COVID-19 Antigen Saliva Test Kit Self Test

To watch a demonstration video, visit our website
ausmedhealth.com.au

1. INTENDED USE

The COVID-19 Antigen Saliva Test Kit is an in vitro immunoassay that detects SARS-CoV-2 variant alpha, beta, gamma, kappa and delta. The kit is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from human saliva samples collected from individuals suspected of having COVID-19 within the first 7 days of symptom onset. The COVID-19 Antigen Saliva 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 saliva samples during the acute phase of infection.

2. PRINCIPLE

The COVID-19 Antigen Saliva Test Kit detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti-SARS-CoV-2 antibodies are immobilised on the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 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 saliva samples, will be released into the extraction buffer individually packed in the kit. 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 complex will be captured by the anti-SARS-CoV-2 antibodies at the test region. Excess colored particles are captured at the internal control zone.

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 the proper volume of specimen has been added and membrane wicking is working.

3. MATERIALS

Materials Provided

- 2 Pack: 2 Individual packaged test • 1 Package insert • 2 Waste bags
- 5 Pack: 5 Individual packaged test • 1 Package insert • 5 Waste bags

Materials Required but Not Provided Clock, timer, or stopwatch

4. 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 collecting saliva. DO NOT swallow. Avoid choking being cautious when inserting the sponge in the mouth.
- Keep out of the reach of children. Children 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 children 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 result may occur if test reagents or components are improperly stored.
- Do not use the kit when any component including test device, protector, base, package insert is 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 base include salts, surfactants, preservative is sodium azide and water is the solvent. Avoid skin or eyes contact with buffer.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use. Place the swab in the base immediately after collecting the sample.
- COVID-19 Antigen Saliva Test Kit could detect SARS-CoV-2 variant alpha, beta, gamma, kappa and delta.

5. STORAGE AND STABILITY

- Store the COVID-19 Antigen Saliva Test Kit at 2~30℃when not in use.
- DO NOT FREEZE.
- **D**o not use kit or components beyond the expiration date.

6. QUALITY CONTROL

Internal Procedural Controls

The COVID-19 Antigen Saliva Test Kit 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.

7. LIMITATIONS OF THE TEST/WARNINGS

1. The COVID-19 Antigen Saliva Test Kit is for in vitro diagnostic use and should only be used once 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."
2. Children below 15 years old need adult supervision.
3. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
4. If the result is positive, one must still confirm the results immediately by a laboratory PCR test and seek follow-up clinical care.
5. 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.
6. A positive result does not necessarily mean the patient is infected
7. Negative results do not preclude SARS-CoV-2 infection and the person not being infectious. Therefore, the results should be confirmed via a laboratory PCR test especially if the person has symptoms and should seek follow-up clinical care.
8. Even if the result is negative, you still need to observe all protective and hygienic measures.
9. If there is ongoing suspicion of infection or high rate of infection in the area, repeat testing within 1-3 day(s) is recommended.
10. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
11. False negative results may appear if testing is not performed within the first 7 days of symptom onset.
12. There may be false negatives due to new unknown variants of SARS-Cov-2 prior to validation data available
13. A negative result does not rule out infection of other type of respiratory virus.

8. PERFORMANCE

Detection Limit: The detection limit for the COVID-19 Antigen Saliva Test Kit is less than 32 TCID50/mL..

Clinical Evaluation:

The performance of the COVID-19 Antigen Saliva 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 results were summarized below:

Table: COVID-19 Antigen Saliva Test Kit vs. RT-PCR

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

Relative Sensitivity: 88.9% (76.5% ~ 95.2%)* **Relative 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 age and different education to establish the performance and usability of COVID-19 Antigen Saliva 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 Saliva 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:

Cross reactivity with the following organisms has been studied. Positive samples of the following organisms have no cross reactivity with the COVID-19 Antigen Saliva Test Kit. Adenoviruses, Epstein-Barr virus, Enterovirues, Echovirus 6, HCoV viruses, Bordetellas, Candida albicans, Chlamydia pneumoniae, Group C Streptococcus, Haemophilus influenzae, Legionella pneumophila, MERS-coronovirus, SARS-coronavirus, Human metapneumovirus, Influenza A (H1N1)pdm09, Influenza viruses, Novavirus, Parainfluenza viruses, Respiratory syncytial viruses, Rhinovirus B52, Mycoplasma pneumoniae, Mycobacterium tuberculosis, Staphylococcus, Streptococcus. COVID-19 Antigen Saliva Test Kit might have cross-reactivity with human coronavirus HKU1 and SARS-CoV because they have high homology to the SARS-CoV-2

Interfering Substances:

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 Saliva Test Kit.

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

9. 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 syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

IVD

CE

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou,
310011 Zhejiang, P.R.China

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, le Verd,
2595AA,The Hague, Netherlands

Manufactured for:
Emergence Technology Pty Ltd.
Add: 6/3 Hill St, Toorak, VIC, 3142, Australia

FREQUENTLY ASKED QUESTIONS (FAQ)

1. How do I know if the Test worked well?

The COVID-19 Antigen Saliva Test Kit is a rapid chromatographic immunoassay and detects SARS-CoV-2 viral antigens in saliva samples through visual interpretation of colour 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 after 15 minutes as long as a coloured band or line appears in the Control region (C). Do not read result after 30 minutes.

