# SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold)

# Package Insert

watmind

English

REF LFA0401-1M REF LFA0401-5M REF LFA0401-25M

**A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in only anterior nasal swab specimens.**

**For in vitro diagnostic use only. For self-testing**.

**Materials Provided:**

| Size | Contents |
|---|---|
| 1T | 1 Cassette, 1 Tube, 1 Dripper, 1 Sample Extraction Solution, 1 Swab, 1 Biohazard Waste Bag and 1 Package Insert. |
| 5T | 5 Cassettes, 5 Tubes, 5 Drippers, 5 Sample Extraction Solution, 5 Swabs, 5 Biohazard Waste Bags and 1 Package Insert. |
| 25T | 25 Cassettes, 25 Tubes, 25 Drippers, 25 Sample Extraction Solution, 25 Swabs, 25 Biohazard Waste Bags and 1 Package Insert. |

**Materials required but not provided**

• Clock, timer or stopwatch

**Carefully read the instructions before performing the test.**

Before testing, scan the QR code to watch the operating video, or visit https://youtu.be/dQVzFUutXfI

For more instructions printed in other languages and formats, please mail to globalbusiness@watmind.com.

**For support and user assistance**, **Contact us on**:
**Tel:+61 2-9139-2850 (24 hours, 7 days)**
**Email: globalbusiness@watmind.com**
**Web: en.watmind.com**
**The service is available between 9 am and 7 pm (AEST) or 9am and 8pm (AEDT),7 days a week**

## PREPARATION

1.Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.

2.Read instruction for use (IFU) carefully prior to use and followed.


3. Check the expiration date printed on the cassette foil pouch.

4. Open Pouch and place the card on a clean, dry, flat surface.

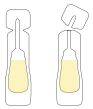
## SPECIMEN COLLECTION

**SELF COLLECTION OR COLLECTION BY AN ADULT CAREGIVER**

A nasal swab sample can be self-collected by an individual aged 15+ years. Individuals aged four years or older should be performed by a parent or legal guardian. Do not use the test in children under the age of 2.

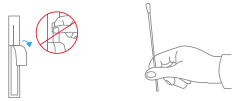
## TEST PROCEDURE

1. Open the sample extraction solution sealed vial.



2. Drop all the liquid into the tube

3.Open swab package and take the swab out.



4. Carefully insert the entire absorbent tip of the swab into the nostrils (about 1.5~2 cm). Firmly sample the nasal wall by rotating the swab in a circular path five times against the nasal wall.

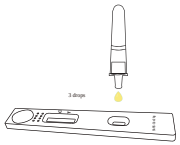

5. Repeat the same process with the same swab in the other nostril.


6. Place the swab into the sample tube and then completely immerse the swab head in the sample. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) and squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the sample extraction buffer.

7. Squeeze the swab head along the inner wall of the tube to keep the liquid in the tube as much as possible.

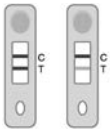
8. Discard the swab, cover the drip head and waggle tube for 5-6 times.

9. Dispense 100μL (3drops) of the specimen into the sample well (“S” well) on the card.




10. Wait 15 minutes.


## INTERPRETATION OF TEST RESULTS

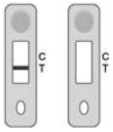



**Positive**

Both red/purplish test band (T) and red/purplish control band (C) appear in window.
**Note:** The red/purplish band in the test area (T) can show the color depth. However, within the specified observation time, regardless of the color of the ribbon, even a very weak ribbon should be judged as a positive result.


**Negative**

Only the red/purplish control band (C) appears in window. The absence of a test band (T) indicates a negative result.




**Invalid**

There should always be a red/purplish control band (C) in the control region regardless of test result. If control band (C) is not seen, it indicates that the incorrect operation process or the kit has deteriorated or damaged.

## DISPOSE IN TRASH

After test is completed, all used test components should put in biohazard waste bag and seal it. The trash must be disposed of in your household waste or in accordance with local disposal regulations.

**Wash Your Hands after Testing**

After completing all test steps, wash your hands or use hand sanitizer.

## INTENDED USE

This kit is a lateral flow chromatographic immunoassay test for detection of the nuclecapsid Nucleocapsid (N) Protein of SARS-CoV-2 virus and used for in vitro qualitative detection of SARS-CoV-2 antigen in human anterior nasal swab specimens. The test is intended for use in symptomatic individuals meeting the case definition for COVID-19 within the first 7 days of symptom onset.

