Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab)

An Antigen rapid test for the detection of SARS-Cov-2 in nasal swab. For self-testing use.

Read the instructions carefully before taking the test.

REF:K601416D English

◆ QR CODE INSERT

Scan the QR code for information on how to use the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab).

Australia Distributor Contact

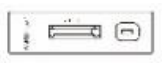
Solasta Life Pty Ltd

Customer Support Number: 1800 288 438

Address: 9/204 Alice Street, Brisbane, 4000, Queensland, Australia

Hours: 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week

◆ MATERIALS PROVIDED



Test device

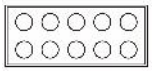
Sterilized Swab

Extraction Tube with buffer

Nozzle

Package Insert

Biohazard Specimen Bag



Tube stand(The 25 tests/kit package contains the tube stand,the 1 test/kit and 5 tests/kit package use the test box itself as tube stand.)

Materials required but not provided

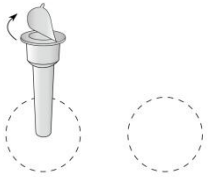
Timer

◆ TEST PROCEDUR

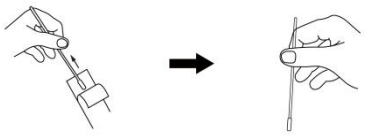
Step 1
Wash or clean your hands and make sure they are dry before starting the test.

Step 2
Read the instruction for use carefully.

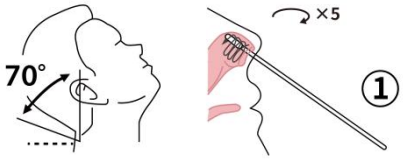
Step 3
Take out one extraction tube,pell off the sealed aluminum foil on the extraction tube.



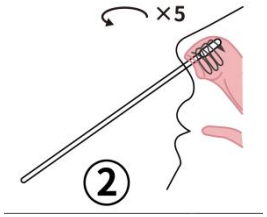
Step 4
Unpack the swab. **Caution: The swab should not contact with anything else, otherwise the result could be falsified.**



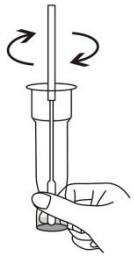
Step 5
Tilt your head back slightly. Insert the swab about 2 cm - at least with the entire soft swab tip - into the left nostril. Gently rotate the swab at least five times against the nasal wall.



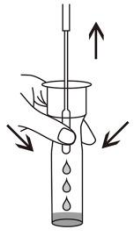
Step 6
Insert the same swab about 2 cm - at least with the entire soft swab tip - into the right nostril. Again, gently rotate the swab at least five times against the nasal wall. Remove the swab from the second nostril. **Caution: If the swab stick breaks during specimen collection, please use a new swab.**



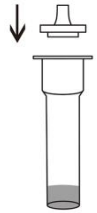
Step 7
Dip the soft swab tip into the liquid. Rotate the swab for at least 15 seconds while pressing the head against the inside of the tube to dissolve the specimen in the liquid.



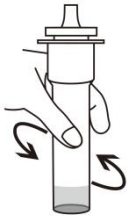
Step 8
Now pull the swab out of the extraction tube and wipe it off the edge of the tube. Discard the swab in a trash bag.



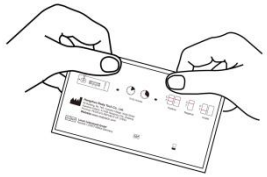
Step 9
Screw on and tighten the nozzle onto the extraction tube.



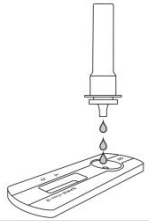
Step 10
Shake the extraction tube vigorously to mix the specimen and the sample extraction buffer.



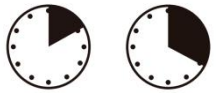
Step 11
Open the foil pouch and take out the test cassette.Place the checked test cassette on a flat, clean surface. **CAUTION: Perform the test within 60 minutes after the foil pouch is opened.**



Step 12
Add 3 drops of the solution from the specimen collection tube to the sample well of the test cassette.

