Genrui

SARS-CoV-2 Antigen Test Kit (Colloidal Gold) - self-testing

Instructions for Use

- For self-testing
- For use with nasal swab specimens

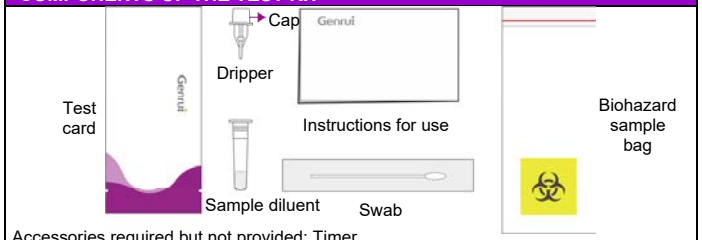
REF	Σ
52104097	1
52112086	5
52129004	20

QR CODE AND HOTLINE

Instructional Video

Please scan the QR code to access the Instructional Video.
Hotline: 1300 988 527
Operating hours: Monday - Sunday, 9am-7pm AEST/ 9am-8pm AEDT.

COMPONENTS OF THE TEST KIT



Accessories required but not provided: Timer

A. PREPARE FOR THE TEST

1.Wash your hands thoroughly before the test. Take out all kit components at room temperature, make sure the sample diluent and test card reach the room temperature.

2.Use the dripper tip to pierce the sealed foil of the sample diluent tube, pull out the dripper and insert the tube into the box hole for later use. (Note: pierce the sealed foil thoroughly, but there should be a gap between the dripper and the tube to pull out that dripper.)

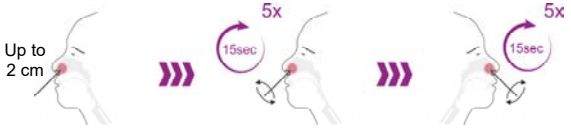
B. COLLECT THE NASAL SAMPLE

1.Tear the swab packaging bag, keep the swab tip clean and make sure it does not touch any surface before use.

2.Insert the entire swab tip (usually 2 cm) into left nostril.

3.Firmly brush against insides of nostril in a circular motion 5 times or more for at least 15 seconds.

4.Remove swab and insert it into right nostril, firmly brush against insides of nostril in a circular motion 5 times or more for at least 15 seconds.



5.Remove the dripper, put the swab into the sample diluent and proceed to sample processing. `

Note: It is recommended that specimens are tested at the time of collection.

C. PERFORM THE TEST

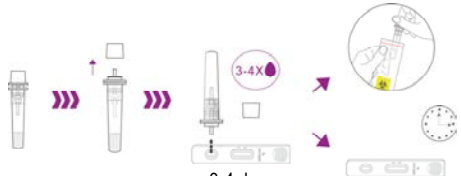
1.Pinch the tube wall with fingers as shown below, meanwhile rotate the swab against the tube wall 5-6 times to allow the swab to soak well. After the sample is completely dissolved, let it stand for 1 minute.

2.Pinch the tube wall to squeeze the swab gently to keep as much liquid in the tube as possible. Remove the swab and put it into the biohazard sample bag.

3.Press the dripper thoroughly onto the tube and shake it at least 10 times to mix it evenly.

4.Take out the test card from the package and lay it flat on a dry surface.

5.Remove the dripper cap at the top, add 3 to 4 drops (about 0.1 mL) of evenly mixed solution from the tube vertically into the sample hole of test card, close dripper cap and put the used sample diluent tube into the biohazard sample bag. Wait for the test results from test card.



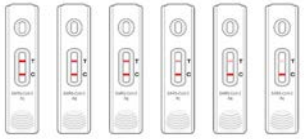
3-4 drops

Read the result in 15-20 minutes

Note: Read and interpret the test result at 15 minutes, the test result should not be read and interpreted after 20 minutes.

D. INTERPRET TEST RESULTS

Positive Result: The appearance of both control line (C) and test line (T) indicates the test result is positive. **Look very closely! The T line can be very faint. Any pink/purple line visible here indicates a Positive Result.** Below are examples of the colors of T line:



If positive, please 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 Result: The appearance of only the control line (C) and no test line (T) indicates a negative result.

A negative result does not rule out infection with another type of respiratory virus. If symptoms like headache, migraine, fever, loss of taste, etc. continue, you should repeat the test after 1-2 days, as the coronavirus cannot be detected with complete accuracy during all stages of an infection. Please continue following local guidelines for self-isolation and consult your doctor.

