IVD CE 1434 For self-test use

SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method) Instruction for Use

【Product Name】

SARS-CoV-2 Virus Antigen Detection Kit (colloidal gold method)

【Package Specification】

1 test/kit, 5 tests/kit, 10 tests/kit

【Catalogue Number】

1 test/kit	MFG030029
5 tests/kit	MFG030050
10 tests/kit	MFG030030

【Intended Use】

This kit is an immunoassay used for in vitro qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swabs specimens from symptomatic suspects of COVID-19 within the 7 days post symptom onset. This kit is for personal use by untrained layman as a rapid test method for SARS-CoV-2 antigen detection. It is suitable for users over 15 years old. Users under 15 years of age should be tested with assistance of adult. The kit is used to aid in clinical diagnosis of COVID-19. The kit can detect Delta variants of COVID-19.

【Detection Principle】

This kit uses the double-antibody sandwich method to detect the nucleocapsid protein antigen from SARS-CoV-2. Colloidal gold is used as a tracer to label the specific antibodies of the SARS-CoV-2. The detection line on the nitrocellulose membrane is coated with SARS-CoV-2 antigen-specific antibody, and the quality control line is coated with a goat anti-mouse IgG antibody.

During detection, the test substance will react with the pre-coated colloidal gold-labeled antibody to form an antigen-antibody complex, and then the complex will move forward by capillary action, will be captured by the antibody and aggregated to the detection line, thus showing a purple-red band. The band indicates that the new coronavirus (SARS-CoV-2) antigen test is positive; if the sample does not contain the new coronavirus (SARS-CoV-2), it will not form an antigen-antibody complex and will not be captured by the antibody at the detection line. No purple-red bands are produced, indicating that the sample is negative. Regardless of whether the sample contains the substance to be tested, a purple-red band should appear at the quality control line C as an internal control standard for whether the chromatography process is normal and whether the reagent is valid. By visually observing whether a purple-red band appears on the detection line, it can be determined whether the sample to be tested contains the new coronavirus (SARS-CoV-2) antigen.

【Key Components】

Pack size	Contents
1 test/kit	1 SARS-CoV-2 Ag Detection Card, 1 Sample Extraction Solution, 1 Swab, 1 instruction for use
5 tests/kit	5 SARS-CoV-2 Ag Detection Card, 5 Sample Extraction Solution, 5 Swab, 1 instruction for use
10 tests/kit	10 SARS-CoV-2 Ag Detection Card, 10 Sample Extraction Solution, 10 Swab, 2 instruction for use

Note: The detection cards and sample extraction solution between different batches cannot be mixed.

Material required but NOT provided: Clock, timer or stopwatch.

【Warning and Precaution】

1. For ***in vitro*** diagnosis. Please read the instructions carefully before testing.
2. Only use the test once and use it within the validity period.
3. Keep out of reach of children.
4. Users under the age of 15 must be tested under adult supervision.
5. At room temperature (39.2-86 °F (4-30 °C)), the detection card should be used as soon as possible within 1 hour after being taken out from the aluminum foil bag to avoid exposure of air and moisture which may affect the test results.
6. All samples and reagents should avoid direct contact with skin and eyes, and do not swallow. Once this happens, rinse immediately with plenty of water and go to the hospital for treatment.
7. To ensure the accuracy of the interpretation result, please obtain the result within the specified 15-20 minutes reaction time in the manual.
8. Follow government instruction about self-testing.
9. The test should not be used if the kit is stored or transported in abnormal conditions.
10. The test should not be used in the event of damage to the protective packaging.
11. All specimens as potentially might have infectious, even if the test result is negative, they contain perhaps infectious material all waste from the used self-test must be placed in a plastic bag , close the bag tightly. If the result was positive, be very careful with the detection card, sample extraction solution and the swab. Also take care of a good hygiene at home. The table or timer surface also needs to be disinfected in timeand then wash your hands. All waste shall be disposed of in accordance with government instruction.

【Storage and Sability】

Stored at 39.2-86 °F (4-30 °C), the validity period is 12 months. **DON'T FREEZE. Do not use beyond the expiration date.** After opening the aluminum foil bag, please use it up within 1 hour. It can be stable for 7 days when shipped at 37°C or at 40°C.

