SARS-CoV-2 Antigen Rapid Qualitative Test
Instructions for Use Type A

IVD

Scan me for more information including how to use video and further support.

https://www.xiamenbiotime.com/sars-cov-2-antigen-rapid-qualitative-test-type-a_p96.html

Customer Support Helpline: +61416633305
Operation Hours: 9am-7pm AEST / 9am-8pm AEDT, 7 days per week

Please read these instructions for use before undertaking a test.
This product is intended as a self-testing in-vitro diagnostic device.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Qualitative Test is intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in human nasal swabs samples from individuals who are suspected of COVID-19. The test is intended as an aid in diagnosis of symptomatic individuals within the first 7 days of symptom onset.

The SARS-CoV-2 Antigen Rapid Qualitative Test is intended for layperson as self-testing at home or similar environment. The test is intended for persons aged 18 years or above.

SUMMARY

A novel coronavirus (2019-nCoV) was identified in December 2019, which has resulted in millions of confirmed human infections worldwide. Cases of severe illness and deaths have been widely reported. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2. SARS-CoV-2 belongs to the broad family of viruses known as coronaviruses [1]. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLES OF THE PROCEDURE

This reagent is based on a colloidal gold immunochromatography assay.

During the test, sample extracts are applied to the test cartridges. If there were SARS-CoV-2 antigen in the extract, the antigen will bind to the SARS-CoV-2 monoclonal antibody. During lateral flow, the complex will move along the nitrocellulose membrane toward the end of the absorbent paper. When passing the test line (line T, coated with another SARS-CoV-2 monoclonal antibody) the complex is captured by SARS-CoV-2 antibody on test line resulting in coloring on line T; when passing the line C, colloidal gold-labeled rabbit IgG is captured by control line (line C, coated with goat anti-rabbit IgG) resulting in coloring on line C.

REAGENTS

Materials Provided
For Reagent with Extraction Buffer Sachet

Catalogue No.: / Component	BT1394	BT1395	BT1396	BT1397	BT1398	BT1399	BT1400	BT1401
SARS-CoV-2 Antigen Test Cartridge	×1	×2	×3	×5	×7	×10	×25	×30
Extraction Tube	×1	×2	×3	×5	×7	×10	×25	×30
Extraction Buffer Sachet	×1	×2	×3	×5	×7	×10	×25	×30
Instructions for Use	×1	×1	×1	×1	×2	×2	×25	×30
Qualification Certificate	×1	×1	×1	×1	×1	×1	×1	×1
Plastic Waste Bag	×1	×2	×3	×5	×7	×10	×25	×30
Extraction Tube Holder (Attach to the box)	×1	×1	×1	×1	×1	×1	×1	×1
Nasal Swab	×1	×2	×3	×5	×7	×10	×25	×30

**Note: The nasal swab is sterile swab*

Main components of the test kits:

SARS-CoV-2 monoclonal antibody	Applied to the nitrocellulose membrane in the test area
Goat anti-rabbit IgG	Applied to the nitrocellulose membrane in the control area
SARS-CoV-2 antibodies, colloidal gold-labeled rabbit IgG	Applied to the conjugate pad
Other supported test devices	/

Main components of the extraction solution:

Na_2HPO_4, NaH_2PO_4, NaCl, Water.

Materials required but not provided:

Timer

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. The test can only be used once.
3. This test has been validated only for the detection of proteins from SARS-CoV-2.
4. Do not use this kit beyond the expiration date printed on the outside carton.
5. Do not use if the sterile swab package or test kit is damaged.
6. Use the test within 30 minutes after unsealing the foil pouch.
7. Do not mix different batches of the test device and extraction solution.
8. Inadequate or inappropriate specimen collection are likely to yield false test results.
9. During use, avoid contacting with the extraction solution. If it accidentally splashes into the eyes, or touches the skin or mucous membrane, rinse with plenty of water as soon as possible. If irritation is found, please contact doctor.
10. The test kit should be stored out of reach of children and pets.
11. It is preferred to test the specimen immediately after collection and should not be repeatedly frozen and thawed.

STORAGE AND STABILITY

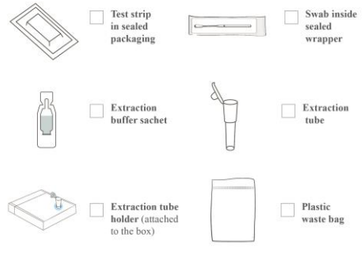
1. Store the test kit at 2-30℃, the shelf life is 24 months.
2. Test Cartridge should be used rightly after opening the pouch.
3. Reagents and devices must be at room temperature (14-30 ℃) when used for testing.

TEST METHODS

1. Wash your hands with running water or hand sanitizer and dry your hands.

2. Gently blow your nose into a tissue.

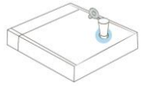
3. Take out SARS-CoV-2 antigen rapid qualitative test, check if it is within the shelf life.
4. Open the test kit, and check the test kit contents. Make sure that nothing is damaged or broken.



5. Read the instruction manual carefully before operation.
6. Carefully twist or snap open the sachet. Open it away from your face and be careful not to spill any of the liquid.

