RightSign®

COVID-19 Antigen Rapid Test Cassette (Nasal Swab) Package Insert (For Self-testing)

REF ICOVN-C81H-1 REF ICOVN-C81H-2 REF ICOVN-C81H-5 REF ICOVN-C81H-10 REF ICOVN-C81H-20	English

A rapid test for the qualitative detection of COVID-19 antigen in Nasal Swab in symptomatic individuals. For in-vitro diagnostics only. For self-testing only.

Please read the instructions carefully before performing the test. The test can only be performed one time. Testing by adult only or under adult supervision.

【INTENDED USE】

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasal Swab. The results are used to identify the SARS-CoV-2 antigen test within the first 7 days of symptom onset when viral shedding/viral load is at its highest. This antigen is generally found in upper respiratory tract samples during the acute phase of infection. Positive results suggest the presence of viral antigens, but an individual medical history and other diagnostic information are necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The pathogen identified may not be the exact cause of the disease. Individuals who test positive should confirm the results with a laboratory PCR test, self-isolate and notify their healthcare provider.

Negative results from individuals with symptoms longer than seven days should be treated as likely negative. If necessary, confirm the results with a laboratory PCR test. Negative results do not rule out SARS-CoV-2 infection. The SARS- CoV-2 rapid antigen test is intended to support the diagnosis of a SARS-CoV-2 infection.

A usability study has been performed with minimum age group of 3-13 years of age. It is recommended that anyone under the age of 18 should be tested by an adult. Age 18 and above can complete the test independently. Adolescents aged 13-17 can complete the test with the help of an adult. Children under 13 years should be tested by an adult.

【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.

【PRINCIPLE】

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasal Swab.

Supplied Materials	Test Kit Contents				
	1Test	2Tests	5Tests	10Tests	20Tests
Test cassette	1	2	5	10	20
Prefilled Buffer	1	2	5	10	20
Dropper tip	1	2	5	10	20
Sterile Nasal Swab	1	2	5	10	20
Disposal bag	1	2	5	10	20
Quick Reference Guide	1	1	1	2	4
Package Insert	1	1	1	2	4

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 coloured line in the test regions. The presence of this coloured line of the test regions indicates a positive result. To serve as a procedural control, a coloured line will always appear in the control region if the test has performed properly.

【REAGENTS】

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein particles and anti-SARS-CoV-2 Nucleocapsid protein coated on the membrane.

【PRECAUTIONS】

Please the package insert for the SARS-CoV-2 rapid antigen test carefully before performing a test. Failure to follow the instructions can result in inaccurate test results.

- Do not use the test after the expiration date printed on the sachet.
- Do not eat, drink or smoke before or during the test.
- Do not use the test if the pouch is damaged or not at room temperature.
- All tests, samples and potentially contaminated materials used should be disposed of in accordance with local waste regulations.
- Humidity and temperature can negatively affect the results.
- The test line for a sample with a high viral load may become visible within 10 minutes or as soon as the sample passes the test line area.
- Do not collect the nasal swab sample if you have a nosebleed.
- Wear glover or alternately wash hands before and thoroughly after use.
- If the extraction buffer accidentally comes into contact with the skin or eyes, rinse it off with large amounts of water and consult a doctor if necessary.
- DO NOT FREEZE

【STORAGE AND STABILITY】

Store as packaged 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.
Only used the test at room temperature.

Materials not provided

Stopwatch

INSTRUCTION VIDEO:

【QUALITY CONTROL】

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

【SUPPORT & LOCAL HEALTH CONTACT】

Customer Support Helpline
☎ 1300 587 200 8am-5pm (AEST)
https://www.med-supply.com.au

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
☎ 1800 809 361
https://www.tga.gov.au/

【LIMITATIONS】

1. The SARS-CoV-2 antigen rapid test 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 need to be confirmed by a laboratory PCR test 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 be confirmed immediately by laboratory PCR test.
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 COVID-19 Antigen Rapid Test Cassette (Nasal Swab) was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. 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 obtained using the COVID-19 Antigen Rapid Test Cassette (Nasal Swab) to PCR. Specimens were considered positive if PCR indicated a positive result.

- For 103 cases of PCR positive, the Relative Sensitivity the COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is **93.2%** (96/103).
- For 250 cases of PCR negative, the Relative Specificity of COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is **99.2%** (248/250).
- For 103 cases of PCR positive and 250 cases of PCR negative, the Relative Accuracy of COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is **97.5%** (344/353).

A usability study was performed by lay person, 150 subjected were enrolled and self-tested with package insert and quick reference guide only, relative sensitivity was 93.75% (30/32), relative specificity was 99.12% (112/113). 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 COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is 1000 $TCID_{50}$ /mL.

2. Will other diseases affect the result?

No cross reactivity has been observed on testing by following commonly found respiratory/ oropharyngeal pathogens:
Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type1, Parainfluenza Virus Type2, Parainfluenza Virus Type3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group B, Streptococcus sp. group C, Candida albicans, Human Metapneumovirus (hMPV), Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii(PJP)-S cerevisiae Recombinant, Pseudomonas aeruginosa, Staphylococcus epidermis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63 and MERS-coronavirus positive specimens.
However, a false result due to presence of these organisms at a level higher than tested cannot be ruled out.

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 pain, please stop the test and seek advice from a healthcare provider.

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 consult a healthcare professional. 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?

You must take a laboratory PCR test immediately, self-isolate and contact your local health authority or the National Coronavirus Helpline on 1800 020 080 for further advice. You should also inform the immediate contacts you have had in past 24 hours so they can take any appropriate precautions.

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

Negative results may require additional testing to confirm your results if you are symptomatic. If symptomatic, continue antigen testing every 24 hours for 3 days or take a laboratory PCR test. 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 RightSign COVID-19 Antigen Test detect various variants of COVID-19?

Yes, RightSign COVID-19 Antigen Test can detect Alpha, Beta, Gamma and Delta COVID-19 mutants based on the studies conducted so far.

9. Can any substances interfere with the RightSign COVID-19 Antigen Test

The COVID-19 Antigen Rapid Test Cassette has been tested for Ambroxol Hydrochloride Tablets (7.5 mg/mL), Nasal antibioitic (Mupirocin Ointment), Mometasone furoate nasal spray (0.05% g/g), Oxymetazoline Hydrochloride Spray, Nin Jiom Pei Pa Kao cough syrup, Beclomethasone Dipropionate Nasal Aerosol, Dextromethorphan Hydrobromide Oral Solution(1.5 mg/ml), Triamcinolone Acetonide Nasal Spray, MucosolvanAmbroxol Hydrochloride Oral Solution, Azelastine Hydrochloride Nasal Spray, Nasal cleansing solution, NaCl (5 g/L), Fluticasone Propionate Nasal Spray, Hyland's 4 Kids Cold Cough Liquid Safe Natural Relief, Physiological Seawater Nasal Spray, Durham's Canker-Rid, Tobramycin Eye Drops, Listerine mouthwash ,Whole blood (4%), Scope mouthwash, Mucin (0.05%). No substances above showed any interference with the test.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. 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		Tests per kit		Do not use if package is damaged
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number	**REF**	Catalog #
	Keep away from sunlight		Keep dry		

CUSTOMER SUPPORT:
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