EN LABNOVATION

SARS-CoV-2 Antigen Rapid Test Kit

(Immunochromatography)

Self-test for Use at Home

INSTRUCTION FOR USE

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab specimens directly from individuals who are suspected of COVID-19 and onset of symptoms within 7 days.

INTRODUCTION

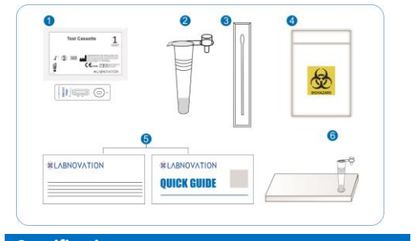
In December 2019, the novel respiratory disease (COVID-19) caused by the coronavirus (SARS-CoV-2) was reported in Wuhan, China. According to WHO, most of the people infected with SARS-CoV-2 have mild to moderate respiratory diseases, fever, cough and recover without treatment. However, people with weak immune systems, such as the elderly or people with previous illnesses (e.g., cardiovascular disease, diabetes, chronic respiratory diseases, cancer, etc.) are more likely to develop a serious illness that can lead to the death of the infected person.

This rapid test kit is intended for the qualitative detection of SARS-CoV-2 viral nucleocapsid antigens from human anterior nasal of secretion from individuals suspected of COVID-19. Positive result of the antigen test can be used for early isolation of patients with suspected infection, but it cannot be used as diagnosis basis of SARS-CoV-2 infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment. Further nucleic acid detection should be carried out for suspected population whose antigen test result is positive or negative.

This kit is an immunochromatography assay which detects SARS-CoV-2 nucleocapsid antigen in the samples with the help of the double antibody sandwich method. If there is virus antigen presence in the sample, it binds with the corresponding colloidal gold antibody. This complex “migrates” across the membrane and binds to the monoclonal antibody at the Test line (T). This creates a visible red line, which indicates a positive result. However, if the sample does not contain any antigen, then the complex cannot be formed and thus no reddish line forms in the Test line (T). Regardless of whether the sample contains antigen or not, a reddish line forms in the Control line (C).

MAKE SURE YOUR TEST KIT CONTAINS

1. Sealed Pouch (Test cassette)
2. Sample tube with prefilled sample extraction buffer
3. Swab
4. Bio Safety Bag
5. Instruction for use
6. Tube Stand (in the outer box)



Specifications

Components \ Specifications	LX-401302 (1Test/Kit)	LX-401303 (2Tests/Kit)
Test cassette (Sealed in Pouch (pcs))	1	2
Sample tube with prefilled sample extraction buffer (pcs)	1	2
Bio Safety Bag (pcs)	1	2
Swab (pcs)	1	2
Instruction for use (pcs)	1	1

Components \ Specifications	LX-401305 (5Tests/Kit)	LX-401320 (20Tests/Kit)
Test cassette (Sealed in Pouch (pcs))	5	20
Sample tube with prefilled sample extraction buffer (pcs)	5	20
Bio Safety Bag (pcs)	5	20
Swab (pcs)	5	20
Tube Stand (pcs)	1	1
Instruction for use(pcs)	1	4

Additionally required materials:

1 Timer

STORAGE & SHELF LIFE

The product should be stored at 2-30°C, and its shelf life is 24 months.

The test cassette and sample extraction buffer should be used immediately after opening.

WARNINGS AND IMPORTAN INFORMATION

- This kit is a qualitative detection, which cannot determine the exact content of antigen.
- The test is intended for use outside the body only.
- The test kits are less reliable in the later phase of infection and in asymptomatic individuals.
- Not to be taken internally. Avoid sample buffer contact with skin and eyes.
- Protect from sunlight, do not freeze. Store in a dry place between 2°C and 30°C. Do not use after the expiration date printed on the package.
- Keep out of the reach of children. Any child under age 16 shouldn’t perform the test without parental guidance, or professional aid.
- Not following the exact instructions can affect the outcome of the test. The final diagnosis must be confirmed by a physician.
- Do not use the test if the packaging is damaged. Do not use broken test components.
- All test components are only intended to be used for this test. Do not reuse the test or test components.
- The test should be carried out immediately or within one hour after opening the foil pouch (15-30℃, humidity <60%).
- Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
- DISPOSAL The test kit can be disposed of with normal household waste in accordance with applicable local regulations.
- After use, rinse hands or, in case of contact with the buffer solution, the affected body parts thoroughly with water.
- If symptoms persist: Seek medical advice.

