Biopen®

Biolink

COVID-19

Antigen Oral Test Kit for Self-Testing

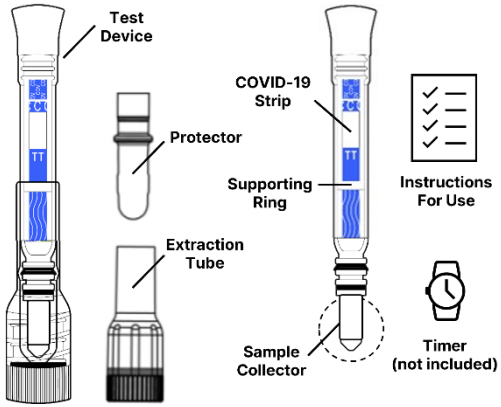
Quick Reference Instructions

Scan QR Code for video or visit
www.biolink.net.au/biopen/v/oral

Customer Support Helpline 1800 728 439
Customer Service Hours: 9AM-7PM AEST, 7 Days a week.

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

PACKAGE CONTENTS



STORAGE AND STABILITY

- Store at 2-30°C when not in use.
- DO NOT FREEZE.
- Do not use kit or components beyond the expiration date.

NOTE

!!! Children aged between 2 and 18 years old must be supervised or tested by an adult when carrying out the test.

!!! Do not use this test on anyone under 2 years of age.

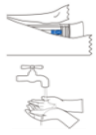
!!! Caution when inserting the sample collector into the oral cavity.

INTENDED USE

The COVID-19 Antigen Oral Test Kit is an in vitro immunoassay that detects SARS-CoV-2 variants alpha, beta, gamma, kappa, and delta. The kit is for the direct qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from human oral secretions collected from individuals suspected of having COVID-19 within the first 7 days of symptom onset. The COVID-19 Antigen Oral Test Kit is intended for use by laypersons and enables self-testing at home. The test identifies SARS-CoV-2 viral nucleoprotein antigen. Antigen is generally detectable in oral samples during the acute phase of infection. The assay obtains a preliminary result only, aiding in the diagnosis of COVID-19. This test has not been cleared for use in asymptomatic individuals. Children aged between 2 and 18 years old must be supervised or tested by an adult when carrying out the test.

BEFORE THE TEST

WARNING: DO NOT eat, drink, smoke, brush teeth, or chew gum up to 30 minutes before the test.



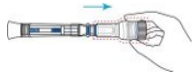
1. Bring devices, reagents, and specimens to room temperature (15~30°C) before use.

2. Remove the test device from its pack. For the best results, the assay should be performed within 1 hour.

3. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

ORAL SWAB COLLECTION

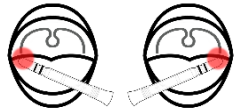
1. Take the test device out of the extraction tube.



2. Remove the protector.

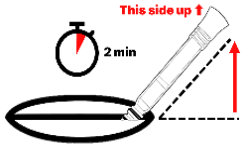
3. Deeply cough 4 times into your mouth. Cover your mouth while coughing.

4. Rub the sample collector on the back of your tongue and mouth 3-5 times on each side:



NOTE: Rubbing the back of your tongue may feel uncomfortable. Do not apply pressure. **If the throat is swollen and/or painful, gently roll the swab over the back of tongue.**

5. Place the sample collector on the side of your tongue, taking care to position the device at an **upward angle**.

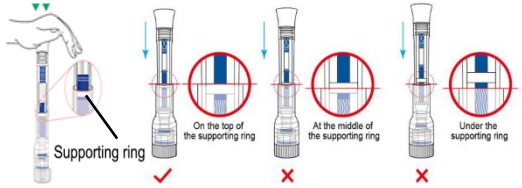


6. With your mouth closed, wait for **2 minutes**, always making sure the device is sitting at an **upward angle**.

8. **At the end of the 2 minutes**, remove the device from your mouth taking care to not touch the sample collector.

PROCESSING THE SAMPLE

1. Place the test device vertically into the extraction tube until the top edge of the extraction tube reaches the top of the supporting ring.



WARNING: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.

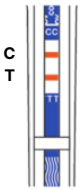
2. Read the results at **15 minutes**. Do not read the results after 30 minutes.

3. Place the used test kit into a waste bag and discard it as general waste. Follow the local regulations for household waste disposal.

Note:
- This test cannot be reused. One use per test only.
- Test within the first 7 days of symptom onset.
- Testing by an adult or under adult supervision only.

