SARS-CoV-2 Antigen Saliva Lolly Test Package Insert

REF COVG-603 **Specimens:** Saliva

Version: B **Effective Date: 2022.3**

For self-testing. IVD

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in saliva specimen. For self-testing in vitro diagnostic use.

INTENDED USE

The SARS-CoV-2 Antigen Saliva Lolly Test is a single-use test kit intended to detect the SARS-CoV-2 that causes COVID-19 with self-collected saliva specimen from individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset.

This test kit is intended to be used as a aid in diagnosis only and repeatedly abnormal results should be discussed with doctor or follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Results are for the detection of SARS-CoV-2 Nucleocapsid protein Antigens.An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens,but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.

Positive results are indicative of the presence of SARS-CoV-2. Individuals who test positive should self-isolate and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

The SARS-CoV-2 Antigen Saliva Lolly Test is intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).

SUMMARY

The novel coronaviruses belong to the beta genus. COVID-19 is an acute infectious disease of the respiratory tract. Currently, patients infected with the novel coronavirus are the main source of infection. Infected people without symptoms can also infect others. According to the current state of knowledge, the incubation period is 1 to 14 days, usually 3 to 7 days.

The main symptoms are fever, fatigue and a dry cough. Nasal congestion, runny nose, sore throat, muscle pain, and diarrhea occur in some cases[1].

PRINCIPLE

The SARS-CoV-2 Antigen Saliva Lolly Test is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in human saliva.

In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the lolly test.During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For self-testing in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Store in a dry place at 2-30℃ (36-86℉), avoiding areas ofexcess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the lolly test.
- The kit must not be frozen or used after the expiration date printed on the package.
- Keep out of the reach of children.
- Test for children and young people should be used with an adult.
- Do not use the test on children under 2 years old.
- Small children should be swabbed with the help of a second adult.
- Wash hands thoroughly before and after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- All tests, samples and potentially contaminated materials used should be disposed of in the disposal bag provided with the test in the appropriate waste stream bin and wash your hands.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C).The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.**DO NOT FREEZE.** Do not use beyond the expiration date.

MATERIALS PROVIDED

Materials Required and Provided
- SARS-CoV-2 Antigen Lolly Test
- Package Insert
- Biohazard Waste Bag
- Qualification Certificate

Note: Components of different batches cannot be mixed.

Materials Required but not Provided

The timer and Disinfection products, such as hand sanitizer, rubbing alcohol, soap, etc

LIMITATIONS

1. The SARS-CoV-2 Antigen Saliva Lolly test is only intended for personal use. The test should only be used once for the detection of SARS-CoV-2 nucleocapsid antigens in saliva specimens. The intensity of the test line does not necessarily relate to the SARS-CoV-2 viral load in the sample.
2. A false negative test can result if the amount of antigen in a sample is below the detection limit of the test or if the sample was taken incorrectly or not properly stored.
3. A false negative test can result if testing is not is performed within the first 7 days of symptom onset.
4. Tests are less reliable in the later phase of infection and in asymptomatic individuals.
5. Tests are presumptive only and any positive results (**contain any shade of color in the test line(T) should be considered positive**) need to follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance and for follow-up clinical care.
6. Repeat antigen rapid testing is recommended every 24 hours for 3 days if there is a suspicion of infection, exposure to high-risk settings or other occupational risks.
7. If symptomatic and a negative result is obtained this should follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
8. Excess blood or mucus on the specimen may interfere with test performance and may yield a false positive result.
9. A positive test result for COVID-19 does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
10. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
11. A negative test result does not rule out other viral or bacterial infections.
12. There exists a very small probability of a false positive results to be encountered due to presence of non-SARS-COV-2 coronavirus strains such as coronavirus HKU1, NL63, OC43 or 229E.
13. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
14. All materials including the extraction buffer used in the testing should be considered potentially infectious and should be disposed of in the disposal bag provided with the test in the appropriate waste stream bin.
15. Test can only be performed by adults over 18 years of age. Any persons or children under 18 years will require adult supervision or assistance.
16. The performance of SARS-CoV-2 Antigen Saliva Lolly Test was established based on the evaluation of a limited number of clinical specimens. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

CLINICAL PERFORMANCE

1.A clinical evaluation was conducted comparing the results obtained using the SARS-CoV-2 Antigen Saliva Lolly Test to PCR. Specimens were considered positive if PCR indicated a positive result.

Accuracy-comparison test:

Positive coincidence rate: 108/115*100%=93.91%

Negative coincidence rate:116/117*100%=99.15%

Accuracy: 224/232*100%=96.55%,

2.A usability study was performed by lay person, 127 subjected were enrolled and self-tested with package insert and quick reference guide only, relative sensitivity was 97.92% (47/48), relative specificity was 100% (79/79). The results showed that the labeling provided with the test kit was comprehensive for its intended population, the ease of use was suitable for its intended population.

FREQUENTLY ASKED QUESTIONS

1.What is the LOD?