7. Open the extraction tube and gently squeeze all of the liquid from the buffer sachet into the tube.

8. Place the filled tube in the extraction tube holder (attached inside the box) to avoid spilling the liquid.

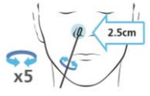


9. Take the test strip out of the sealed packaging and place it onto the cleaned flat surface.

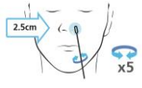
10. Remove the swab from the packet. Make sure you do not touch the soft part of the swab.

11. Hold-up your head slightly. Insert the swab into one nostril.

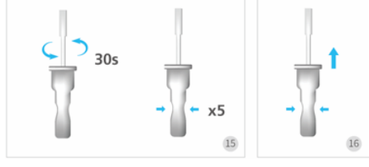
12. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril.



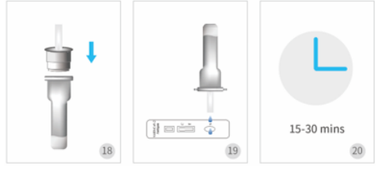
13. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.



14. Remove the swab slowly.
15. Insert the swab tip into the extraction tube. Rotate the swab for about 30 seconds. gently press the swab head five times to remove as much liquid as possible from the swab.



16. Hold and press the swab head against the wall of tube with force in order to release the sample into the extraction solution from swab head while removing the swab out of the extraction tube.
17. Dispose of swab into the swab packet.
18. Install the nozzle cap onto the extraction tube.
19. drip 2 drops of extraction solution into the specimen well marked “S” on the test strip.
20. set a timer for 15 minutes. Read the results at 15~30 minutes. Results must not be read after 30 minutes.



Note: The test should be operated at room temperature（14-30℃).

INTERPRETATION OF TEST RESULTS

Line C must be colored to have a valid test result.

Valid results:

Negative result: There is coloration on line C only showing as the following picture, suggesting that there is no SARS-CoV-2 antigen in the specimen.

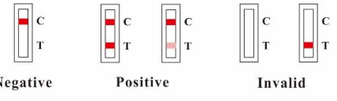
If the test result is negative:

That means that you are negative or that the viral load is too low to be detected by the test. A negative result does not mean you do not have COVID-19. If symptomatic, please follow the guidance from your local State or Territory Health Department. If unwell, seek medical assistance.

Positive result: There are coloration on both line C and line T showing as follow pictures, suggesting that there is SARS-CoV-2 antigen in the specimen.

If the test result is positive:

A positive result indicates suspicion of COVID-19 infection. Please follow the guidance from your local State or Territory Health Department, including for reporting positive results and/or confirmatory testing if required. If unwell, seek medical assistance.



Invalid result:

There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.

If the test result is invalid:

It is possibly caused by incorrect test operation. Please repeat the test and repeat testing must be performed using a freshly collected specimen and a new test cassette. If the repeated test results continue to be invalid, please contact your doctor or a COVID-19 test centre.

SAFELY DISPOSE OF YOUR TEST KIT

Dispose of all used test kit components in the plastic waste bag provided then dispose of this with normal household waste.

Wash your hands thoroughly after handling.

LIMITATIONS OF THE PROCEDURE

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swabs only.
2. Positive test results do not rule out co-infections with other pathogens and cannot necessarily determine whether a person is infectious.
3. A negative result does not rule out infection with another type of respiratory virus.
4. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
5. Repeat testing within 1-3 days if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
6. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
7. the tests are less reliable in the later phase of infection and in asymptomatic individuals.

CLINICAL PERFORMANCE

A clinical evaluation was conducted comparing the results obtained using the SARS-CoV-2 Antigen Rapid Qualitative Test with RT-PCR test result. The clinical trial included 550 nasal swab specimens. The results demonstrated 99.64% specificity and 85.40% sensitivity with an overall accuracy of 93.82%.

Method		PCR Test		Total Results
Evaluation reagent	Results	Positive	Negative	
	Positive	193	1	194
	Negative	33	323	356
Total Results		226	324	550

*** 95% Confidence Interval**

Statistic	Value	95% CI
Sensitivity	85.40%	80.11%～89.73%
Specificity	99.69%	98.29%～99.99%
Accuracy (*)	93.82%	91.47%～95.68%

ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

SARS-CoV-2 Rapid Qualitative Test LoD in nasal swab was confirmed at 5.50 x 10^2 $TCID_{50}$/mL by repeating 20 times of testing (19/20).

Cross Reactivity

No cross-reactivity was observed in the testing with following microorganisms.