Positive result from the test need further analyze with clinical history of patient and other diagnostic information to determine patient infection status. Positive value is only a reference guide for clinical diagnosis. The test results only reflect the current state of the sample. Negative result cannot exclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The usability of self-testing by an individual aged under 15 years has not been determined. It is suggested that individual under 15years of age should be tested by an adult. Do not use the test in children under the age of 2. It cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by SARS-CoV-2.

## SUMMARY

The new coronaviruses belong to the beta genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the new coronavirus are the main source of infection; infected people without symptoms can also infect others. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

## PRINCIPLE

The SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) is a colloidal gold enhanced double antibody sandwich immunoassay for the qualitative determination of Nucleocapsid(N)Protein of SARS-CoV-2 virus in human nasal swab samples. If SARS-CoV-2 antigen present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the antigen will be caught by the specific anti-SARS-CoV-2 monoclonal coated on the region T. Results appear in 15 to 20 minutes in the form of a red line that develops on the strip. Whether the sample contains the SARS-CoV-2 antigen or not, the solution continues to migrate to encounter another reagent that binds the remaining conjugates, thereby producing a red line on the region C.

## REAGENTS

The test cassette contains anti-SARS-CoV-2 antibodies, Chicken IgY and Goat anti chicken IgY. The extraction buffer tube contains detergent and tris buffer.

## WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

Read the SARS-CoV-2 Antigen Rapid Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.

The test is intended to aid in the diagnosis of a current COVID-19 infection.Please consult the State or Territory Coronavirus testing services to discuss yourresults and if any additional testing is required.

Do not use on anyone under two years of age.

Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.

Do not reuse any kit components. Do not use with multiple specimens.

Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.

Remove any piercing(s) from the nose before starting the test.

Inadequate or improper nasal swab sample collection may yield false-negative test results.

Do not touch swab tip when handling the swab sample.

Do not mix test card and sample extraction solution from different kit lots.

The likelihood of false-negative would increase after 7 days from the onset of symptoms. If you test negative and continue to experience symptoms or symptoms become more severe, please contact your State or Territory Coronavirus testing services to get a laboratory PCR test immediately.

The viral load declines in the later stage of infection and the viral load is considered to be low in asymptomatic individuals. The test could be less sensitive in these scenarios.

*Repeat testing within 1-2 days if there is an ongoing suspicion of infection, youare exposed to a high-risk setting, or if it is an occupation requirement.*

Leave test card sealed in foil pouch until just before use.

Do not use the test if the pouch is damaged or unsealed.

Do not eat, drink, or smoke before and during the test.

All used tests, specimens and potentially contaminated materials should be discarded according to local regulations.

Humidity and temperature can adversely affect results.

The test line for a high viral load sample may become visible within 15 minutes,or as soon as the sample passes the test line region.

The test line for a low viral load sample may become visible within 30 minutes.

Do not collect the nasal swab specimen when nosebleed happens.

Wash hands thoroughly after use.

Keep the test kit away from children and animals.

The extraction buffer can inactivate the virus which can minimize the risk for microbiological hazards. Its stillnecessary to handle and dispose of the used swab and other test kit contents withcaution as if they contained infectious agents to reduce the spread of SARS-CoV-2 tothe general population.

If the extraction buffer comes in contact with the skin or eyes, flush with plentyof water. If irritation persists, seek medical advice from a doctor or contact First Aid poisons information center.

## STORAGE AND STABILITY

The kit can be stored at temperatures between 2-30℃.

The test is stable until the expiration date printed on the sealed pouch. Do not use after the expiration date.

The test must remain in the sealed pouch until use.

DO NOT FREEZE.

## QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control line region (C) is an internal procedural control. It confirms that enough specimen volume was added, and the correct procedure was carried out.

## LIMITATIONS

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
2. Due to the limitation of the detection method, the negative result cannot exclude the possibility of infection. The positive result should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms and further diagnosis methods.
3. Positive test results do not rule out co-infections with other pathogens.
4. False negative results are more likely after 8 days or more of symptoms.
5. Negative results, from patients with symptom onset beyond 7 days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
6. This reagent can only qualitatively detect SARS-CoV-2 antigens in human nasal swab samples. It cannot determine the certain antigen content in the samples.
7. The accuracy of the test depends on the sample collection process. Improper sample collection will affect the test results.
8. False negative results may occur if swabs are stored in their paper sheath after specimen collection.
9. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
10. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
11. Cross reactions maybe exist due to the N protein in SARS has a high homology with the new coronavirus (SARS-CoV-2). However, the interpretation of the results is not affected during seasons without SARS infection.