The limit of detection (LOD) for the Lolly Test is 400 $TCID_{50}$/mL.

2.Will other diseases affect the result?

The SARS-CoV-2 Antigen Saliva Lolly Test was tested with the following viral strains. No cross below these concentrations, Cross-reaction may occur if the following concentrations are exceeded:

HCOV-HKU1(10^5PFU/ml), Staphylococcus aureus(10^5CFU/ml), Group A streptococci (10^5CFU/ml), Measles virus(10^5PFU/ml), Mumps virus (10^5PFU/ml), Adenovirus type 3(10^5PFU/ml), Mycoplasmal pneumonia (10^5CFU/ml), Paraimfluenzavirus type1(10^5PFU/ml), Paraimfluenzavirus type2 (10^5PFU/ml), Paraimfluenzavirus type 3(10^5PFU/ml), Paraimfluenzavirus type4 (10^5PFU/ml), Human metapneumovirus (10^5PFU/ml), Human coronavirus OC43(10^5PFU/ml), Human coronavirus 229E(10^5PFU/ml), Bordetella parapertusis(10^5CFU/ml), Influenza B Victoria STRAIN(10^5PFU/ml), Influenza B YSTRAIN(10^5PFU/ml), Influenza A H1N1 2009(10^5PFU/ml), Influenza A H3N2(10^5PFU/ml), H7N9(10^5PFU/ml), H5N1(10^5PFU/ml), Epstein-Barr virus(10^5PFU/ml), Enterovirus CA16(10^5PFU/ml), Rhinovirus(10^5PFU/ml), Respiratory syncytial virus(10^5PFU/ml), Streptococcus pneumoni-ae(10^5CFU/ml), Candida albicans(10^5CFU/ml), Chlamydia pneumoniae(10^5CFU/ml), Bordetella pertussis(10^5CFU/ml), Pneumocystis jiroveci(10^5CFU/ml), Mycobacterium tubercu-losis(10^5CFU/ml), Legionella pneumophila (10^5CFU/ml), Human coronavirus NL63(10^5PFU/ml), MERS coronavirus (10^5PFU/ml), SARS coronavirus(10^5PFU/ml), Haemophilus influenzae (10^5CFU/ml),Streptococcus pneumoniae(10^5CFU/ml), Streptococcus pyrogenes(10^5CFU/ml), Pneumocystis jirovecii(10^5CFU/ml), Pooled human nasal wash positive specimens(The concentration can't be tested for bacterial complex).

3. Will this test hurt?

No, the Saliva collector is not sharp and it should not hurt. Sometimes the tongue can feel slightly uncomfortable or dry. If you feel pain, please stop the test and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

4. After I put the Saliva collector into the mouth,I felt my tongue was dry and somewhat paralyzed.What should I do?

In the unlikely event You can rinse with water until the symptoms relieve and consult a healthcare professional. Do not put the saliva collector in your mouth again.

5. How do I know that the test was run properly?

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control.

It confirms adequate membrane wicking.

6. What should I do if the result shows 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. What should I do if the result shows negative?

Negative results may require additional testing to confirm your results if you are symptomatic.Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance, continue antigen testing every 24 hours for 3 days. A negative test result, however, is not a guarantee that you do not have coronavirus. Please continue to follow social distancing, washing hands regularly and wearing masks as directed.

8. Can Sejoy SARS-CoV-2 Antigen Saliva Lolly Test detect various variants of COVID-19?

Yes,Sejoy SARS-CoV-2 Antigen Saliva Lolly Test can detect below COVID-19 mutants based on the studies conducted so far.

No	Name
1	Alpha
2	Beta
3	Gamma
4	Delta

9. Can any substances interfere with the Sejoy SARS-CoV-2 Antigen Saliva Lolly Test?

The SARS-CoV-2 Antigen Saliva Lolly Test has been tested for Whole Blood,Ibuprofen,tetracycline,Mucin, Erythromycin, Tobramycin, menthol,Afrin, Compound Benzoin Gel, Cromolyn glycate, chloramphenicol, Mupirocin, Oseltamivir,Naphazoline Hydrochlo-ride Nasal Drops,Fluticasone propionate spray , Deoxyepinephrine hydrochloride.At common concentrations, the above substances did not interference with the test.

BIBLIOGRAPHY

1.Weiss SR,Leibowitz JZ.Coronavirus pathogenesis. Adv Virus Res 2 011;81:85-164

2.Cui J,Li F,Shi ZL.Origin and evolution of pathogenic coronaviruses .Nat Rev Microbiol 2019;17:181-192.

3.Su S,Wong G,Shi W,et al.Epidemiology,genetic recombination,and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit		Do not use if package is damaged
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2℃ 30℃	Store between 2- 30°C	LOT	Lot Number	REF	Catalogue number
	Keep away from sunlight		Keep dry		

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Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

Australian Sponsor: Alpha-Medics Australia Pty. Ltd.
133 Market Street, South Melbourne, VIC 3188, Australia

【SUPPORT & LOCAL HEALTH CONTACT】

Australian Capital Territory Department of Health, please To Locate your nearest Covid testing center and Laboratory.
☎ 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/

You can contact the TGA to report poor performance or usability issues via email iris@tga.gov.au or call 1800 809 361

Please scan the QR code to access instructional guides and additional information or visit https://alpha-medics.com.au/support.

