
Step 2:

Add Buffer to the Extraction Tube

a. Twist off the top of the buffer bottle, slowly dispense all of the buffer into the extraction tube.

b. Dispose of empty buffer bottle in the biological garbage bag.

c. Place extraction tube in the tube rack.



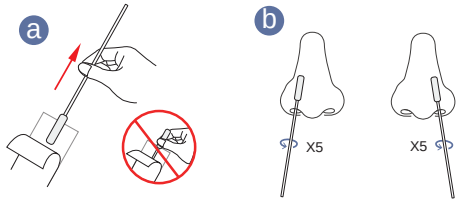
Step 3:

Nasal Swab Specimen Collection

a. Remove the swab from its wrapper, being careful not to touch the swab head.

b. Insert the swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times. Using the same swab, repeat this process in the other nostril. Ensure that an adequate sample is collected from both nasal cavities.

Note: With children, the maximum depth of insertion into the nostril may be less than an inch, and you may need to have a second person to hold the child's head while swabbing.

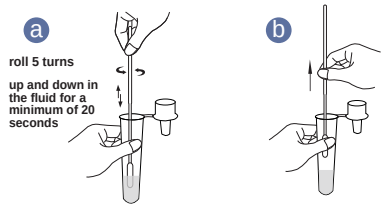


Step 4:

Sample Processing

a. Insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of 20 seconds, then hold the swab against the bottom of the tube and roll 5 turns, taking care not to splash contents out of the tube.

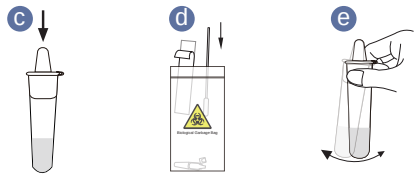
b. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



c. Press the nozzle cap firmly onto the extraction tube containing the processed sample.

d. Dispose of the swab in the biological garbage bag.

e. 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.

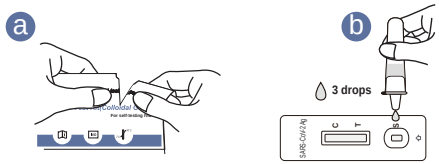


Step 5:

Test Your Sample

a. Tear off the foil pouch, take out the test device and place the test kit on a clean and level surface.

b. Gently squeeze the ridged body of the tube, dispensing 3 drops of the processed specimen into the sample well.



Step 6:

Wait for the Result

Read the test results between 15 and 20 minutes. Do not read the results after 20 minutes.


15-20 Minutes

Step 7:

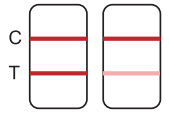
Check Your Results

There are three possible results.

Check for a Positive Result

If two lines appear, a Control (C) line and a Test (T) line, Covid-19 was detected.

Note: *Look closely! The test device on the upper right is a positive result. Any T line, no matter how faint, should be considered as a positive result.*

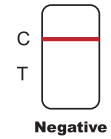


Positive

A positive test result means that proteins from the virus that causes COVID-19 were found in your sample and it is very likely you have COVID-19.
There is a very small chance that this test can give you a positive test result that is wrong (false positive.)
Positive test results do not rule out co-infections with other disease.
All positive results must follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Check for a Negative Result

If only a C line appears and no visible T line, COVID-19 was not detected.



Negative

A negative test result means that it is unlikely that you have COVID-19 at the time of testing. The test did not detect any antigens in your nasal swab sample, but it is possible that your test gave a false negative test result. False negative test results can be caused by several factors:

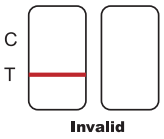
- The amount of antigen in the swab sample may decrease over the duration of the infection.
- The test was performed after the first 7 days of symptom onset.
- The test may be negative before you develop symptoms.
- The test was not performed per the instructions.
- Specimen collection, extraction or transport was not performed correctly.

Seek medical assistance if symptoms persist or unwell.