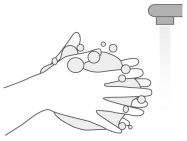


Step 13
Set timer for 10 minutes. CAUTION: **Do not read the result beforehand, even if a line has already appeared at control region C.**

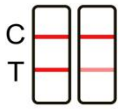
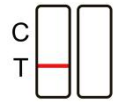


Step 14
Please dispose of the test materials in a closed plastic bag with the household refuse.If there are local regulations, please follow them.

Step 15
Wash hands thoroughly after test completion.



◆ INTERPRETATION OF RESULTS

Positive 	Negative 	Invalid 
Two red lines appear. A red line appears in the control region (C) and a red line in the test region (T). **The shade may vary, but if even a faint line appears, it should be considered positive**. If you have a **POSITIVE** result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance. Isolate yourself according to current guidelines.	Only one red line appears in the control region(C), and no line in the test region (T). The negative result indicates that there are no Novel coronavirus particles in the sample or the number of viral particles is below the detectable range. However, a negative result does not rule out COVID-19. **If you have symptoms like fever, cough and/or shortness of breath. Please retest in 1-3 days. You must continue following the applicable hygiene and distancing rules even with a negative result.**	No red line appears in the control region(C). The test is invalid even if there is a line on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. **Review the test procedure and repeat the test using a new test device.**

INTENDED USE

This kit is intended for the qualitative detection of the N protein of SARS-CoV-2 antigens in human anterior nasal swab specimens from individuals within 7 days of onset of symptoms as an aid for diagnosis of COVID-19 .

This kit is intended for layperson’s home use in a non-laboratory environment (e.g. in a person's residence or certain non-traditional places such as offices, sporting events, airports, schools, etc.). Test results of this kit are for clinical reference only. It is recommended that a comprehensive analysis of the disease be conducted based on clinical manifestations of individuals and other laboratory tests.

PRINCIPLE

This kit is based on colloidal gold immunochromatographic technology for rapid detection the N protein of SARS-CoV-2 antigens in human anterior nasal swab specimen. The sample is dropped into the test cassette during the test, and the liquid is chromatographed through the capillary action to the top. After the test is complete, observe the color reaction of the colloidal gold on the T-line and C-line to determine the SARS-CoV-2 antigen result.

PRECAUTIONS

- For in vitro diagnostic use only.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform the test at room temperature 15 to 30° C.
- Do not substitute the swab and sample extraction buffer provided in this kit with components from other kits.
- Place the soft tip of the swab into the nostril.
- Strictly follow the operating instructions.
- The samples should be tested immediately after collection.
- Children must be tested under supervision.

STORAGE AND STABILITY

•The test can be stored at 2℃-30℃ for 12 months from the date of manufacture.

•Do not use after expiry.

LIMITATIONS

• Test should be performed within 7 days of the onset of symptoms. False negative rate for Result of individual not performed within 7 days after the onset of symptoms or asymptomatic will increase significantly Because of low level of concentration. The reliability of the product's result detection 7 days after the onset of symptoms or in asymptomatic people still needs to be verified.

•The test is less reliable in the later phase of infection and in asymptomatic individuals.

•Repeat testing within 1 - 3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection.

• Negative results may not mean that a person is not infectious and if symptoms are present the person must seek professional medical advice.

•A negative result does not rule out infection with another type of respiratory virus.

•If you have a POSITIVE result, 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 test result of this kit is not the only confirmatory indicator for clinical indications. The infection should be confirmed by a specialist in combination with other laboratory results, clinical symptoms, epidemiology, and additional clinical data.

•In the early stages of infection or before symptoms appear, low antigen expression may lead to negative results. Individuals with a history of exposure to the virus should be tested for 3 consecutive days to determine whether they are infected

• The test results are related to the quality of the specimen collection, processing, transportation and storage. Any faults can lead to imprecise results. If the cross-contamination is not controlled during specimen processing, false-positive results may occur.

•A positive result cannot necessarily determine if a person is infectious.

SAFETY INFORMATION

•Please dispose of the test materials in a closed plastic bag with the household refuse.

