

COVID-19 Antigen Rapid Test Kit (Colloidal Gold)

Instructions for Use with Saliva Swab Specimen

For in vitro diagnostic use only

For home use.

Important: Before you begin the test, please read the instructions carefully. This test is single use only, it cannot be reused for subsequent tests. Testing by an adult only or under adult supervision.

[INTENDED USE]

This test kit is used for in vitro qualitative detection of SARS-CoV-2 antigens in human saliva swab samples. It is intended for rapid detection of suspected COVID-19 cases within the first 7 days of symptom onset.

A positive test result indicates that the sample contains the SARS-CoV-2 antigen.

Individuals who test positive should follow the directions of their local Government Health Authority, consult their health care professional and self-isolate for the period directed by their Health Authority.

Based on usability studies, this test is intended to be performed by adults over the age of 18, individuals aged 13 – 17 years under adult supervision, or adult collected saliva swab samples from individuals aged 7 years or older.

[TEST PRINCIPLE]

This kit uses immunochromatography for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens present in saliva swab specimen. The specimen will move forward along the test card under capillary action. If the specimen contains a novel corona virus antigen, the antigen will bind to the colloidal gold-labelled new corona virus monoclonal antibody labelled T (Test) on the test card. The immune complex will be captured by corona virus monoclonal antibodies which are membrane fixed, form the fuchsia line, the display will be Coronavirus antigen positive, if the line does not show colour, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

[MATERIALS PROVIDED]

Components	Specification	
	1 Test/Kit CG01Ag-01S-ST	5 Tests/Kit CG01Ag-05S-ST
Test card	1	5
Saliva swab	1	5
Extraction tube with extraction solution	1	5
Instructions for use	1	1
Tube rack	1 (packaging)	1

[PERFORMANCE CHARACTERISTICS]

Variants

The AmonMed COVID-19 Antigen Rapid Test Kit (Colloidal Gold) can detect Alpha, Beta, Gamma, Delta, and Omicron variants of COVID-19

Clinical performance

Method	PCR Comparator (nasopharyngeal swab specimen)		Total
	Positive	Negative	
COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	196	0	196
	7	474	481
	203	474	677

Sensitivity (true positive rate): **96.55%** (95% CI, 93.05% -98.32%)
 Specificity (true negative rate): **>99%** (95% CI, 99.20% -100.00%)
 Accuracy (true positive and negative rate): **98.97%** (95% CI, 97.88% -99.50%)

Limit of Detection: 5x10²TCID₅₀/mL

[CROSS-REACTIVITY]

To evaluate the cross reactivity, the following panel of common organisms were tested with COVID-19 Antigen Rapid Test Kit (Colloidal Gold). Each of samples was tested in triplicate and no cross-reactivity was found.

Potential Cross-Reactant	Potential Cross-Reactant
Adenovirus	EBV
Human metapneumovirus (hMPV)	CMV
MERS-coronavirus	SARS-coronavirus
Human coronavirus HKU1	Influenza B
Human coronavirus OC43	Influenza A
Human coronavirus 229E	Chlamydia pneumoniae
Human coronavirus NL63	Haemophilus influenzae
Human parainfluenza virus1	Legionella pneumophila
Human parainfluenza virus2	Mycoplasma pneumoniae
Human parainfluenza virus3	Streptococcus pneumoniae
Human parainfluenza virus4	Rhinovirus
Streptococcus pyogenes (group A)	Pseudomonas aeruginosa
Staphylococcus epidermidis	Streptococcus salivarius
Respiratory Syncytial Virus A	Candida albicans
Mycobacterium tuberculosis	Bordetella pertussis

[INTERFERENCES]

The following substances have been tested and no interference was found with the AmonMed COVID-19 Antigen Rapid Test Kit (Colloidal Gold):

Zincum gluconium (i.e. Zicam)	Cromolyn	Whole Blood
Benzocaine, Menthol	Alkalol	Phenylephrine
Galphimia glauca, Sabadilla	Oxymetazoline	Tobramycin
Sodium Chloride (i.e. NeilMed)	Fluconazole	Fluticasone Propionate
Tamiflu (Oseltamivir Phosphate)	Phenol	Mupirocin
		Mucin

[LIMITATIONS]

- The SARS-CoV-2 antigen rapid test is only intended for personal use. The test should only be used once for the detection of SARS-CoV-2 nucleocapsid antigens in human saliva swab samples.
- Whether the test line is faint or intense does not necessarily relate to the SARS-CoV-2 viral load sample.
- As tests are less reliable in the later phase of infection, and in asymptomatic individuals, testing more than 7 days after the onset of symptoms is more likely to produce a negative result. The risk of a false negative result is higher in these circumstances.
- It is recommended to repeat the test within 1-3 days of the first test if there is a suspicion of infection or the individual is exposed to a high-risk setting.