To generate a DIGITAL CERTIFICATE or share your test result, please download the SELF CHECK APP.

Customer Support Helpline:1800 575 090 9:00am-7:00pm (AEST) www.alpha-medics.com.au For information on the correct use of this test and for interpretation of the test results

SELF-TEST Quick Reference Guide

SARS-CoV-2 Antigen Saliva Lolly Test

Please scan the QR code to access instructional guides and additional information.
To generate a DIGITAL CERTIFICATE or share your test result, please download the SELF CHECK APP.

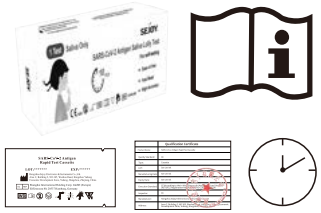
TEST PROCEDURE STEPS

① 

30 minutes before saliva collection procedure, DO NOT eat, drink, smoke or chew gum.

② 

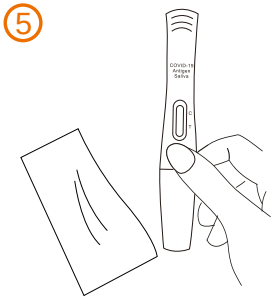
30 minutes before saliva collection procedure, use running water to clean mouth.

③ 

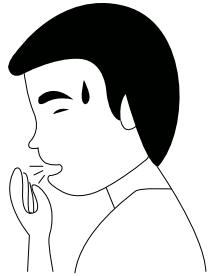
Open the box carefully as it will be used in a later step.
Note: A timer device (clock, timer, etc) is required, but not provided.

④ 

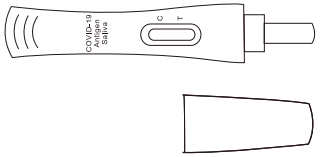
Wash your hand before start test.

⑤ 

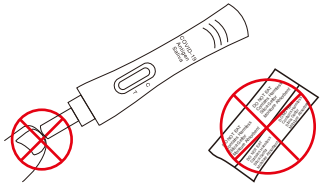
Remove the cassette from the sealed foil pouch and use it within 15 minutes.

⑥ 

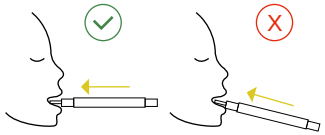
Deeply cough 3 - 5 times
Note: Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.

⑦ 

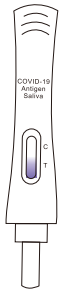
Remove the cap of cassette.

⑧ 

DO NOT touch the flat pad with your fingers.
DO NOT eat or swallow the preservative.

⑨ 

Swab the flat pad **in the mouth** and tongue to collect oral fluid.

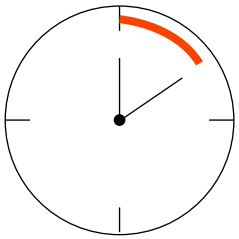
⑩ 

Take the flat pad out from the mouth when the purple color move across the result window in the center of the cassette.

⑪ 

Put the cap on.

⑫ Start Timer (10min)

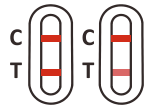


Wait for **10 minutes**.
Do not read test results **after 30 minutes**.

⑬ READ THE RESULTS

POSITIVE RESULT

One coloured line should be in the control region (C) and another coloured line should be in the Test region (T).
***Note: The intensity of the colour in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of colour in the test region (T) should be considered positive.**
A positive result means it is very likely you have COVID-19, but the positive samples should be confirmed to reflect this. **Immediately** go into self-isolation in accordance with the local guidelines and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

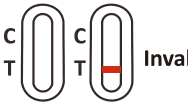


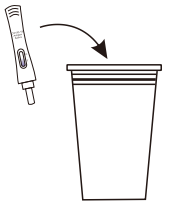
NEGATIVE RESULT

Only a single coloured line appears in the control region (C).
You are unlikely to have COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. **This means you could possibly still have COVID-19 even though the test is negative.**
If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, **Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.**
In addition, you can repeat the test with a new test kit. In case of suspicion repeat the test after 1-2 days, as the corona virus cannot be precisely detected in all phases of an infection.
Even with a negative test result, distance yourself and hygiene rules must be observed migration/traveling,attending events, etc, you should follow your local COVID guidelines/ requirements.

INVALID RESULT (Test did not work)

The line in the control region (C) does not appear. Even if a line appears in the test region (T), the test is still invalid.
Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test or contact our COVID-19 test sponsor.



⑭ 

Throw away all used test kit components in the trash.

Customer Support Helpline:1800 575 090 9:00am-7:00pm (AEST) www.alpha-medics.com.au For information on the correct use of this test and for interpretation of the test results