## CONTACT INFORMATION AND ONLINE SUPPORT

**State Government Covid-19 Support Line**

| State Authority | Helpline | Website |
|---|---|---|
| Australian Capital Territory Department of Health | 02 6207 7244 | https://www.health.act.gov.au/ |
| New South Wales Department of Health | 1377 88 | https://www.health.nsw.gov.au/ |
| Northern Territory Department of health | 1800 0 2008 0 | https://www.health.nt.gov.au/ |
| Queensland Department of health | 134268 | https://www.health.qld.gov.au/ |
| South Australian Department of Health | 1800253787 | https://www.sahealth.sa.gov.au/ |
| Tasmanian Department of Health | 1800671738 | https://www.health.tas.gov.au/ |
| Victorian Department of Health | 1800675398 | https://www.dhhs.vic.gov.au/ |
| Western Australian Department of Health | 1800595206 | https://www.healthywa.wa.gov.au/ |

**Product Support Line**

Contact Australian Representative for support services: Vandart Diagnostics Pty Ltd. For test kit related queries, Call: +61 2-9139-2850 (24 hours, 7 days)

**Therapeutic Goods Australia**

Contact the TGA to report 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)

## PERFORMANCE CHARACTERISTICS

### Clinical Sensitivity, Specificity and Accuracy

Clinical study was conducted to compare the results obtained on SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) verses RT-PCR. Nasal swabs collected from 357 participants with or without symptom were tested. The results show that the Sensitivity is 89.81%, Specificity is 99.02% and the Accuracy is 93.84%.

### Usability Study

A usability study was conducted with a pool of 100 lay persons in the self-testing environment. The sensitivity is confirmed as 90 % and specificity is confirmed as 100% in the hands of the lay person, comparing with professional RT-PCR testing.

The lay person questionnaire together with the observation recorded by a healthcare professional showed that the package insert can be easily followed by a lay person, and that the test can be easily operated by a lay person.

### Limit of Detection

The SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) can detect out SARS-CoV-2 heat-inactivated virus strain as low as 1.5 x $10^2$ $TCID_{50}$/ml.

### Variant

The following SARS-CoV-2 variants were tested on SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold). All the variants can be detected at above mentioned limit of detection level.

| SARS-CoV-2 Variants of Concern tested | | |
|---|---|---|
| B.1.1.7 | Alpha | United Kingdom |
| B.1.351 | Beta | South Africa |
| B.1.429+B.1.427 | Epsilon | United States |
| P.1 | Gamma | Japan/Brazil |
| P.2 | / | Brazil |
| B.1.617.2 | Delta | India |
| B.1.617.3 | VUI-21ARP-03 | India |
| B.1.1.529 | Omicron | South Africa |

### Cross-Reactivity (Analytical Specificity) and Microbial Interference

The following commensal and pathogenic microorganisms that may be present in the nasal cavity have no effect on the test results.

| | |
|---|---|
| Human coronavirus 229E | Respiratory Syncytial Virus B |
| Human coronavirus OC43 | Respiratory Syncytial Virus A |
| Human coronavirus HKU1 | Chlamydia pneumoniae-TWAR strain TW-183 |
| Human coronavirus NL63 | Haemophilus influenzae |
| MERS-coronavirus | Legionella pneumophila |
| Adenovirus Type 3 | Mycobacterium tuberculosis-CDC1551 |
| Adenovirus Type 7 | Mycobacterium tuberculosis(96-2081) |
| Human Metapneumovirus | Mycobacterium tuberculosis(00-2170) |
| Parainfluenza virus 1 | Streptococcus pneumoniae-STREP2 |
| Parainfluenza virus 2 | Streptococcus pneumoniae-EMC9V |
| Parainfluenza virus 3 | Streptococcus pneumoniae-GA41565 |
| Parainfluenza virus 4A | Streptococcus pyrogenes |
| Influenza A-H1N1 | Bordetella pertussis-NCCP13671 |
| Influenza A-H3N2 | Mycoplasma pneumonia |
| Influenza A-H5N1 | Pneumocystis jirovecii (PJP) |
| Influenza A-H7N9 | Pooled human nasal wash-to represent diverse microbial flora in the human respiratory tract |
| Influenza B-Yamagata | Candida albicans-23B |
| Influenza B-Victoria | Pseudomonas aeruginosa-Pa1651 |
| Enterovirus -Type68 | Staphylococcus epidermis-FDAstrain PCI 1200 |
| Rhinovirus | Staphylococcus salivarius-SK126 |

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for SARS-coronavirus. SARS-coronavirus shows 90.52% homology across 100% of the nucleocapsid sequence. Therefore, cross-reactivity is highly likely.

