SEJOY®

SARS-CoV-2 Antigen Rapid Test Cassette Package Insert

REF COVG-602ST

Specimens: Nasal Swab

Version: A

Effective Date: 2022.3

For self-testing

IVD

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in nasal swab specimen. Aid for diagnosis of COVID-19.For self-testing in vitro diagnostic use.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test Cassette is a single-use test kit intended to detect the SARS-CoV-2 that causes COVID-19 with self-collected nasal swab 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 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 Rapid 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 Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in human Nasal swabs.

In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. 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

- 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.
- **Do not drink the buffer in the kit.** Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
- Store in a dry place at 2-30 ℃(36 -86 ℉),avoiding areas of excess 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 test cassette.
- 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 ℃).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 Test Cassette
- Extraction Buffer with Integrated Extraction Tube， 0.27ml per Tube
- Sterile Swabs
- Package Insert
- Workstation
- 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 Rapid Test Cassette is only intended for personal use. The test should only be used once for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab 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 to dispose in rubbish 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 Rapid Test Cassette 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.

FREQUENTLY ASKED QUESTIONS

1. How accurate is the test?

A clinical evaluation was conducted comparing the results obtain using the SARS-CoV-2 Antigen Rapid Test Cassette to PCR. Specimens were considered positive if PCR indicated a positive result.

- For 109 cases of PCR positive, the Relative Sensitivity the SARS- CoV-2 Antigen Rapid Test Cassette is 94.5% (103/109).
- For 300 cases of PCR negative, the Relative Specificity of SARS- CoV-2 Antigen Rapid Test Cassette is 100% (300/300).
- For 109 cases of PCR positive and 300 cases of PCR negative, the Relative Accuracy of SARS-CoV-2 Antigen Rapid Test Cassette is 98.5% (403/409).

A usability study was performed by lay person, 132 subjected were enrolled and self-tested with package insert and quick reference guide only, relative sensitivity was 95.83% (23/24), relative specificity was 100% (105/105). 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.

Detection Limit: The detection limit for the SARS-CoV-2 Antigen Rapid Test Cassette is 400 TCID50/mL.

2. Will other diseases affect the result?

SARS-CoV-2 Antigen Rapid Test Cassette 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(10^5CF U/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 nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly.If you feel strong resistance or pain.Nasal swab collection is not recommended.

4. I have a nosebleed after swabbing my nose. What should I do?

In the unlikely event your nose starts bleeding, apply pressure to your nose until the bleeding stops and nasal swab collection is not recommended. Do not insert the Swab 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. If asymptomatic, it is likely that you were not infectious at the time the test was taken. 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 Test detect various variants of COVID-19?

Yes, Sejoy SARS-CoV-2 Antigen Rapid Test Cassette 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 Test?

The SARS-CoV-2 Antigen Rapid Test Cassette 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. No substances above showed any interference with the test.

BIBLIOGRAPHY

1. Weiss SR,Leibowitz JZ.Coronavirus pathogenesis. Adv Virus Res 2011;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		Manufacturer

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Website: www.sejoy.com

【SUPPORT & LOCAL HEALTH CONTACT】

Australian Capital Territory Department of Health
☎ 02 6207 7244
https://health.act.gov.au/
New South Wales Department of Health
☎ 137 788
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Victorian Department of Health
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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 information or visit https://alpha-medics.com.au/support

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

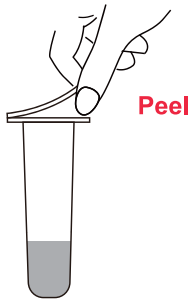
SARS-CoV-2 Antigen Rapid Test Cassette

Please scan the QR code to access instructional guides and additional information.