STEP-BY-STEP INSTRUCTION

Choose a location to do this test where it can sit UNDISTURBED for 20 minutes.

Let test cassette and test components stand at a room temperature (10℃ to 30℃) before performing the test.

Please refer to the **Quick Reference Guide** for the test steps.

INTERPRETATION OF RESULTS

Please refer to the **Quick Reference Guide** for the interpretation of test results.

QUESTION & ANSWER

Q1. How does Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) work?

The Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) that is to detect the presence of protein fragments (antigen) from the 2019-nCoV in nasal swab specimen.

Q2. What is the difference between a COVID-19 Antigen? molecular, and antibody test?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus.

The Labnovation SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) is an antigen test which detects small parts or proteins from the virus. Antigen tests are very specific for the virus but are not as sensitive as molecular tests.

Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection.

Q3. Will this test hurt?

No, the disposable sterile swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly.

Q4. Why do I swab both nostrils?

Swabbing both nostrils gives you the best chance of collecting sufficient sample to generate an accurate result. It has been observed in some cases that only one nostril has detectable virus, so it is important to collect from both nostrils. Correct swabbing is important to obtain a correct result.

Q5. What does it mean if I have a positive test result?

A positive result means it is very likely you have COVID-19. You should immediately go into self-isolation in accordance with the local guidelines and immediately contact your State or Territory Government Coronavirus testing service where you will be explained the next steps. Refer to your relevant health authority for advice on whether a PCR test is required to confirm your result. Please check the Local Contact Details at the end of the text.

Q6. What does it mean if I have a negative test result?

A negative result means the virus that causes COVID-19 was not found in your sample.

A negative test result does not guarantee that you do not or have never had COVID-19, nor does it confirm whether or not you are currently contagious.

Do you have cold symptoms in addition to the negative? at-home test? Since the at-home test does not provide complete certainty, you should assume that you have COVID-19. You can contact your doctor to find out if another test is needed. In the meantime, try to avoid leaving your home and have as little contact as possible with others, including the people you live with. Use disposable tissues and throw them straight in the bin. Sneeze and cough into the crook of your elbow. Wash your hands regularly and wear a face mask. Are your symptoms getting worse (difficulty breathing, high fever, etc.)? Contact your doctor/health provider immediately.

Q7. Is there any chance that I get a “false” negative result with this test?

It is possible for this test to give an incorrect negative (false negative) result”. This means that you could still have COVID-19 even though the test result is negative. If your result is negative and you still experience symptoms **related to COVID-19，such as fever, cough and/or** shortness of breath, you should seek help from your healthcare provider.

Q8. Is there any chance that I get an incorrect positive result?

There is a very small chance that this test gives you a positive result that is incorrect (false positive). If you get a positive result, please refer to local state / territory coronavirus helpline for advice.

Q9. I have used the test but no colored band appears at control line (C). What should I do?

If there is no colored band appears at control line (C) within 15 minutes of performing the test, then the test has not worked. You should test again, using a new test, taking care to follow the instruction.

Q10. What are the possible risks of this test?

Possible Risks:

- Discomfort during the sampling
- Incorrect test results (see Interpreting Results and Limitations Sections).

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect 2019-nCoV antigen in human nasal swab specimen.
2. This test should be performed within the first 7 days of symptom onset when viral load is at a high level to ensure the result accuracy, otherwise, may result in incorrectly negative (false negative) result.
3. The test may give an incorrect negative result (false negative) if not taken within the first 7 days of symptoms.
4. If the test result is negative and symptoms persist, the individual is employed in or has been exposed to a high risk environment, this may be due to virus levels being too low to detect. This can occur in the early stage of contracting Covid-19. It is recommended that a new test be performed again in 1-3 days. If a negative result is still returned, a PCR is recommended to confirm the negative result or otherwise.
5. A positive result for COVID-19 may be due to infection with a non-SARS-CoV-2 coronavirus strain or other interfering factors, such as SARS-CoV-1 coronavirus.
6. Failure to follow the instructions for the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
7. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
8. False negative results can occur if specimens are improperly collected or processed.
9. This reagent is a qualitative assay. As it is with any diagnostic procedure, a confirmed 2019-nCoV infection diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
10. False negative test results may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection, and the negative results are not intended to exclude other non 2019-nCoV virus infections.
11. Positive test results do not exclude co-infections with other pathogens and does not identify specific 2019-nCoV virus subtypes, like SARS-CoV virus.
12. The SARS-CoV-2 antigen rapid tests are less reliable in late infection and asymptomatic individuals.
13. A negative result does not rule out infection with another respiratory virus.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