WARNING: Inaccurate test results may occur if the oral swab specimen is not properly collected.

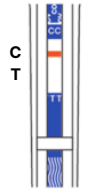
READING THE RESULTS



COVID-19 Positive: Two colored bands appear on the strip. One band appears in the control region (C) and another band appears in the test region (T).

A positive test result means it is very likely patients currently have COVID-19 disease. **Please follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if necessary. If unwell, please consult a medical practitioner for follow up clinical care.**

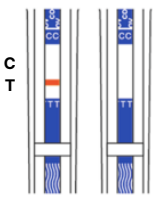
NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens. **The shade of lines may vary. If a faint or weak line appears, it should be considered a positive result.**



COVID-19 Negative: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

A negative result for COVID-19 does not mean a person does not have COVID-19. If a person has symptoms, they should follow the guidance from the local state or territory health departments, and if unwell seek medical assistance.

NOTE: A negative result does not mean you are not infected with SARS-CoV-2. If you are unwell, please consult a medical practitioner for follow up care and continue to follow all public health advice on limiting the spread of COVID-19. If symptoms persist, test again within at least 24 hours and no more than 48 hours between tests as SARS-Cov-2 antigen present in COVID-19 cannot be precisely detected in all phases of an infection.



COVID-19 Invalid: No colored band appears in the control region (C), whether a test band(s) is present or not.

NOTE: Results from any test which has not produced a control band at the specified read time must be discarded. **Please review the procedure and repeat with a freshly collected sample and a new test. If the problem persists, please report repeated invalid results to the sponsor.**

PRINCIPLE

The COVID-19 Antigen Oral Test Kit detects SARS-CoV-2 viral nucleoprotein antigens through visual interpretation of color development on the internal strip. AntiSARS-CoV-2 monoclonal antibodies (mAb) are immobilized on the test region of the nitrocellulose membrane. Additionally, anti-SARS-CoV-2 mAb antibodies conjugated to colored particles are immobilized on the conjugated pad. A sample is added to the extraction buffer in the base, which is optimized to release the SARS-CoV-2 antigens from the specimen.
During testing, target antigens, if present in the oral secretions, will be released into the extraction buffer. The extracted antigens will bind to anti-SARS-CoV-2 antibodies conjugated to colored particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 mAb antibodies at the test region. Excess colored particles are captured at the control region of the nitrocellulose membrane.
The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Each device is for single use only and cannot be reused.
- **DO NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before testing.**
- Avoid choking. Carefully insert sample collector into the mouth.
- **DO NOT chew, bite, or swallow sample collector.**
- Keep out of the reach of children.
- Children between 2-15 years of age should be tested by an adult.
- Children aged 15 and over should be assisted by an adult.
- Do not use this test on anyone under 2 years of age.
- Use a separate test for each person.
- This test is for human use only.
- Read the Package Insert prior to use.
- Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices with holes in the foil or pouch not completely sealed. Erroneous results may occur if test reagents or components are improperly stored.
- Do not use the kit when any component including the test device, protector, extraction buffer, or package insert are missing.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity or may lead to false positive results. Inaccurate or inappropriate specimen collection, storage, and transport may also yield false test results.
- The buffer components in the extraction tube include salts, surfactants, sodium azide as preservative and water as solvent. Avoid skin or eye contact with the buffer. In the event of contact with buffer, rinse with plenty of water. Do not ingest.
- Keep the sample collector clean. Do not touch the collector and make sure it does not touch any surfaces before use. Place the sample collector in the extraction tube buffer base immediately after collecting the sample.
- COVID-19 Antigen Oral Test Kit could detect SARS-CoV-2 variants alpha, beta, gamma, kappa, and delta.
- Use only the supplied test components.
- Do not replace the buffer with any other liquid.
- Do not puncture the foil membrane in the extraction tube before testing.
- Do not use the test if you have a mouth ulcer. If your mouth bleeds after swabbing, consult your health professional. Do not insert the swab again.
- If you have a mouth piercing, sample around the piercing.
- Small test components can pose a choking hazard.
- Test results should not be the sole basis for treatment or other management decisions.
- Dispose all parts of the used test kit into a waste bag, then discard the waste bag in the general waste.