3. How to interpret the test if the colour and the intensity of the lines vary?

The intensity of the colour 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. Make sure you do not eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva. Not pushing the collector into the extraction tube, insufficient sample size, expired tests are the most likely reasons for the missing.

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, please contact a doctor or the local health department immediately for a confirmatory PCR test and for follow-up clinical care. Call your State and Territory hotline for further advice

6. What do I have to do if the result is negative?

Negative results do not completely rule out SARS-CoV-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 or have a RT-PCR test, as the coronavirus cannot be accurately detected in all phases of an infection.

7. Contact information for locally available support services.

For advice on medical assistance or get confirmation tested for COVID-19 please contact your state or territory

Customer Support Helpline	
1800 728 439	9am-7pm (AEST)
Australian Capital Territory Department of Health	
02 6207 7244	https://health.act.gov.au/
New South Wales Department of Health	
137 788	https://www.health.nsw.gov.au/
Northern Territory Department of Health	
1800 020 080	https://health.nt.gov.au/
Queensland Department of Health	
134 268	https://www.health.qld.gov.au/
South Australian Department of Health	
1800 253 787	https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	
1800 671 738	https://www.health.tas.gov.au/
Victorian Department of Health	
1800 675 398	https://www.health.tas.gov.au/
Western Australian Department of Health	
1800 595 206	https://www.healthywa.wa.gov.au/
TGA Contact Information	
Contact TGA to report an issue via the Users Medical Device Incident Report on email iris@tga.gov.au or call 1800 809 361 or https://www.tga.gov.au/	

COVID-19 Antigen Saliva Test Kit Self Test Instruction Guide

Note: Use test only one time. Test within first 7 days of symptoms.
Testing by adult only or under adult supervision

Version 2
21.10.21

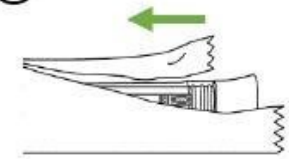
Test Kit

① 

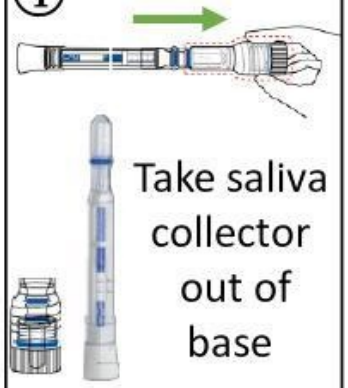
Do Not eat, drink, smoke, brush teeth or chew gum **30 mins** before test

② 

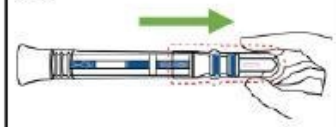
Wash hands before test

③ 

Remove test from package

④ 

Take saliva collector out of base

⑤ 

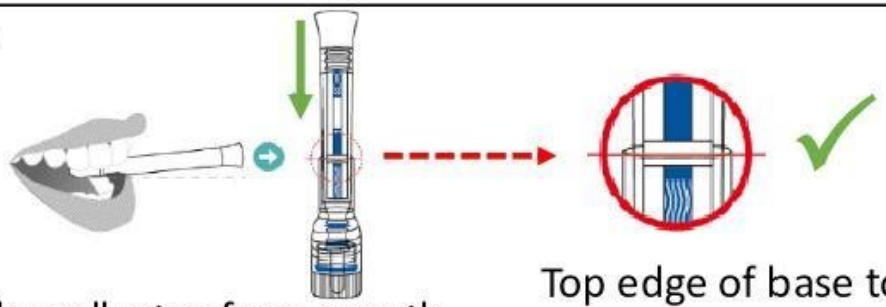
Remove the protector

⑥ 

Deeply cough 4 times into your mouth

⑦ 

Place collector on top, under or side of tongue for 2 mins

⑧ 

Take collector from mouth and push vertically into the base

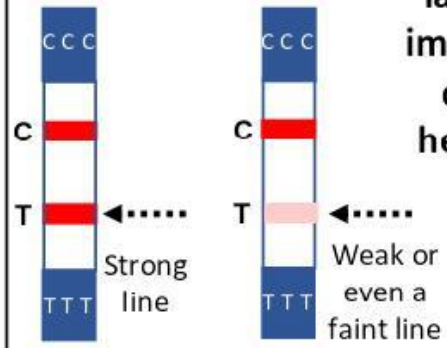
Top edge of base to be in middle of supporting ring

⑨ 

Read results at 15 mins

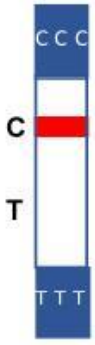
Do not read after 30 mins

⑩ Positive



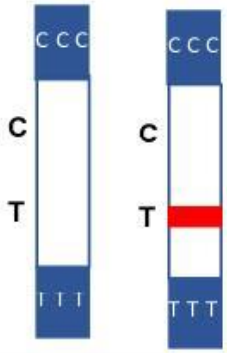
Take a PCR laboratory test immediately and contact your health provider

Negative



Monitor for symptoms

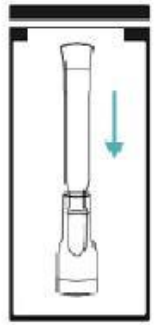
Invalid



Invalid if no control line

Make sure to push the collector into the base.
Re-test and call 1800 728 439 for further assistance

⑪



Put test in disposal bag and dispose into household waste bin