Analytical results for all samples from two clinical studies:

SARS-CoV-2 Antigen Rapid Test	RT-PCR		TOTAL
	Positive	Negative	
Positive	340	0	340
Negative	9	660	669
TOTAL	349	660	1009

Sensitivity: > 97 %*

Specificity: > 99 %*

Total accuracy: > 99 %*

*95 % Confidence Interval.

Note 1: The positive samples were almost from infected patients within the first 7 days after the onset of symptoms.

Note 2: The SARS-CoV-2 variant Delta (Indian B.1.617.2), Alpha (UK B.1.1.7) can be detected by the rapid test kit at specific concentrations.

Analytical Results with correlation to the days post-onset of symptoms of the positive samples:

Day since symptom onset	RT-PCR positive	SARS-CoV-2 Antigen Rapid Test Positive	Sensitivity of Antigen Rapid Test Kit (95%CI)
No Symptoms	47	44	93.62%
0-2 days	70	69	98.57%
3-5 days	144	143	99.31%
6-7 days	88	84	95.45%

2. Lay-user Study

A total of 190 non-professional users with different educational backgrounds, different age distributions, and different genders participated in the SARS-CoV-2 antigen rapid test non-professional user research in Poland. 30 of them that are known antigen positive, 60 of them that are unknown their status, and 100 of them read and interpret the contrived test result including non-reactive, reactive, weak reactive, and invalid.

For 30 participants with known positive results, their test results were confirmed by PCR testing. At the same time, compared with the professional test results, there are 3 inconsistent results. The concordance of results with the professional test is 90%. After analysis by observers, they did not collect enough samples, resulting in low viral load to false negative results. It is recommended that explanations on false negative results be added to the instructions, and patients are recommended to repeat the test.

For 60 participants who did not know their status, their PCR test results were negative. At the same time, compared with the professional test results, the concordance of results with the professional test is 100 %.

The results of these non-professionals are compared with the results of RT-PCR, and the concordance of results with the professional test is 100 %.

The 100 participants were interpreted the pictures of the test card designed with different results. Compared with reading results of professionals, 100% of the participants can know the condition indicating positive (reactive), weak positive, negative and invalid test result.

3. Limit of detection

LOD concentration	30 TCID50/mL

4. Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed as follows at certain concentrations:

Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Adenovirus, Human Metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A, Influenza B, Enterovirus, Respiratory syncytial virus, Rhinovirus, MERS-coronavirus, Haemophilus influenza, Streptococcus pneumonia, Streptococcus pyogenes, Candida albicans, Pooled human nasal wash, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Malaria and Dengue.

5. Cross-reactivity continued

The nucleocapsid protein of SARS-CoV-2 shares 90.52% homology with SARS-CoV-1. It suggests that there will be significant cross reactivity with SARS-CoV-1 virus.

6. Interfering

The following interfering substances commonly found in the sample, such as blood, mucin, and pus, have no effect on the test results.

Test results will not be interfered by following substances at certain concentrations:

Whole Blood, Mucin, Sodium Chloride, Fluticasone Propionate, Gluconic Acid Zinc, Fluconazole, Oxymetazoline, Cromolyn, Phenol, Benzocaine, Menthol, Tamiflu (Oseltamivir Phosphate), Ribavirin, Tobramycin 4.0.

LITERATURE

1.) Nanshan Chen*, Min Zhou*, Xuan Dong*, Jieming Qu*,Fengyun Gong, Yang Han, Yang Qiu, Jingli Wang, Ying Liu,Yuan Wei, Jia’an Xia, Ting Yu, Xinxin Zhang, Li Zhang Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. LANCET. January 29, 2020.