【Limitations】

1. This test is a qualitative analysis test and cannot be used for quantitative detection.
2. This kit is intended for the detection of SARS-CoV-2 antigen in human swab samples from patients who are symptomatic suspected of COVID-19 within the first seven days of symptom onset. This kit has no clinical evaluation for individuals without symptoms.
3. If individuals without symptoms used the kit, the test may result in either true positive (i.e. when the viral load is high) or false negative (i.e. when the viral load is lower than the limit of dectecion of this kit). Additional confirmatory testing with a molecular test for positive results and negative results may also be necessary.
4. A positive result cannot determine whether a person is infectious.
5. A positive test result cannot differentiate between SARS-CoV and SARS-CoV-2 Virus.
6. **If the test is positive, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.**
7. If the analyte in the sample is lower than the detection sensitivity of the detection card, it will cause false negative results. False negative results may occur if testing is performed after 7 days of symptom onset and in asymptomatic individules. False negative results may also occur due to improper sampling.
8. A negative result does not rule out infection with another type of respiratory virus, the person must seek immediate further testing.
9. Negative results do not rule out SARS-CoV-2 infection, **if you are experiencing COVID-like symptoms or if symptoms persist, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.**
10. Even if the result is negative, you still need to observed all protective and hygienic measures.
11. Repeat testing after within 24-48 hours is recommend if ongoing suspicion of infection, high risk setting or occupational or other requirement.
12. Do not use the test for anyone under 2 years of age.
13. The test cannot differentiate between SARS-CoV-1 and SARS-CoV-2 Virus.

【Analytical Performance】

Limit of Detection (LoD):

The LoD of the Antigen Detection kit is 200 $TCID_{50}$/mL.

Interference Substances:

The following interference substances have been tested using the Antigen Detection kit and no interference was observed.

Mucoprotein	Flunisolide	α-interferon	Lopinavir
Human blood	Tobramycin	Ribavirin	Ritonavir
Phenylephrine	Budesonide	Oseltamivir	Arbidol
Oxmetazoline	Mometasone	Levofloxacin	Ceftriaxone
Sodium chloride	Fluticasone	Azithromycin	Meropenem
Beclomethasone	Zanamivir	Triamcinolone acetonide	
Dexamethasone	Peramivir	Histamine hydrochloride	

Cross Reactivity and Microbial Interference:

The Antigen Detection kit has been tested for potential pathogens virus in the absence or presence of heat-inactivated SARS-CoV-2 virus. No cross-reactivity or interference was observed with the following microorganisms:

Human Coronavirus (HKU1,OC43,NL63,229E)	EB virus	Legionella pneumophilia
Novel influenza A H1N1 (2009)	Measles virus	Mycobacterium tuberculosis
Influenza A (H1N1, H3N2, H5N1, H7N9)	Human cytomegalovirus	Streptococcus pneumoniae
Influenza B (Yamagata, Victoria)	Rotavirus	Streptococcus pyogenes
Respiratory syncytial virus (A and B)	Norovirus	Bordetella pertussis
Respiratory syncytial virus B	Mumps virus	Pneumocystis jirovecii (PJP)
Parainfluenza (1, 2, 3 and 4)	Varicella-zoster virus	Candida albicans
Rhinovirus (A, B, C)	MERS	Staphylococcus aureus
Adenovirus (1, 2, 3, 4, 5, 7, 55)	Mycoplasma pneumonia	Staphylococcus epidermis
Human metapneumovirus	Chlamydia pneumonia	
Enterovirus (A, B, C and D)	Haemophilus influenzae	

【Usability Study】

90 people self-sampled and self-tested using the Antigen Detection kit, people were also tested with a PCR. The tests correctly identified 96.67 % (1 out of 30 people) of positive samples and 100 % (0 out of 60 people) of negative samples.

100 participants were interpreting the pictures of the test card designed with different results. At least 99% of the result interpretation of the 100 lay people are completely consistent with those of laboratory technician.

【Clinical Performance】

The performance of the Antigen Detection Kit was evaluated in 570 specimens of anterior nasal swabs collected from symptomatic suspects of COVID-19 within 7 days post symptom onset comparing to RT-PCR assay. The results showed that the Sensitivity is 89.09% (98/110), Specificity is 100% (460/460) and an Overall Accuracy is 97.89% (558/570).

Table 1 Performance with anterior nasal swab specimens compared to RT-PCR

Antigen assay	RT-PCR assay		
	Positive	Negative	Total
Positive	98	0	98
Negative	12	460	472
Total	110	460	570
Sensitivity	89.09% (98/110) (95% CI: 81.72% - 94.23%)		
Specificity	100% (460/460) (95% CI: 99.20% - 100%)		

If there are poor performance or usability issues, please contact the TGA to report an issue via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.

【Variants of COVID-19 Detection】

The Antigen Detection Kit has been tested and proven to detect multiple variants of COVID-19, including Alpah, beta, Gamma, Kappa, Delta and Omicron Variant. The R&D department is constantly working to ensure that the test performance won't be affected.