LIMITATIONS

- The COVID-19 Antigen Oral Test Kit is for in vitro diagnostic use and should only be used for the qualitative detection of the SARS-CoV-2 antigen. The brightness of a positive band should not be evaluated as “quantitative or semi-quantitative”.
- Children under 15 years old need adult supervision.
- Failure to follow the test procedure and interpretation of results may adversely affect and/or invalidate the test result.
- If the result is positive, follow the advice of your local state or territory health department for guidance on confirmation testing if necessary.
- Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease.
- A positive result does not necessarily mean the patient is infected.
- Negative results do not preclude SARS-CoV-2 infection and the person not being infectious. If you have symptoms or feel unwell, seek medical assistance, and ensure you follow the advice from your local State or Territory Health Department for guidance on confirmation testing if necessary.

- Even if the result is negative, you still need to observe all protective and hygienic measures.
- If there is ongoing suspicion of infection or high rate of infection in the area, repeat testing within 1-3 day(s) is recommended.
- The tests are less reliable in the later phase of infection (more than 7 days after the onset of COVID-19 symptoms) and in asymptomatic individuals.
- This test has not been cleared for use in asymptomatic individuals.
- False negative results may appear if testing is not performed within the first 7 days of symptom onset.
- There may be false negatives due to new unknown variants of SARS-Cov-2 prior to validation data available.
- A negative result does not rule out infection with another type of respiratory virus.
- A negative result does not mean you are not infected with SARS-CoV-2. If you are unwell, please consult a medical practitioner for follow up care and continue to follow all public health advice on limiting the spread of COVID-19.
- As with all diagnostic tests, a clinical diagnosis must not be based on the results of a single test, but rather be made by the doctor after all clinical and laboratory results have been evaluated.
- This test does not discriminate between HKU1, SARS-coronavirus and SARS-CoV-2 (COVID-19). Positive results may be due to present infection with HKU1 or SARS-CoV.

QUALITY CONTROL

Internal Procedural Controls: The COVID-19 Antigen Oral Test Kit for Self-testing has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the "C" region is present before reading the result.

PERFORMANCE

DETECTION LIMIT
The detection limit for the COVID-19 Antigen Oral Test Kit was determined to be less than 32 $TCID_{50}$/mL.

CLINICAL EVALUATION
The performance of the COVID-19 Antigen Oral Test Kit was established with 184 specimens collected and enrolled from individual symptomatic patients who were suspected of COVID-19. FDA EUA RT-PCR assay for the detection of SARS-CoV-2 was utilized as the comparator method for the study. The were summarized below:

COVID-19 Antigen Oral Test Kit vs. RT-PCR

		RT-PCR		
		Positive	**Negative**	**Total**
COVID-19 Antigen Oral Test Kit	**Positive**	40	2	**42**
	Negative	5	137	**142**
	Total	**45**	**139**	**184**

Diagnostic Sensitivity: 88.9% (76.5%~95.2%) *
Diagnostic Specificity: 98.6 % (94.9%~99.6%)*
Overall Agreement: 96.2 % (92.4%~98.1%)*
***95% Confidence Interval**

A Layperson study was evaluated with 106 laypersons from different ages and different education to establish the performance and usability of COVID-19 Antigen Oral Test Kit in a self-testing environment. The laypersons did the test while being observed by neutral trained personnel. The result shows the COVID-19 Antigen Oral Test Kit and the underlying instructions for use are rated as a test that is easy to understand and perform and suitable for self-testing by laypersons was performed by 106 laypersons, 150 subjects were enrolled and self-tested with package insert and quick reference guide only, relative sensitivity was 100.0% (14/14), relative specificity was 100.0% (100/100). The results showed that the labelling provided with the test kit was comprehensive for its intended population, the ease of use was suitable for its intended population.

CROSS REACTIVITY STUDIES
Cross reactivity with the following organisms has been studied. Positive samples of the following organisms have no cross reactivity with the COVID-19 Antigen Oral Test Kit. **COVID-19 Antigen Oral Test Kit might have cross-reactivity with human coronavirus HKU1 and SARS-CoV because they have high homology to the SARS-CoV-2.**

Adenoviruses	Human metapneumovirus
Epstein-Barr virus	Influenza A (H1N1) pdm09
Enteroviruses	Influenza viruses
Echovirus 6	Norovirus
HCoV viruses	Parainfluenza viruses
Bordetellas	Respiratory syncytial viruses
Candida albicans	Rhinovirus B52
Chlamydia pneumoniae	Mycoplasma pneumoniae
Group C Streptococcus	Mycobacterium tuberculosis
Hemophilus influenzae	Pseudomonas Aeruginosa
Legionella pneumophila	Staphylococcus
MERS-coronavirus	Streptococcus
SARS-coronavirus	

INTERFERING SUBSTANCES STUDIES
The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated. None of them were found to affect the test performance of the COVID-19 Antigen Oral Test Kit.