• 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.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Using Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) by professional was compared to the RT-PCR kit. A sensitivity of 95.51% (234/245 known confirmed Positives) and a specificity of 100.00% (430/430 known confirmed Negatives) were determined for the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab).

Using Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) by layperson was compared to the RT-PCR kit. A sensitivity of 93.33% (42/45 known confirmed Postives) and a specificity of 100.00% (65/65 known confirmed Negatives) were determined for the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab).

Variants Information

Using Recombinant protein and clinical specimen of different variants perform the study of analytical sensitivity of the product, the result demonstrated this test is not affected by variants Alpha, Beta, Gamma ,Epsilon and Delta.

Limit of Detection (LOD)

The Limit of Detection (LoD) of the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab) is confirmed as 625 $TCID_{50}$/mL.

Cross Reaction

The Cross reactive study results show that the microorganisms below do not affect the test results of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab):

MERS-coronavirus,Adenovirus Type 1,Adenovirus Type 3,Adenovirus Type 5,Adenovirus Type 7,Adenovirus Type 8,Adenovirus Type 11,Adenovirus Type 18,Adenovirus Type 23,Adenovirus Type 55, Influenza A H1N1 Denver,Influenza A H1N1 WS/33,Influenza A H1N1 A/Mal/302/54,Influenza A H1N1 New Caledonia,Influenza A H3N2 A/Hong Kong/8/68,Influenza B Nevada/03/2011,Influenza B B/Lee/40, Influenza B B/Taiwan/2/62,Respiratory syncytial virus,Legionella pneumophila Bloomington-2,Legionella pneumophila Los Angeles-1,Legionella pneumophila 82A3105,Rhinovirus A16,Mycobacterium tuberculosis K,Mycobacterium tuberculosis Erdman,Mycobacterium tuberculosis HN878,Mycobacterium tuberculosis ,Mycobacterium tuberculosis ,Streptococcus pneumonia 4752-98,Streptococcus pneumonia [Polen 23F-16],Streptococcus pneumonia 262 [CIP 104340],Streptococcus pneumonia Slovakia 14-10 [29055],Streptococcus pyrogens Typing strain T1[NCIB 11841, SF 130],Mycoplasma pneumoniae Mutant 22,Mycoplasma pneumoniae FH strain of Eaton Agent [NCTC 10119],Mycoplasma pneumoniae 36M129-B7,Coronavirus 229E,Coronavirus OC43, Coronavirus NL63,Coronavirus HKU1,Human etapneumovirus (hMPV) 3 Type B1 Peru2-2002,Human Metapneumovirus 16 Type A1 IA10-2003,Parainfluenza virus Type 1,Parainfluenza virus Type 2,Parainfluenza virus Type 3,Parainfluenza virus Type 4A.

Interfering Substances Reaction

The interfering study results show that the substances below do not affect the test results of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (nasal swab):

Mucin,Whole Blood ,Biotin,Neo-Synephrine (Phenylephrine),Afrin Nasal Spray (Oxymetazoline),Saline Nasal Spray,Sodium Cromoglycate,Olopatadine Hydrochloride,Zanamivir ,Oseltamivir ,Artemether -lumefantrine ,Doxycycline hyclate ,Quinine ,Lamivudine ,Ribavirin,Daclatasvir,Acetaminophen,Pooled human nasal wash,Acetylsalicylic acid,Ibuprofen,Mupirocin,Tobramycin,Erythromycin,Ciprofloxacin, Ceftriaxone,Meropenem,Tobramycin,Histamine Hydrochloride,Peramivir,Flunisolide,Budesonide,Fluticasone,Lopinavir,Ritonavir,AbidorStaphylococcus aureus.

FREQUENTLY ASKED QUESTIONS

● **When can I test myself?**

You can always test yourself Within 7 days of symptoms onset. Please note that the test result is a snapshot valid for a specific point in time. Tests should be repeated in accordance with the rules of the competent authorities.