【References】

1. Wang Lei, Wu Yingsong, Tang Yongping, et al. Preliminary study on the detection of SARS virus antigen by time-resolved fluorescence immunoassay technique[J]. Chinese Journal of Nosocomiology, 2005, 15(1):1-4.
2. Lorena Porte, Paulette Legarraga, Valeska Vollrath, et al. Evaluation of novel antigen-based rapid detection test for the diagnosis of SARS-CoV-2 in respiratory samples[J]. Journal Pre-proof, 2020,05(098):1-20.
3. O. Vandenberg, Development and potential usefulness of the COVID-19 Ag RespiStrip diagnostic assay in a pandemic context, Infectious Diseases (except HIV/AIDS),(2020), https://doi.org/10.1101/2020.04.24.20077776.

IVD	In vitro diagnostic medical device	CE 1434	CE mark
	Manufacturer		Consult instructions for use
	Use by date		Keep away from sunlight
LOT	Batch code		Keep dry
	Date of manufacture/country of manufacture		Do not reuse
REF	Catalogue number	Σ	Contains sufficient for n tests
	Caution		Temperature limitation
CE 0413	CE MARK（SWAB）		DO NOT USE IF PACKAGE IS DAMAGED
STERILE EO	STERILIZED USING ETHYLENE OXIDE （SWAB）		

【Contact Information】

Manufacturer: BGI Europe A/S

Manufacturer Address: Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark

Manufacturing Site: BGI Biotechnology (Wuhan) Co.,Ltd

Site Address: Building B2, B1, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan

Local state and territory health departments

Information regarding available support sevices can also be obtained by contacting your local state and territory health department at:

State Authority	Coronavirus Hotline	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/

Australian Authorised Representative:

BGI HEALTH (AU) COMPANY PTY LTD

Level 6 CBCRC Bld., 300 Herston Road, QLD 4006 Australia

For Customer Support :

Tel : +61733620475

Email : bgi-australia@genomics.cn

For information on the correct use of this test and for interpretation of the test results.

Customer Service Hours : 9am—7pm(AEST) or 9am——8pm(AEDT), 7 Days a week

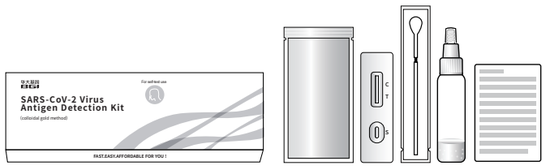
Scan the QR code to watch the how to use video, or visit https://bgi-australia.com.au/bgi-rat or https://www.youtube.com/watch?v=TflFqJdqcj8

【Revision history】

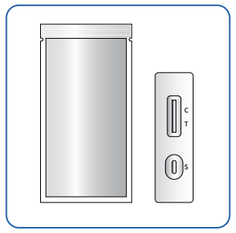
Version	Chapter	Revision contents	Date
V1.0	All	First release	2021/10/17
V2.0	All	Revise according to the requirement of TGA	2022/01/23
V3.0	All	1.Revise according to the requirement of TGA; 2. Add 5 tests/kit, 10 tests/kit	2022/02/25

SARS-CoV-2 Antigen Self Test

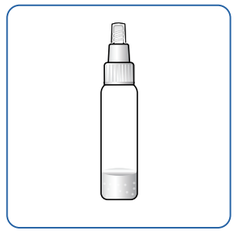
Quick Reference Instruction for Anterior Nasal Swab Specimen from patients who are suspected of COVID-19.
Read this step-by step guide carefully before you start the test.



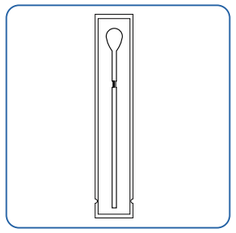
COMPONENTS OF THE TEST KIT



SARS-CoV-2 Ag Detection Card



Sample Extraction Solution

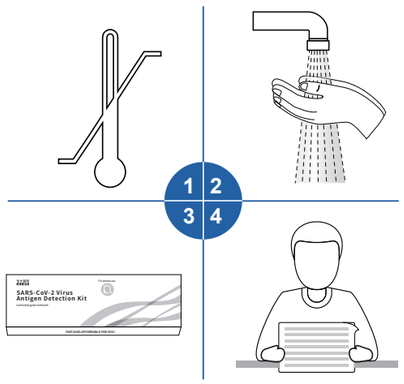


Sterile Swab

Instruction Manual

Material required but NOT provided:clock, timer or stopwatch

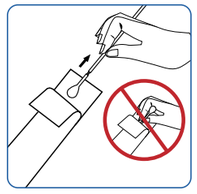
1. Ensure the test be carried out at room temperature 39.2-86 °F (4-30 °C).
2. Disinfect the surface where you will open the test kit. Wash your hands for at least 20 seconds before you handle the test kit.
3. Check your kit. Check the expiry date on the box. Do not use the kit when packaging is damage or any kit components is damage, missing or has expired.
4. Read the instruction carefully before you start the test.