2.) World Health Organization (Coronavirus disease 2019) https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it(Zugriff am 27.03.2020)

3.) World Health Organization (Coronavirus disease 2019) https://www.who.int/health-topics/coronavirus#tab=tab_1 (Zugriff am 27.03.2020)

MANUFACTURER

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Swabs MANUFACTURER

Accessory	Manufacture	EC-Representative	CE-Mark
Swab A	Shenzhen KangDaAn Biological Technology co., LTD Address: East-1, 3rd floor, Building 2, Shunheda factory, Liuxiandong industrial zone, Xili street, Nanshan district, Shenzhen	Share Info Consultant Service LLC Reprasentanzburo Heerdter Lohweg 83,40549 Dusseldorf	CE 1432
Swab B	CITOTEST LABWARE MANUFACTURING CO., LTD Address: No. 339 Beihai West Road, Haimen 226100 Jiangsu, P.R. China	Wellkang Ltd Enterprise Hub, NW Business Complex, 1 Beraghmore Rd., Derry, BT48 8SE, Northern Ireland	CE 0197

IMPORTER

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Customer Services 1300 581 810
Email: info@happyhygiene.com.au
Website: https://vitrylaust.com.au/intro

LOCAL CONTACT DETAILS

TO LOCATE YOUR NEAREST COVID TESTING CENTRE AND LABORATORY PLEASE CONTACT
STATE AND TERRITORY CONTACT NUMBERS

- Australian Capital Territory Coronavirus Helpline (8am-8pm daily) : 02 6207 7244 https://health.act.gov.au/
- New South Wales Coronavirus Helpline (Service NSW 24/7): 137 788 https://www.health.nsw.gov.au/
- Northern Territory Coronavirus National Hotline (National Helpline): https://health.nt.gov.au/1800 020 080
- Northern Territory Coronavirus National Hotline (National Helpline): 1800 020 080 https://health.nt.gov.au/
- Queensland Coronavirus Helpline (134COVID): 134 268 https://www.health.qld.gov.au/
- South Australia Coronavirus Helpline (9am -5 pm Daily): 1800 253 787 https://www.sahealth.sa.gov.au/
- Tasmanian Public Health Hotline (Coronavirus): 1800 671 738 https://www.health.tas.gov.au/
- Victoria Coronavirus Hotline (24/7): 1800 675 398 https://www.health.tas.gov.au/
- Western Australia Coronavirus Hotline 13COVID (8am-6pm Mon-Fri): 1800 595 206 https://www.healthywa.wa.gov.au/

Contact the TGA to report the poor performance or usability issues in the self-test environment via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361.

INSTRUCTIONS OF SYMBOL

Manufacturer	LOT Batch number (see imprint on package)
Consult instruction for use	2 for single use
Contains sufficient for n tests	Store at 2°C - 30°C Do not freeze.
REF Order number	IVD In vitro diagnostic medical device (for external use)
Expire date (see imprint on package)	Keep dry
manufacturing date	STERILE R Sterilization by irradiation

SARS-CoV-2 Antigen Rapid Test Kit

SELF-TEST Quick Reference Guide

"Note: Use test kit only once. Testing within first 7 days of symptoms. Testing by adult or under adult supervision."

How to use

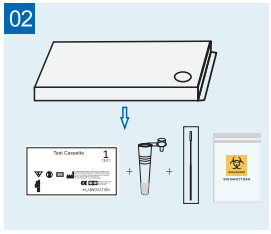
Instruction video is also available
https://www.vitrylaust.com.au/intro

TEST PROCEDURE STEPS

01

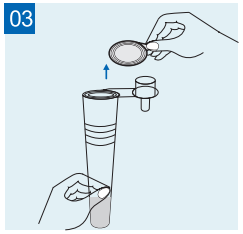
Wash your hands before starting your test

02



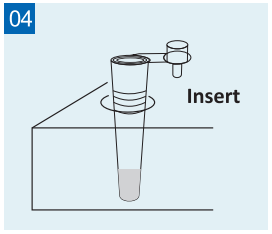
Please check the expiration date printed on the BOX Do not use it beyond the expiration date. Lay all the supplied materials on a clean, dry and flat surface.

03



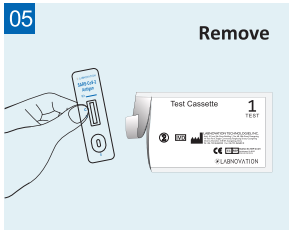
Take a sample tube, remove the aluminum foil sealing of the prefilled sample extraction tube.

