SARS-CoV-2 Ag Self-test Kit (Nasal Swab)

watmind

Package Insert

English

REF LFA0401-1AE REF LFA0401-5AE REF LFA0401-25AE

A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in 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 Bag and 1 Package Insert.
25T	25 Cassettes, 25 Tubes, 25 Drippers, 25 Sample Extraction Solution and 25 Swabs, 25 Biohazard Waste Bag and 25 Package Inserts.

Materials required but not provided
• Clock, timer or stopwatch

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

For support and user assistance, contact Australia Representative on 042 569 8666 (24 hours, 7 days)
OR contact watmind on
Email: globalbusiness@watmind.com
Web: www.watmind.com
The service of watmind is available between 9 am and 7 pm (AEST) or 9am and 8pm (AEDT), 7 days a week

Before testing, scan the QR code to watch an instructional video, or visit https://www.watmind.com/en/h-col-245.html

PREPARATION

1. Wash or sanitize your hands.Make sure they are dry before proceeding.

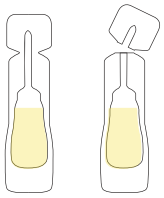
2. Check components and Read package insert carefully prior to use and followed.

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

4. Open pouch and place the cassette on a clean, dry, flat surface.

TEST PROCEDURE

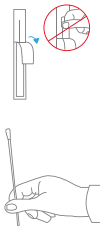
1. Open the sample extraction solution sealed vial.



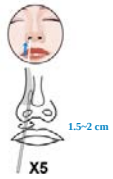
2. Drop all the solution into the tube

3. Open swab package and take the swab out.

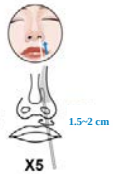
DO NOT touch the swab head.



4. Swab both nostrils carefully with the soft tip as shown.
Step 1)
Insert 1.5~2cm.
DO NOT insert swab further if you feel any resistance
Step 2)
Using medium pressure, rub and rotate the swab against the inside of the first nostril, making at least 5 circles

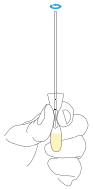


5. Repeat the same process with the same swab in the other nostril.



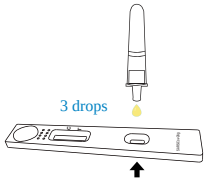
6. Completely immerse the swab tip in the solution in the tube and mix well by rotating at least 10 times. Be sure to mix thoroughly.

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



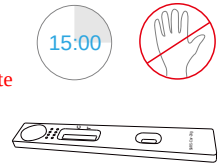
8. Discard the swab, cover the drip head and waggle tube for 5-6 times.

9. Dispense 100μL (3 drops) of the specimen into the sample well on the cassette.

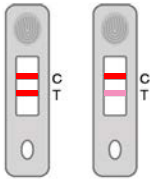


10. Wait 15 minutes.

DO NOT disturb cassette during this time.



11. Interpretation of Test Results.

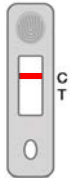


Positive

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.

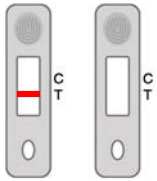
If you have a positive result:
Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.



Negative

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

If you have a negative result:
If symptoms persist or if unwell, please consult the State and Territory Health Department for guidance and seek medical assistance.



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.

If you have a invalid result:
It may be a result of incorrect test procedure. Contact the sponsor and wait 4 hours before repeating the test.

12. After Test

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

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 for aid in diagnosis of COVID-19. 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 Self-test Kit (Nasal Swab) 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. 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