Invalid Result: The control line (C) does not appear, it will be considered as invalid regardless of whether there is T line. The test should be repeated.

The control line may be faulty due to insufficient sample volume or improper operation. Please review the test procedure and repeat with a new test. If the problem persists, stop using the test kit and contact the Australian Sponsor.

E. DISPOSE THE TEST KIT

1.Put test card, sample diluent and swab into the biohazard sample bag, then seal it tightly.

2.Dispose of the sealed biohazard sample bag in household waste and then wash your hands.

INTENDED USE

Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold) is an immunochromatographic assay for the rapid and qualitative detection of SARS-CoV-2 nucleocapsid protein in nasal swab specimens from individuals suspected of COVID-19 within the first 7 days of the onset of symptoms, as an aid in identifying SARS-CoV-2 infection. The product does not differentiate between SARS-CoV and SARS-CoV-2.

Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information should be considered to determine infection status. Positive results do not rule out other bacterial or viral infections. If positive, please 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 results do not rule out SARS-CoV-2 infection and should be used only to support diagnosis. Negative results from patients with symptoms beyond 7 days should follow the guidance from the local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

The product is intended to be used for self-testing by adults, between 18 and 12 years of age under adult supervision. Children under 12 should be tested by adults. For *in vitro* diagnostic use only.

WARNINGS AND PRECAUTIONS

- Read these instructions and follow the steps to ensure accurate results.
- For *in vitro* diagnostic use.
- Do not use a test kit that is expired.
- All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.
- Keep test kit and materials out of the reach of children and pets before and after use.
- Do not mix components from different kit lots.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Humidity and temperature can affect test results. Carry out the test at room temperature (18-28°C).
- Do not touch the reaction area of the test strip.

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

●Inadequate or improper nasal swab sample collection may yield false negative test results. Too many or insufficient droplets of sample diluent may lead to incorrect results.

●The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 20 minutes, false negative or false positive results may occur, and the test should be repeated with a new test card.

●If the sample diluent contacts the skin or eye, flush with copious amounts of water. If irritation persists, please seek medical advice.

TEST PRINCIPLE

During the test, the processed samples to be tested are added to the sample wells. When the sample contains SARS-CoV-2 antigen, it first combines with the colloidal gold-labelled anti-SARS-CoV-2 antibody. Chromatography is then performed. When it binds to the anti-SARS-CoV-2 monoclonal antibody previously immobilized on another membrane, a purple-red band will appear in the test area (T). A purple-red band will appear in the quality control area (C) regardless of the presence of new coronavirus antigen in the sample, which is used as a criterion to determine whether there is enough sample or the chromatography is processed properly.

MATERIALS PROVIDED

Materials Provided	Quantity (pcs)		
	1T	5T	20T
Test Card	1	5	20
Sample Diluent	1 x 0.5 mL	5 x 0.5 mL	20 x 0.5 mL
Dripper	1	5	20
Swab	1	5	20
Biohazard sample bag	1	5	20
Instructions for use	1	1	4

STORAGE AND STABILITY

●Store the test kit at 2°C-30°C. It is stable until the expiration date printed on the outer package. Do not use after expiry.

QUALITY CONTROL

Each test card has a built-in control. The purple-red band at the control line can be considered as an internal positive program control. If the procedure was performed correctly, the control line will appear.

LIMITATIONS

●Test results cannot be used as a sole basis for diagnosis. Comprehensive judgments should be made based on clinical symptoms, epidemiological conditions and further clinical data.

●This is only a presumptive test, please follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

●A positive result cannot necessarily determine whether a person is infectious.

●The accuracy of the test depends on the sample collection process. Improper sample collection will affect the test results.

●If the test is not performed within the first 7 days of symptom onset, false negatives might occur.

● The negative result may be caused by:

a) Improper sample collection, improper sample transfer or handling so that the amount of virus in the sample is too low.

b) The level of SARS-CoV-2 antigen is lower than the limit of detection.

c) Variations in viral genes may lead to changes in antibody determinants.

●Repeat the test within 1-3 days is recommended in occupational risk, high risk settings or in case there is an ongoing suspicion of infection.

●There may be other unlisted reasons that cause the detection to be abnormal.

●This product can only qualitatively detect the SARS-CoV-2 antigen in the sample, but cannot determine the concentration of the antigen in the sample.

●The tests are less reliable in the later phase of infection and in asymptomatic individuals.