Check for an Invalid Result

The test result is invalid if a C line does not appear, regardless of the appearance of a T line or not.

Please repeat test with a freshly collected sample and new test kit components, and to report repeated invalid results to the sponsor.

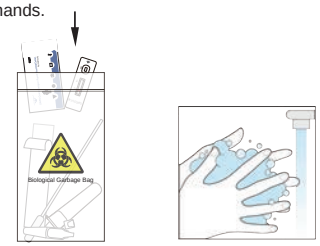


Invalid

Step 8:

Throw all used items into the biological garbage bag and dispose of the bag in accordance with local regulations.

Wash your hands.



For support and user assistance, contact us on 1300848102

This service is available between 9am and 7pm (AEST), or 9am and 8pm (AEDT), 7 days a week.

SARS-CoV-2 Antigen Rapid Test Kit(Colloidal Gold) Instructions for Use (IFU)
For self-testing IVD

【Warnings, Precautions and Safety Information】

1. Read the instruction fully before starting the test procedure.
2. To ensure correct results, you must follow the instructions.
3. Keep test kit and materials out of the reach of children and pets before and after use.
4. Do not open the materials until ready for use. If the test strip is open for an hour or longer, invalid test results may occur.
5. Do not use a test kit that is expired.
6. Do not use kits with damaged packaging.
7. Do not use kits stored in improper conditions.
8. Do not touch the swab head when handling the swab.
9. The test is intended to be read at 15-20 minutes. If the test is read more than 20 minutes after the indicated read time, results may be inaccurate and the test should be repeated.
10. Improper swab collection may result in incorrectly negative (false negative) results.
11. Possible discomfort during sample collection. If you feel pain, discontinue testing and seek advice from your healthcare provider.
12. The results of this test may help limit the spread of COVID-19 to your family and others in your community.
13. Positive test results do not rule out co-infections with other pathogens. The agent detected may not be the definite cause of disease.
14. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
15. Negative test results are not intended to rule out other non-SARS viral or bacterial infections.
16. As with all in vitro diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
17. If the differentiation of specific sars viruses and strains are needed, additional testing is required.
18. The test result is less reliable in the later phase of infection and in asymptomatic individuals.
19. The test can only be used once.

【STORAGE AND STABILITY】

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

【PERFORMANCE CHARACTERISTICS】

Clinical Performance:

The performance of the kit is determined by 831 samples collected from Poland and Switzerland。

The kit showed 83.12% of sensitivity and 99.70% of specificity.

Table 1. Clinical Study Results

Reagent test results	PCR Comparator		Subtotal
	positive	negative	
positive	128	2	130
negative	26	675	701
Subtotal	154	677	831

Positive Percent Agreement (PPA)= 128/154(83.12%)
（95%CI:76.25%~88.67%）
Negative Percent Agreement (NPA)= 675/677(99.70%)
（95%CI:98.94%~99.96%）
Accuracy=(128+675)/831×100%=96.63%
Kappa=2×86348/195964=0.8813≥0.75

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	Cross-Reactivity (Yes/No)
Influenza A	NO
Influenza B	NO
Human coronavirus HKU1	NO
6Human coronavirus OC43	NO
Haemophilus influenzae	NO
MERS-coronavirus	NO
SARS-coronavirus	YES
Adenovirus C1	NO
Adenovirus 71	NO
Candida albicans	NO
Respiratory syncytial virus	NO
Enterovirus	NO
Malaria	NO
Dengue	NO
Human coronavirus NL63	NO
Human coronavirus 229E	NO
Streptococcus pneumoniae	NO
Pneumocystis jirovecii	NO
Legionella pneumophila	NO
Chlamydia pneumoniae	NO
Human Metapneumovirus (hMPV)	NO
Parainfluenza virus 1	NO
Parainfluenza virus 2	NO
Parainfluenza virus 3	NO
Parainfluenza virus 4	NO
Rhinovirus	NO
Mycoplasma pneumoniae	NO
Bordetella pertussis	NO
Mycobacterium tuberculosis	NO
Pooled human nasal wash-representative of normal respiratory microbial flora	NO
Streptococcus pyogenes	NO