1. Read the SARS-CoV-2 Antigen Rapid Test Package Insert carefully before performing a test. Failure to follow directions may produce inaccurate test results.
2. 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 your results and if any additional testing is required. If necessary or unwell, seek follow-up clinical care.
3. Do not use on anyone under two years of age.
4. 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 use if pouch is damaged or open.
5. Do not reuse any kit components. Do not use with multiple specimens.
6. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
7. Remove any piercing(s) from the nose before starting the test.
8. Inadequate or improper nasal swab sample collection may yield false-negative test results.
9. Do not touch swab tip when handling the swab sample.
10. Do not mix test card and sample extraction solution from different kit lots.
11. 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 follow the State and territory guidance, if unwell seek medical assistance.
12. The viral load declines in the later stage of infection and the viral load is considered to be low in asymptomatic individuals. The test are less reliable in these scenarios.
13. Repeat testing within 1-2 days if there is an ongoing suspicion of infection, you areexposed to a high-risk setting, or if it is an occupation requirement.
14. Do not eat, drink, or smoke before and during the test.
15. All used tests, specimens and potentially contaminated materials should be discarded according to local regulations.
16. Humidity and temperature can adversely affect results.
17. 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.
18. The test line for a low viral load sample may become visible within 30 minutes.
19. Do not collect the nasal swab specimen when nosebleed happens.
20. Wash hands thoroughly after use.
21. Keep the test kit away from children and animals.
22. The extraction buffer can inactivate the virus which can minimize the risk for microbiological hazards.
23. It's still necessary to handle and dispose of the used swab and other test kit contents with caution as if they contained infectious agents to reduce the spread of SARS-CoV-2 to the general population.
24. It should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and pets before and after use.
25. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.

STORAGE AND STABILITY

The kit can be stored at temperatures between 2 - 30 °C, valid for 18 months.
The test is stable until the expiration date printed on the sealed pouch. Do not use after the expiration date.
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. And a negative result does not rule out infection with another type of respiratory virus.
4. There is a risk of false negative results, particularly if testing is not performed within the first 7 days of symptom onset.
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. Information on other limitations of the test such as a positive result cannot necessarily determine whether a person is infectious.Negative results may not mean that a person is not infectious and if symptoms are present the person must seek immediate further testing by PCR.
10. 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.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

Two clinical studies was conducted to compare the results obtained on SARS -CoV-2 Ag Self-test Kit (Nasal Swab) verses RT-PCR. The results shown below:

Study No.1

		PCR		Total
		Positive	Negative	
SARS-CoV-2 Ag Self-Test Kit	Positive	104	0	104
	Negative	6	450	456
	Total	110	450	560
Statistic	Value		95% CI	
Sensitivity	94.55%		88.61%~97.48%	
Specificity	100.00%		99.15%~100.00%	
Accuracy	98.93%		97.68%~99.51%	

The kit showed 94.55% of sensitivity and 100.00% of specificity in this clinical study.

Study No.2

		PCR		Total
		Positive	Negative	
SARS-CoV-2 Ag Self-Test Kit	Positive	132	2	134
	Negative	20	203	223
	Total	152	205	357
Statistic	Value		95% CI	
Sensitivity	86.84%		80.55%~91.32%	
Specificity	99.02%		96.51%~99.73%	
Accuracy	93.84%		90.85%~95.90%	

The kit showed 86.84% of sensitivity and 99.02% of specificity in this clinical study.

Usability Study

A usability study was conducted with a pool of 90 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.

		PCR		Total
		Positive	Negative	
SARS-CoV-2 Ag Self-Test Kit	Positive	27	0	27
	Negative	3	60	63
	Total	30	60	90
Statistic	Value		95% CI	
Sensitivity	90.00%		72.38%~96.54%	
Specificity	100.00%		93.98%~100.00%	
Accuracy	96.67%		90.65%~98.86%	

Limitation of Detection

The SARS-CoV-2 Ag Self-test Kit (Nasal Swab) 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 Self-test Kit (Nasal Swab). All the variants can be detected at above mentioned limit of detection level.

SARS-CoV-2 Variants of Concern tested		
B.1.617.2	Delta	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 Self-test Kit (Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in human nasal swab. When the control line(C) appears, it means the test 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 Self-test Kit (Nasal Swab) 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. Contact the sponsor and 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. Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance

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.
If symptoms persist or if unwell, please consult the State and Territory Health Department for guidance and seek medical assistance

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?
This components in this product does not contain latex. For any allergy concerns please contact your general practitioner for advice.

13. I am pregnant; Can I use this product?
This components in this product does not require ingestion. Henceforth the test is safe for use during pregnancy. Should not be 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		

CONTACT INFORMATION AND ONLINE SUPPORT

State Government Covid-19 support Line:

State Authority	Helpline	Website
Australian Capital Territory Department of Health	02 62077244	https://www.health.act.gov.au/
New South Wales Department of Health	137788	https://www.health.nsw.gov.au/
Northern Territory Department of Health	1800020080	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/

Therapeutic Goods Australia
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)

Product Support Line
For support and user assistance, contact Australia Representative on 042 569 8666 (24 hours, 7 days)

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