● **What do I have to do in order to get the most precise test result possible?**

Always follow the instructions very carefully. Perform the test immediately after the specimen is collected and prepared. Add the drops from the specimen collection tube only into the sample well of the test cassette. Add three drops from the specimen collection tube. Adding too many or too few drops may lead to an incorrect or invalid test result.

● **The test strip is heavily discolored. What is the reason, or what did I do wrong?**

The reason for a clearly visible discoloration of the test strip is that too many drops have been added from the tube into the well of the test cassette. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is heavily discolored, please repeat the test with a new test cassette according to the instructions.

● **What should I do if I have taken the test, but I saw no control line?**

In this case, the test result is to be considered invalid. Please repeat the test with a new kit according to the instructions. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

● **I'm not sure how to interpret the results. What should I do?**

In case you cannot clearly determine the result of the test, contact the nearest medical facility that applies your local regulations.

● **My result is negative. What should I do?**

If there is only one horizontal colored line in the control region (C), it could mean that your result is negative or that the number of viral particles is below the detectable range.

If you encounter symptoms such as headache, migraines, fever, losing your sense of smell and taste, contact the nearest medical facility that applies your local regulations. You can also repeat the test with a new test kit.

If the test user tests negative it does not mean they are free to disregard social distancing and other measures to socialize, travel, attend events, etc. Please follow local Covid-19 guidelines or requirements.

● **Can this test cassette be reused or used by more than one person?**

This test device is intended for a single use only. It cannot be reused or shared by several people.

STATE AND TERRITORY CONTACT NUMBERS

Medical Device Incident Report

You can contact the Therapeutic Goods Administration (TGA) to report performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361.

Local state and territory health departments

Contact details and websites of the local state and territory health departments

•Australian Capital Territory Coronavirus Helpline

Business hours：02 5124 9213

Coronavirus helpline (8am to 8pm daily)：02 6207 7244

Website：https://health.act.gov.au/

•New South Wales Department of Health

General enquiries：1300 066 055

Coronavirus hotline (Service NSW, 24/7)：137 788

Website：https://www.health.nsw.gov.au/

•Northern Territory Department of Health

General enquiries：08 8922 8044

Coronavirus hotline (National helpline)：1800 020 080

Website：https://health.nt.gov.au/

•Queensland Department of Health

General enquiries：13HEALTH or 13 432 584

Coronavirus hotline: 134COVID or 134 268

Website：https://www.health.qld.gov.au/

•South Australian Department of Health

General enquiries：1300 232 272

Coronavirus hotline (9am to 5pm daily)：1800 253 787

Website：https://www.sahealth.sa.gov.au/

•Tasmanian Department of Health

General enquiries：1300 135 513

Public Health Hotline (coronavirus)：1800 671 738

Website：https://www.health.tas.gov.au/

•Victorian Department of Health

Department of Health and Human Services：1300 650 172

Victorian coronavirus hotline (24/7)：1800 675 398

Website：https://www.dhhs.vic.gov.au/

•Western Australian Department of Health

General enquiries：08 9222 4222

Coronavirus hotline: 13COVID (8am to 6pm, Mon – Fri) or 1800 595 206

Website：https://www.healthywa.wa.gov.au/

SYMBOL

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number	Σ	Contains sufficient for <n> tests

For the test device

Hangzhou Realy Tech Co., Ltd.
#2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Website: www.realytech.com

EC REP **Luxus Lebenswelt GmbH**
Kochstr.1,47877, Willich, Germany

For the sterilized swab

Shenzhen Kangdaan Biological Technology Co., Ltd.
East-1, Floor 3, Building 2, Shunheda Plant Area, Liuxiandong Industrial Zone, Xili Street, Shenzhen.

EC REP **Share info consultant service LLC Repräsentanzbüro**
Heerdter Lohweg 83,40549 Düsseldorf, Germany.

CE 0197

Number:1100067202
Version: 1.1
Effective Date: 2022-01-30

Australia Distributor Contact
Solasta Life Pty Ltd
Customer Support Number:1800 288 438
Address:9/204 Alice Street, Brisbane, 4000, Queensland, Australia
Hours: 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week