- A negative result does not rule out infection with another type of respiratory virus.
- A positive result does not determine whether an individual is infectious.
- A negative test result does not rule out the possibility of infection. A negative result does not mean the individual is not infectious. If symptoms are present immediate further testing must be sought (e.g. PCR test).
- A negative test result may occur if the specimen was collected or extracted improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by a molecular assay.
- The components of this test kit are to be used exclusively for the qualitative detection of SARS-CoV-2 antigen in saliva swab specimens. Other specimen types may lead to incorrect results and must not be used.
- Failure to follow the instructions for test procedures and interpretation of test results may adversely affect test performance and/or produce invalid results.
- Improper storage, collection, or even freezing and thawing of the specimen can lead to inaccurate test results.
- If the viral load of the specimen is below the detection limit of the test, the test may produce a negative result.

[WARNINGS AND PRECAUTIONS]

- Children under 18 years of age should be assisted by an adult.
- Read the Instructions for Use (this leaflet) carefully before use.
- Do not re-use. Do not drink any liquid in the test kit.
- Do not use the test kit beyond the expiry date.
- Do not use the test kit if any of the kit components are missing, broken, or unsealed.
- Store the test kit at 2-30 °C. **Do not freeze.**
- Handle all specimens as potentially infectious.
- The specimens should be tested immediately after collection.
- Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
- Correct specimen collection is a quite important step during the testing procedures. Make sure to collect enough specimens with the saliva swab.
- The test should be used at room temperature (8-30 °C). If the test has been stored in a cool area (less than 8 °C), leave it at normal room temperature for 30 minutes before using.
- Use the saliva swab provided in the test kit to ensure optimal performance of the test.
- Apply the drops of test specimen only to the specimen well (S) on the test card.
- Too many or too few drops of the extracted specimen may result in an **invalid or incorrect test result**.
- Keep the test kit and kit components out of the reach of children and pets before and after use.

[STORAGE AND SHELF LIFE]

- The test kit should be stored at 2-30 °C, and the shelf life is 18 months.
- After the aluminium foil pouch is unsealed, it is recommended to use the test card within 1 hour at room temperature.
- The extraction solution is recommended to be used within 1 hour after opening at room temperature.

[PREPARATION BEFORE TEST PROCEDURES]

- Make sure all kit components are equilibrated to room temperature on a flat and clean surface.
- Make sure the kit components are complete without any missing or damaged after opening.
- Make sure to check the kit expiry date before testing, do not use the test if it is past its expiration date.
- Make sure to wash or sanitize your hands, and make sure they are dry before starting the test.
- Make sure to prepare the following materials required but not provided in the kit.
 - Timer (watch)
 - Waste container

[OPERATION OF TEST PROCEDURES]

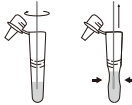


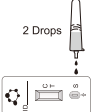

	1. Take out the Instructions for Use sheet and read it carefully.
	2. If the kit is a single test kit, push out the hole in the packaging box and insert the extraction tube. If the kit is a multi-test kit, take out the tube rack and assemble it. Insert the extraction tube into the rack.
	3. Peel off the foil seal from the top of the extraction tube, being sure to keep the extraction tube upright. CAUTION: Carefully peel the foil away from your eyes and face. Do not splash the liquid.
	4. Find the saliva swab in the sealed wrapper. Open the package from the opposite end to the soft fabric tip. CAUTION: Do not touch the soft fabric tip with your fingers to avoid contamination.
	5. Specimen Collection CAUTION: Do not eat or drink anything, or chew gum or use tobacco etc 30 minutes prior to testing. These contaminants can adversely affect the test result. 5.1 Insert the saliva swab into the mouth cavity. 5.2 Place the saliva swab between the upper and lower molars and immobilise the swab tip between the teeth by gently biting down for no less than 10 seconds. Keep your mouth closed for this time to give the saliva time to absorb into the swab. 5.3 After the saliva has been collected, remove the swab gently from your mouth. CAUTION: False negative results may occur if the saliva specimen is not collected properly.

For support and user assistance, contact the Australia Distributor:

Align Laboratories Pty. Ltd.