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	Interfering substances
Whole Blood	Naso GEL(Nei Med)
Fluticasone Propionate	Mucin
CVS Nasal Drops (Phenylephrine)	Ricola(Menthol)
Tamiflu(Oseltamivir Phosphate)	Afrin(Oxymetazoline)
Sucrets(Dyclonin/Menthol)	CVC Nasal Spray(Cromolyn)
Chloraseptic(Menthol/Benzocaine)	Nasal Gel(Oxymetazoline)
Homeopathic(Alkalol)	Mupirocin
Ore Throat Phenol Spray	Fisherman's Friend
Tobramycin	Zicam

Detect SARS-CoV-2 Strains

This kit can detect original strain, Omicron strain, Delta strain，Beta strain and Gamma strain.

Limit of Detection (ANALYTICAL SENSITIVITY)

The LoD for the SARS-CoV-2 antigen rapid test kit is1.6 x 10^2TCID$_{50}$/mL.

【USABILITY CLAIMS 】

During the testing of 90 participants,comparing the results of these participants with the results of RT-PCR, the test results are 96.67%(87/90) of participants are highly consistent with those of laboratory technician. The results indicated the usability of the SARS-CoV-2 Antigen Rapid Test Kit (colloidal gold).

【INTENDED USE】

The SARS-CoV-2 Antigen Rapid Test Kit is a rapid, lateral flow immunoassay intended for the qualitatively aid for diagnosis of COVID-19 from nasal swabs that are self-collected by untrained lay persons between 15 and 70 years old. The test is available to individuals who develop symptoms within 7 days. Tests for children under 15 should always be done or supervised by an adult.

For self-testing IVD.

【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 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.

【EXPLANATION OF LABELS】

IVD	In Vitro Diagnostic Use		See Instruction for Use
LOT	Batch Number		Expiry Date
	Do not Reuse	30°C 2°C	Store between 2～30ºC
	Keep Dry		Manufacturer
Σ n	Contains Sufficient for <n> Tests		Biological Risks
	Caution		Do not Use if Package is Damaged
REF	Catalog #		Keep away from Sunlight
	Manufacturing Date		

Please contact the TGA to report poor performance or usability issues in the self-test environment (report an issue via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.

Contact Details and Websites of Local State and Territory Health Departments:

Australian Capital Territory Department of Health	Business hours: 02 5124 9213 Coronavirus helpline (8am to 8pm daily): 02 6207 7244 https://health.act.gov.au
New South Wales Department of Health	General enquiries: 1300 066 055 Coronavirus hotline (Service NSW, 24/7): 137 788 https://www.health.nsw.gov.au
Northern Territory Department of Health	General enquiries: 08 8922 8044 Coronavirus hotline (National helpline): 1800 020 080 https://health.nt.gov.au
Queensland Department of Health	3HEALTH: 13 432 584 Coronavirus hotline: 134COVID, 134 268 https://www.health.qld.gov.au
South Australian Department of Health	General enquiries: 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	General enquiries: 1300 135 513 Public Health Hotline (coronavirus): 1800 671 738 https://www.health.tas.gov.au
Victorian Department of Health	Department of Health and Human Services: 1300 650 172 Victorian coronavirus hotline (24/7): 1800 675 398 https://www.dhhs.vic.gov.au
Western Australian Department of Health	General enquiries: 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri), 1800 595 206 https://www.healthywa.wa.gov.au

【BASIC INFORMATION】

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For support and user assistance, contact us on 1300848102

This service is available between 9am and 7pm (AEST), or 9am and 8pm (AEDT), 7 days a week.

【DATE OF APPROVALAND AMENDMENT OF IFU】April 25，2023

【VERSION】 V 0.8