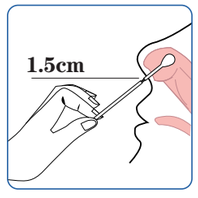


COLLECT AND PROCESS NASAL SAMPLE

1 Unscrew the cap off the sample extraction solution tube and put the tube on a stable place.

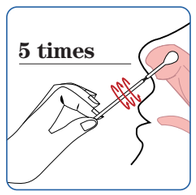
2 Peel off the swab package and take out the swab. Avoid touching the soft end with your hands or anything else.

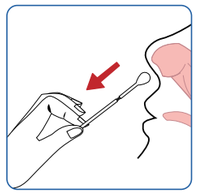




3 Gently insert the entire soft end of the swab into your nostril no more than ¾ of an inch (1.5 cm) into your nose.

4 Slowly rotate the swab, gently pressing against the inside of your nostril 5 times for a total of 15 seconds. Get as much nasal discharge as possible on the soft end of the swab.

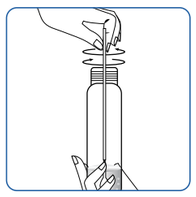


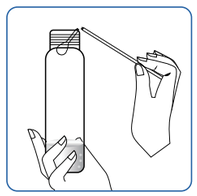


5 Gently remove the swab from your nostril.

6 Using the same swab, repeat steps 3–5 in your other nostril with the same end of the swab.

7 Insert the swab completely into the sample extraction solution, rotate it near the inner wall of the tube for 10 rotations to dissolve the sample.



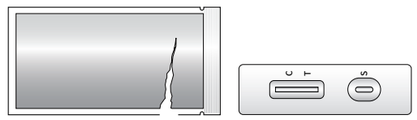


8 Break the swab stick at the breaking point, leaving the soft end in the tube.

9 Screw on the cap, and put the tube on a stable place.

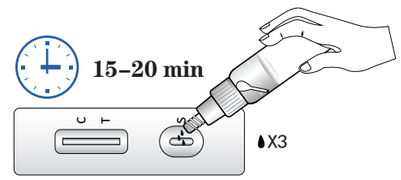
PERFORM THE TEST

1. Take out the detection card from the foil bag and use it within 1 hour. Place the detection card on stationary leveled surface, which is not in direct sunlight.



2. Take off the white cover of the tube with processed sample.

3. Add 3 drops of the processed sample to the sample well of the detection card. The detection card with the sample added should be allowed to stand at room temperature (39.2-86 °F (4-30 ˚C)) for 15-20 minutes to determine the results.**The result should not be read after 20 minutes.**



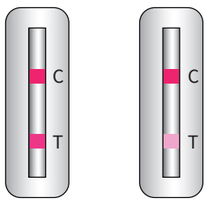
4. Screw on the cap.

INTERPRET THE RESULTS

1. Positive Result: Both the control line (C) and the test line (T) appear

The color intensity of line T depends on the viral load. Read the result CAREFULLY.

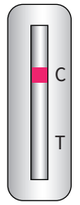
Any faint colored line(s) should be considered as positive, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.



2. Negative Result: Only the control line (C) appear

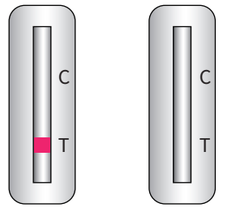
The amount of antigen in a sample may decrease as the duration of illness increases. If the viral load in the sample is lower than the test's limit of detection, it will cause false negative results. Negative results should be reported as preliminary results.

If you are experiencing COVID symptoms, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

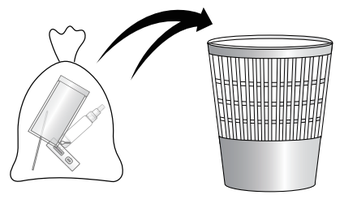


3. Invalid Result: The control line (C) fail to appear

If line C is colorless, regardless of whether the line T is present, the result is invalid. Invalid result indicate that your test has experienced an error and is unable to interpret the result of test. The most frequent causes are insufficient sample volume or inappropriate handling; **repeat the test with a New test kit.**



After the test, seal all of the components used into two layers of plastic bag and dispose in the waste container. Clean the work surface and wash hands.



Australian Authorised Representative:

Australian Authorised Representative:

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For Customer Support :
Tel : +61733620475
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For information on the correct use of this test and for interpretation of the test results.
Customer Service Hours : 9am—7pm(AEST) or 9am——8pm(AEDT), 7 Days a week

Scan the QR code to watch the how to use video, or visit https://bgi-australia.com.au/bgi-rat or https://www.youtube.com/watch?v=TflFqJdqcj8