Address: P.O. Box 158 Bayswater, Victoria, Australia. 3153.

Phone: 1800 577 329/9 am and 8 pm, AEST)

	6. Specimen Handling 6.1. Insert the saliva swab into the extraction tube. Stir the swab at least 5 times. Leave the swab in the tube for about a minute before removing it. 6.2. Squeeze the swab against the inner walls of the extraction tube between your fingers to release as much of the liquid as possible when you remove the swab. You can dispose of the swab with normal household waste in accordance with local regulations.
	7. Press the cap onto the extraction tube tightly.
	8. Unseal the foil pouch and take out the plastic test card. Place the card on a flat surface.
	9. Apply 2 drops of the extracted specimen into the specimen well (S) of the test card. Start your 15-minute timer.
	10. Read the test result in 15–20 minutes. CAUTION: Test results may not be accurate after 20 minutes.

[WASTE DISPOSAL AFTER TEST PROCEDURES]



1. Place the used test card, extraction tube and saliva swab in a disposal bag and seal the disposal bag.

2. Dispose all used devices and other components into normal household waste container in compliance with the applicable local regulations.

3. Wash or sanitise your hands again.

[INTERPRETATION OF TEST RESULT]



Positive

Positive:

If both the control line (C) and the test line (T) appear within 15-20 minutes, the result is positive.

Caution: No matter how faint the coloured band is in the test line(T), the result should be considered as positive.



Negative

Negative:

If there is only a control line (C) and test line (T) is colourless within 15-20 minutes, the test result is negative.



Invalid

Invalid:

If the control line (C) is not observed within 15-20 minutes, the test is invalid. **Results must not be interpreted after 20 minutes.** You conduct the test again with a new test card.

[FREQUENTLY ASKED QUESTIONS (FAQ)]

1. When can/should I test myself?

You can have a test on yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to local regulations.

2. What should I pay attention to in order to have the optimal test result?

Always follow the instructions for use correctly. Perform the test immediately after collecting the sample. Apply two drops from the extraction tube into the specimen well of the test card. Too many or too few drops can lead to an incorrect or invalid test result.

3. The test strip is very discoloured. Why is that?

The reason for a clearly visible discoloration of the test strip is that too many drops has been dispensed from the extraction tube into the specimen well of test card. The indicator strip can only hold a limited amount of liquid. If the control line (C) does not appear or the test strip is very discoloured, please retest by using a new test card according to the instructions for use.

4. I have taken the test, but the control line (C) doesn't appear. What should I do?

According to the instructions for use, this test result is invalid. Please retest by using a new test card.

5. I am not sure about reading test result. What should I do?

Read the instructions for use again, and if this doesn't help, please contact the nearest health facility recommended by your local authorities for help.

6. If my test result is positive, what should I do?

You must follow the instructions of your local Government Health Authority, this may mean that you need to take a laboratory PCR test immediately, and/or self-isolate depending on your direction of your local Government Health Authority. You should also inform the immediate contacts you have had in past 24 hours, so they can take any appropriate precautions.










7. If my test result is negative, what should I do?

Negative results may require additional testing to confirm your results if you are symptomatic. If the patient is symptomatic, continue the use of antigen testing every 24 hours for 3 days and/or take a laboratory PCR test. If the patient is asymptomatic, it is likely that you were not infectious at the time the test was taken. A negative test result, however, is not a guarantee that you do not have COVID-19 and/or a SARS-CoV-2 infection. Please continue to follow all directions as per your local Government Health Authority.

8. Will this test hurt?

No, the saliva swab is not sharp, and it should not hurt.

[EXPLANATION FOR SYMBOLS]

	Expiry date		Batch number		See instructions for use
	Test (s) per kit		Store at 2-30 °C		Catalogue number
	Manufacturer		In vitro diagnostic use		Do not reuse

[ISSUE DATE AND VERSION NO.]

Issue Date: May 5, 2022; Version 1.1

[CONTACT INFORMATION]

Australia Distributor:

For support and user assistance, contact the Australia Distributor:

Align Laboratories Pty. Ltd.

Address: P.O. Box 158 Bayswater, Victoria, Australia 3153.

Phone: 1800 577 329 (9 am and 8 pm, AEST)

Manufacturer:

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Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods Administration (TGA) via the Medical Device Incident Reporting scheme, email iris@tga.gov.au or call 1800 809 361

To contact your local state/territory health department, visit on the following link:

<https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments>

LOCAL STATE AND TERRITORY HEALTH DEPARTMENTS

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