04



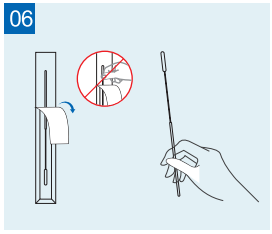
Put the sample tube (with prefilled sample extraction solution) into the hole on the kit as marked.

05



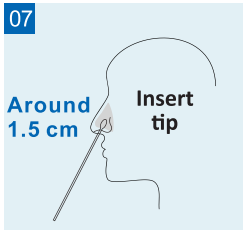
Open the sealed pouch and remove the test cassette. Lay it face up on a clean, dry and flat surface.

06



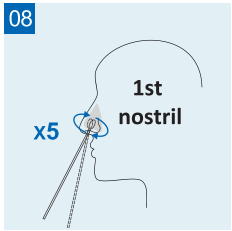
Remove the swab from the container, being careful NOT to touch the soft end, which is the absorbent tip.

07



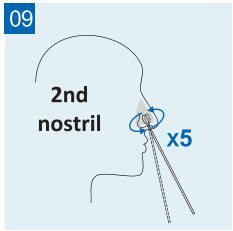
Blow nose first. Gently, insert the entire absorbent tip of the swab (around 1.5 cm) into your nostril.

08



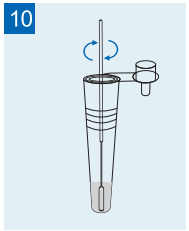
Slowly, rotate the swab in a circular against the inside walls of your nostril 5 times or more.

09



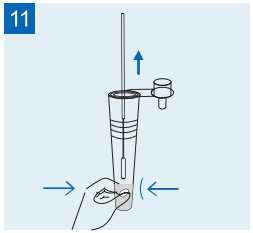
Use the same swab to repeat steps in the other nostril and slowly, take out the swab.

10



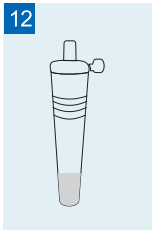
Take the sample tube with sample extraction. Insert the swab into the sample tube with extraction buffer. Mix well.

11



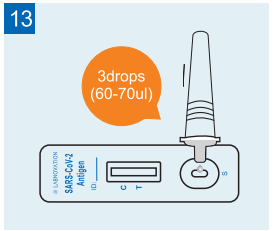
Mix well and squeeze the swab 10-15 times by compressing the walls of the tube against the swab. Roll the swab head against the inner wall of the tubes as you remove it.

12



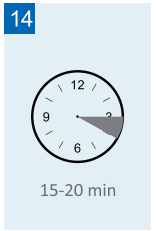
Close the cap of the sample tube.

13



Add 3 full drops of the mixed solution vertically into the sample well (S) of the test cassette. And start the timer.

14



Read the result 15-20 minutes after adding the sample. Result got after 20 minutes is invalid.

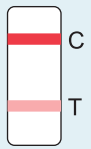
15

All used test components should be put into the bio safety bag before being disposed in the trash.*Note: After completing all steps, wash hands or use hand sanitizer.

INTERPRETATION OF RESULTS

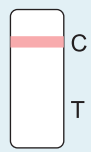
Positive:

Two colored bands appear on the membrane. COVID-19 was detected. (Please see Q5 in IFU) * Note: It does not matter if one of the lines that make up the test line (T) is lighter or darker than the other; the result is "Positive". Please follow the relevant state or territory health authority's advice.



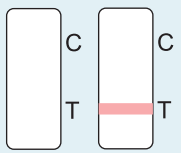
Negative:

Only one colored band appears, in the control region (C) . No apparent colored band appears in the test region (T). COVID-19 was not detected.(Please see Q6 in IFU) * Note: False negative results can be from incorrect sampling, incorrect execution of the test, or insufficient virus in the sample.



Invalid:

If there is no Control line (C) or only a Test line (T) in the result window, the test did not run correctly and the results are not valid.
*Note: It is important that you carefully follow the instructions for the test. You should test again with a new sample and a new test.



LABNOVATION

CUSTOMER SUPPORT HELP LINE:
Call 1300 581 810 9:00am-7:00pm (AEST)
7 days per week.

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