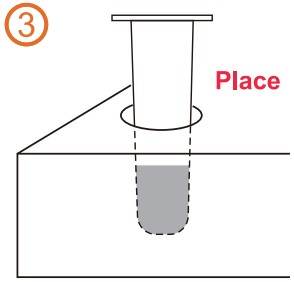
TEST PROCEDURE STEPS

① 

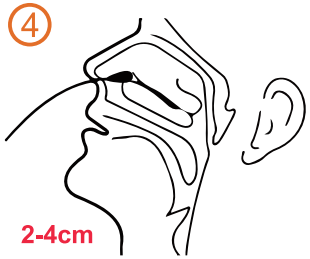
Wash your hand before start test.

② 

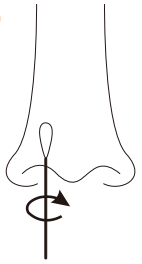
Take out the extraction tube.

③ 

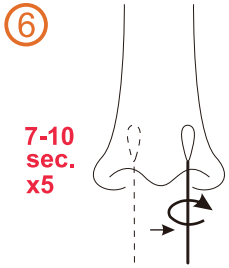
Place the tube on the workstation.

④ 

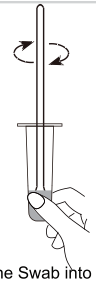
Blow nose first. Gently insert the swab into one nostril for **2-4cm(1-2cm for children)**.

⑤ 

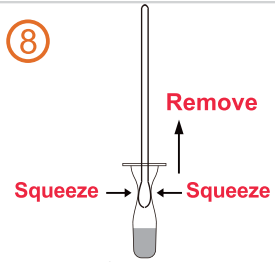
Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril **5 times** within **7-10 seconds**.

⑥ 

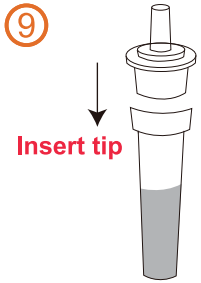
Repeat the same process with the **same swab** in the **other nostril**.

⑦ 

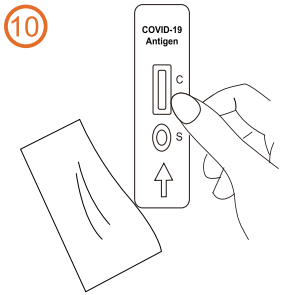
Insert the Swab into the extraction tube. Ensure it is touching the bottom and stir the swab to mix well.
Press the swab head against the tube and rotate the swab about **10 seconds**.

⑧ 

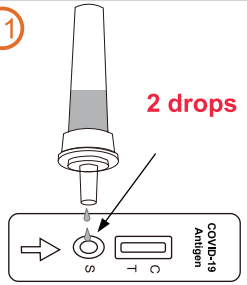
Hold the Tube firmly with one hand. Remove the swab while squeezing the swab head against the inside of the Extraction tube.
Place the swab in the bag.

⑨ 

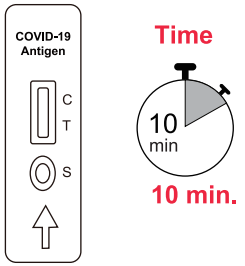
Place the extraction tube cover firmly on the extraction tube.

⑩ 

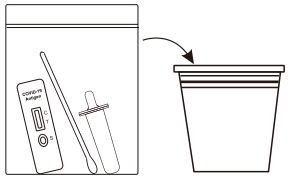
Take out the test cassette from the sealed foil pouch and use it **within 15 mins**.

⑪ 

Invert the specimen extraction tube and add **2 drops of extracted specimen** to the sample well (s) of the test cassette.

⑫ 

Read the test result after adding the sample for **10 minutes**.
The result obtained after **30 minutes** is invalid.

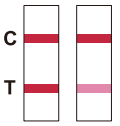
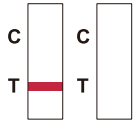
⑬ 

Dispose of all test items in the disposal bag provided.
Throw away all used test kit components in the trash.

⑭ 

Wash your hand when the test end.

Interpretation of the results

Positive	Negative	Invalid
		
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 SARSCoV-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.	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.	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.

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