### Interfering Substances

There is no interference were found to affect the test performance.

| | |
|---|---|
| Whole blood（Human） | Mucin；Bovine submaxillary gland, type I-S |
| Nasal sprays-Afrin | Throat lozenges, oral anaesthetic and analgesic-Cepacol |
| Nasal gel-Zicam | Antibiotic,nasal ointment-Bactroban |
| Anti-viral Drug-Ribavirin | Nasal corticosteroids-Veramyst |
| Anti-viral Drug-Relenza | Human Anti-mouse Antibody(HAMA) |
| Anti-viral Drug-Tamiflu | Antibacterial, Systemic |
| Biotin | |

## FREQUENTLY ASKED QUESTION

**1. How do I know if the Test worked well?**

SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human anterior nasal swab specimens. When the control line(C) appears, it means thetest unit is performing well.

**2. What is the best time to read the results?**

15 minutes.

**3. When is the best time to run the test?**

Test can be done at any time of the day.

**4. Does this test hurt?**

The nasal swab may cause slight discomfort. It is important to follow the nasal swab collection steps as indicated in the procedure. Discomfort may occur if the swab is inserted beyond the recommended depth. If painful, slightly withdraw the swab to finish the sample collection process.

**5.What are the known potential risks and benefits of this test?**

Potential risks include:

Possible discomfort during sample collection.

Possible incorrect test results (see Result Interpretation section).

Potential benefits include:

The results, along with other information, can help you and your healthcare provider make informed decisions about your care.

The results of this test may help limit the spread of COVID-19 to your family and others in your community.

**6.What is the difference between and antigen test and PCR test?**

There are different kinds of tests for COVID-19. PCR tests detect genetic material from the virus. Antigen tests, such as the SARS-CoV-2 Ag Diagnostic Test Kit (Colloidal Gold) detect proteins from the virus. Antigen tests are very specific for the COVID-19 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss.

**7.What does it mean if I have an invalid result?**

This may be a result of incorrect test procedure. Wait 4 hours before repeating the test.

**8.What does it mean if I have a positive result?**

A positive test result means that proteins of the virus that causes COVID-19 have been found in your nasal swab sample. It is likely that you will need to perform self-isolation at home to prevent the spread of COVID-19. A positive result does not rule out coinfection with other pathogens. Please follow local guidelines for social distancing to limit the spread of the virus. All positive results must be confirmed with a laboratory PCR test.

**9. What does it mean if I have a negative result?**

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 preformed correctly.

If symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-isolation and consult your doctor.

**10.Does the test detect new variants?**

WATMIND has processes in place to monitor the mutations of the COVID-19 virus and evaluate the performance of its test kits to detect them and ensure the ability to detect the new variants.

**11.Can people who are vaccinated used this test?**

Yes, individuals with or without symptoms can use this test regardless of vaccination status.

**12.I am allergic to latex; Can I use this product?**

The components in this product do not contain latex. For any allergy concerns, please contact your general practitioner for advice.

**13. I am pregnant; Can I use this product?**

The components in this product do not require ingestion. Henceforth the test is safe for use during pregnancy. For any concerns, please contact your general practitioner for advice.

**14. Can I use my own swab?**

No, you must only use the components included in the test kit.

**15.Can I Re-use any of the components of the test kit?**

No, none of the components of the test kit can be reused or saved for use with another test kit.

**16. Should I swab my left or right nostril?**

Please use the swab to collect specimen from both of your nostrils to ensure sufficient sample collection to generate an accurate result.

## SYMBOLS

| | | | | | |
|---|---|---|---|---|---|
| IVD | In Vitro Diagnostic Use | | Consult instructions for use | REF | Catalog # |
| | Manufacturing Date | | Use-by Date | | Do not reuse |
| | Keep away from Sunlight | LOT | Batch Number | | Keep Dry |
| | Store between 2～30℃ | | Manufacturer | | |


Shenzhen Watmind Medical Co., Ltd.
8th Floor, Building A,No.16-1, Jinhui Road, Jinsha Community, Kengzi Subdistrict, Pingshan District, 518118, Shenzhen, China
Tel: +86 755-86969964
Fax: +86 755-26658059
Website: http://en.watmind.com

Australia Representative：
Vendart Diagnostics Pty Ltd
14/128 Station Road
Seven Hills NSW 2147
Australia
Tel: +61 2-9139-2850


Revision Date: 2022-11-16