PERFORMANCE CHARACTERISTICS

1. Clinical performance

Clinical performance of the Genrui SARS-CoV-2 Antigen Test Kit was established with 727 nasal swabs collected directly from individuals who were suspected of COVID-19. The results showed that the Sensitivity (Positive Percent Agreement) is 90.83% (198/218), Specificity (Negative Percent Agreement) is 99.41% (506/509), and the Overall Accuracy is 96.84% (704/727).

2. Limit of detection

The limit of detection of this test kit is 1.8×10^2 $TCID_{50}$/mL.

3. Usability

104 non-professional subjects were enrolled to perform the self-test without additional assistance, relative sensitivity was 90.91% (30/33), and the relative specificity was 100% (71/71), indicating that lay users can reliably interpret the test results. The IFU and labelling provided with the test kit was comprehensive for its intended population, and the ease of use was suitable for its intended population.

4. Cross-Reactivity and Microbial Interference

The following viruses and microorganisms do not affect the test results: Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Adenovirus, Human Metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A, Influenza B, Enterovirus, Respiratory syncytial virus A, Respiratory syncytial virus B, Rhinovirus, MERS-CoV, Haemophilus influenza, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Staphylococcus epidermidis, Staphylococcus aureus, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii (PJP), Pooled human nasal wash–representative of normal respiratory microbial flora.

Note: Test kit has cross-reactivity with Human SARS-coronavirus nucleoprotein at a concentration of 25 ng/mL or higher because SARS-CoV has high homology (79.6%) to the SARS-CoV-2.

5. Interfering Substances

The following potentially interfering substances had no impact on the performance of the test kit:

Mucin, Blood, Pus, Oxymetazoline, Dexametazoline, Sulfur, Zanamivir, Mupirocin, Benzocaine, Naso GEL, Nasal Drops (Phenylephrine), Nasal Spray (Cromolyn), Nasal Congestion Relief Gel, Tobramycin, Fluticasone Propionate, Tamiflu (Oseltamivir Phosphate).

6. Information on SARS-CoV-2 Variants

The performance of Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold) is not affected by the following SARS-CoV-2 Variants tracked by WHO:

Alpha, Beta, Gamma, Delta, Omicron, Lambda, Mu, Epsilon, Zeta, Theta, Iota, Eta, Kappa, etc.

INDEX OF SYMBOLS

	Do not re-use	IVD	*In vitro* diagnostic medical device		Temperature limit
	Consult instructions for use	LOT	Batch code		Contains sufficient for <n>tests
	Use-by date		Keep away from sunlight		Keep dry
	Do not use if packaging is damaged		Manufacturer		Production date

MANUFACTURER

Genrui Biotech Inc.
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CONTACT INFORMATION

Report any performance or usability issues to TGA by e-mail (iris@tga.gov.au) or call 1800 809 361. For support services, contact your local authorities listed below.
https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments

Australian Capital Territory Department of Health	Coronavirus helpline: 8am to 8pm daily 02 6207 7244	CT Health https://health.act.gov.au/
New South Wales Department of Health	Coronavirus hotline: (Service NSW, 24/7) 137 788	NSW Health https://www.health.nsw.gov.au/
Northern Territory Department of Health	Coronavirus hotline: (National helpline) 1800 020 080	Department of Health Northern Territory https://health.nt.gov.au/
Queensland Department of Health	Coronavirus hotline: 134COVID 134 268	Queensland Health https://www.health.qld.gov.au/
South Australian Department of Health	Coronavirus hotline: (9am to 5pm daily) 1800 253 787	SA Health https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	Public Health Hotline: (coronavirus) 1800 671 738	Department of Health Tasmania https://www.health.tas.gov.au/
Victorian Department of Health	Victorian coronavirus hotline: (24/7) 1800 675 398	Department of Health and Human Services Victoria https://www.dhhs.vic.gov.au/
Western Australian Department of Health	Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri) 1800 595 206	WA Health https://www.healthywa.wa.gov.au/

AUTHORIZED REPRESENTATIVE IN AUSTRALIA

Almitas Group International Pty Ltd
Address: 36 Church Street, Richmond, VIC 3121
Email: enquiries@almitasgroup.com
Website: https://almitasgroup.com/covid-antigen-test-kit/

ALMITAS MEDICAL & INDUSTRIAL

Almitas Group Support Hotline: 1300 988 527
Operating hours: Monday - Sunday, 9am-7pm AEST/ 9am-8pm AEDT

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