3 OTC nasal sprays	Guaiacol glyceryl ether
3 OTC mouth washes	Mucin
3 OTC throat drops	Whole blood
4-acetamidophenol	Mupirocin
Acetylsalicylic acid	Oxymetazoline
Albuterol	Phenylephrine
Chlorpheniramine	Phenylpropanolamine
Dexamethasone	Zanamivir
Dextromethorphan	Adamantanamine
Diphenhydramine	Oseltamivir phosphate
Doxylamine succinate	Tobramycin
Flunisolide	Triamcinolone

LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35-48 (2017).
2. Ithete, N. L. et al. Close relative of human Middle East respiratory syn-drome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697-1699 (2013).

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov .au or calling 1800 809 361 (08: 30am to 5:00pm Monday to Friday).

SAFETY INFORMATION

Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible. Follow the directions of your local state or territory government health department to protect yourself. Test kit solutions 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 mouth; avoid contact with skin and eyes. Keep out of the reach of children and pets before and after use. The extraction buffer contains salts, surfactants, sodium azide (preservative), and water as the solvent. 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.

FREQUENTLY ASKED QUESTIONS

1. How do I know if the test worked well?
The COVID-19 Antigen Oral Test Kit is a rapid chromatographic immunoassay and detects SARS-CoV-2 viral antigens in oral secretions through visual interpretation of color development. Once the control line (C) appears, it means the test kit has performed properly.

2. How soon can I read my results?
The test results can be read after 15 minutes as long as a colored band or line appears in the Control region (C). Do not read results after 30 minutes.

3. How to interpret the test if the color and the intensity of the lines vary?
The intensity of the color in the Test area (T) varies. However, any shade in the Test area (T) should be considered positive.

4. Can the result be incorrect and are there any factors that can affect the test result?
The results will only give accurate results when carefully following the instructions. However, the result can be incorrect. Not pushing the collector into the extraction tube, insufficient sample size, or expired tests are the most likely reasons for the incorrect results.

5. What do I have to do if the test result is positive?
If you get a positive result, it indicates a possible SARS-CoV-2 infection. A positive result also means you are at risk of infecting others. Ensure you follow the advice from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

6. What do I have to do if the result is negative?
Negative results do not completely rule out SARS-Co V-2 infection. Please continue to comply with all applicable rules regarding contact with others and protective measures. An infection can also be present if the test is negative. In case of suspicion, being in a high risk setting or where there is an occupational risk or other requirement, repeat the tests after 1-3 days and follow the advice from your local State or Territory Health Department for guidance on confirmation testing if necessary.

7. Contact information for locally available support services.
For advice on medical assistance or to get confirmation testing for COVID-19 please contact your state or territory helpline.

AUSTRALIA - STATE & TERRITORY HEALTH DEPARTMENTS

Australian Capital Territory Coronavirus hotline
☎ (02)62077244(8:00am-8:00pm daily)
http://health.act.gov.au/

New South Wales Department of health
☎ 137788 http://health.nsw.gov.au/

Northern Territory Department of health
☎ (National helpline): 1800020080 http://health.nt.gov.au/

Queensland Department of Health
☎ 13COVID or 134268 http://health.qld.gov.au/

South Australian Department of Health
☎ (9am to 5pm daily): 1800253787
https://www.sahealth.sa.gov.au/

Tasmanian Department of Health
☎ (coronavirus): 1800671738 http://health.tas.gov.au/

Victorian Department of Health
☎ (24/7): 1800675398 http://www.dhhs.vic.gov.au/

Western Australian Department of Health
☎ 13COVID (8:00am to 6:00pm. Mon-Fri) or 1800595206
http://healthwa.gov.au/

NEW ZEALAND

For COVID-19 health advice and information, contact the Healthline (for free) on 0800 358 5453 or +64 9 358 5453 for international SIMs.

GLOSSARY OF SYMBOLS

REF	Catalog number	2℃ 30℃	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse		Do not use if package is damaged
EC REP	Authorized representative in the European Community	CE	CE Marking according to IVD Medical Devices Directive 98/97/EC

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