Substance	Substance
Endemic human coronavirus HKU1	Adenovirus type 7
Endemic human coronavirus NL63	Adenovirus type 55
SARS coronavirus	Enterovirus group a
MERS coronavirus	Enterovirus group b
New influenza A (H1N1) virus (2009)	Enterovirus group c
Seasonal H1N1 influenza virus	Enterovirus group d
H3N2	Epstein barr virus
Influenza A H5N1	Measles virus
Influenza A H7N9	Human cytomegalovirus
Influenza B virus (Yamagata)	Norovirus
Influenza B virus (Victoria)	Rotavirus
Parainfluenza virus type I	Mumps virus
Parainfluenza virus type II	Chickenpox-herpes zoster virus
Parainfluenza virus type III	Human metapneumovirus
Respiratory syncytial virus type a	Mycoplasma pneumoniae
Respiratory syncytial virus type b	Chlamydia pneumoniae
Rhinovirus group a	Haemophilus influenzae
Rhinovirus group b	Staphylococcus aureus
Rhinovirus group c	Streptococcus pneumoniae
Adenovirus type 1	Klebsiella pneumoniae
Adenovirus type 2	mycobacterium tuberculosis
Adenovirus type 3	Candida albicans
Adenovirus type 4	Endemic human coronavirus OC43
Adenovirus type 5	Endemic human coronavirus 229E

Interference Substances Studies:

The following potential interference substances were evaluated with SARS-CoV-2 Antigen Rapid Qualitative Test at the concentrations listed below and were found not to affect test performance.

Interference substance	Interference
Purified mucin	Meropenem
blood	tobramycin
Interferon α	Histamine hydrochloride
zanamivir	Benfulin
ribavirin	oxymetazoline
Oseltamivir	Sodium chloride (including preservative)
Peramivir	Beclomethasone
Lopinavir	dexamethasone
Ritonavir	pregna 1,4 diene 3,20 dione
Abidor	triamcinolone acetonide
Levofloxacin	budesonide
azithromycin	mometasone
ceftriaxone	Fluticasone

Variants

The performance of SARS-CoV-2 Antigen Rapid Qualitative Test is not affected by Omicron variants.

Usability Study

150 people self-sampled and self-tested using the SARS-CoV-2 Antigen Rapid Qualitative Test and a PCR to test. The SARS-CoV-2 Antigen Rapid Qualitative Test showed 90.32% (28 out of 31 people) of positive samples and 99.16% (118 out of 119 people) of negative samples.

INDEX OF SYMBOLS

Symbol	Description	Symbol	Description
IVD	In vitro diagnostic medical device		Do not re-use
	Use-by date		Consult instructions for use
	Caution		Manufacturer
2℃ 30℃	Temperature limit 2-30℃	LOT	Batch code
	Keep away from sunlight		Keep dry
	Do not use if package is damaged and consult instructions for use		Date of manufacture
REF	Catalogue Number	Σ	Contains sufficient for <n> tests
CE 0197	CE Mark of Swab	STERILE EO	Sterilized using ethylene oxide for Swab
CN	Country of manufacture	MD	Medical device
	Distributor		Importer

REFERENCE

[1] Chen Z, Boon S S, Wang M H, et al. Genomic and evolutionary comparison between SARS-CoV-2 and other human coronaviruses[J]. Journal of virological methods, 2021, 289: 114032.

GENERAL INFORMATION

Manufacturer

Xiamen Biotime Biotechnology Co., Ltd.
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Tel: +86 592-689 5866 Fax: +86-592-6882362
E-mail:baotai@biotime.cn Web:www.biotime.cn

Australian Sponsor: Emergo Australia
Level 20, Tower II, Darling Park, 201 Sussex Street, Sydney NSW 2000, Australia

Scan me for more information including how to use video and further support.

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Customer Support Helpline: +61416633305

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Please see Material Safety Data Sheet at https://www.xiamenbiotime.com/documents_nc6.

Version No.: A/05
Issuing Date: 2023-11-01

How can I contact the TGA?

You can contact the Therapeutic Goods Administration (TGA) to report performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361.

For further advice for coronavirus (SARS-CoV-2) please contact your state or territory health authority, please see your local contact numbers below.

SUPPORT SERVICE CONTACT INFORMATION		
	SERVICE	WEBSITE AND CONTACT NO.
ACT	Australian Capital Territory Coronavirus Hotline	https://health.act.gov.au/ ☎: (02) 6207 7244 (8AM-6PM)
NSW	Service NSW (Coronavirus Hotline)	www.service.nsw.gov.au/covid-19 ☎: 137 788 (24/7)
NT	Northern Territory COVID-19 Hotline	https://health.nt.gov.au/ ☎: 1800 490 484 (8AM-4:30PM)
QLD	Queensland Coronavirus Helpline (134COVID)	www.covid19.qld.gov.au/ ☎: 134 268
SA	South Australia Coronavirus Helpline	www.covid-19.sa.gov.au/ ☎: 1800 253 787 (8AM-8PM)
TAS	Tasmanian Public Health Hotline (Coronavirus)	www.coronavirus.tas.gov.au/ ☎: 1800 671 738
VIC	Victoria Coronavirus Hotline (24/7)	www.coronavirus.vic.gov.au/ ☎: 1800 675 398 (24/7)
WA	Western Australia Coronavirus Hotline 13COVID	www.healthywa.wa.gov.au/COVID19 ☎: 1800 595 206 (8AM-5PM MON-FRI)
AUS	National Advice Hotline (COVID-19)	www.health.gov.au/campaigns/coronavirus-covid-19 ☎: 1800 020 080