INSTRUCTIONS FOR USE

LUCA NK COVID-19 Ag Nasal LLB Self-Test

QR code to access the instructional video

COVID-19 Self-Test for Self-Test use.
One step, rapid, immunochromatographic test for detection of the SARS-CoV-2 antigen in human nasal specimen.

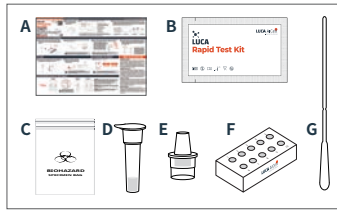
NK Nature-inspired Kit
LLB LUCA LIPID BILAYER

IVD

01 PREPARATION

1. Before the test, wash your hands thoroughly with soap and warm water or hand sanitiser.

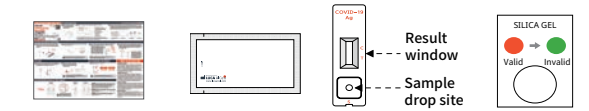
2. Before the test, be sure to check the components below.



A. Instructions for use
B. Test device individually foil pouched with a desiccant
C. Biohazard bag
D. Assay buffer tube
E. Nozzle cap
F. Tube stand
G. Sterile swab

See the "MATERIALS PROVIDED" Table on the next page for the number of each item above which is included in each 20 Tests/Kit, 5 Tests/Kit, 2 Tests/Kit and 1 Test/Kit, as the Tube stand is only in the 20 Tests/Kit.

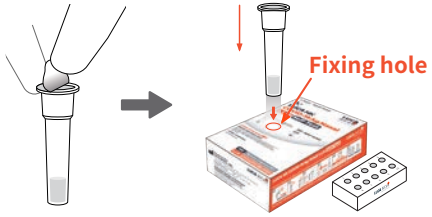
3. Bring the test kit components to room temperature (15~25°C) 15 to 30 minutes prior to testing. Carefully read these Instructions for Use. Check the expiry date at the back of the foil pouch. Do not use the test device if the date is after the expiry date. Then check the colour of the SILICA GEL. If the colour is green, do not use this test.



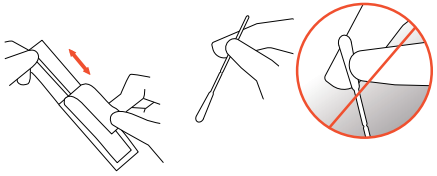
Instructions for use | Foil pouch | Test device | Desiccant

02 COLLECTING OF SPECIMEN

4. Remove the aluminum seal from the assay buffer tube and insert it into the circular fixing hole of the outer box (1T, 2T, or 5T) or the Tube stand (20T) to secure it.

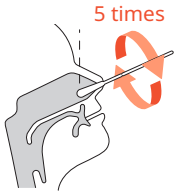


5. Please remove the "OPEN" part of the enclosed sterile swab by tearing it off.



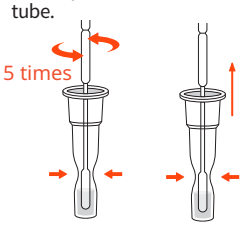
⚠ Please be careful not to touch the tip of the sterile swab with your hands or any foreign material.

6. Insert the tip of the swab 2-4 cm inside one nostril and brush it firmly against the inside wall of the nostril. Rotate the swab in a circular motion 5 complete times around the nostril while keeping the tip of the swab firmly brushed against the inside wall of the nostril. Using the tip of the same swab, repeat the same process in the other nostril.



Samples should be tested immediately after collection. The sample is stable for up to 10 minutes.

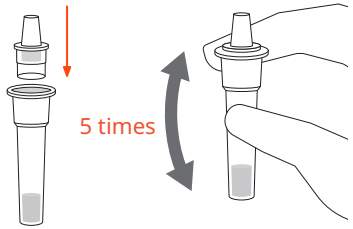
7. Insert the swab into an assay buffer tube. Squeeze the sides of the assay buffer tube against the swab tip. While squeezing, rotate the swab 5 complete times so that the swab tip absorbs some of the liquid in the assay buffer tube.



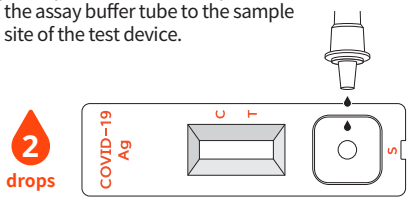
Remove the swab while squeezing the sides of the assay buffer tube to extract the liquid from the swab tip so that the extracted liquid stays in the assay buffer tube.

03 TEST

8. Press the nozzle cap tightly onto the assay buffer tube. Thoroughly mix the sample and the assay buffer by shaking the tube up-and-down 5 times.



9. Apply 2 drops of the extracted specimen from the assay buffer tube to the sample drop site of the test device.



⚠
- Place the test device on a flat surface.
- After the first drop is completely absorbed, then add the second drop

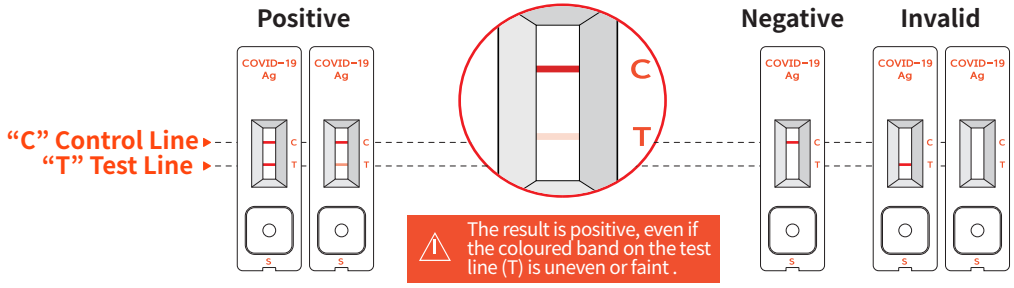
04 READING THE RESULT

10. Read the result in 5 - 10 mins.

Read	Do not read
In 5 - 10 mins	After 10 mins

⚠
- Do not read test results after 10 minutes.
- After 10 minutes, the test may give false results.

05 INTERPRETATION OF TEST RESULT



⚠ The result is positive, even if the coloured band on the test line (T) is uneven or faint .

POSITIVE Coloured bands appear on both the control line (C) and the test line (T) in the result window, even if either the coloured band on the test line (T) is uneven or faint or the coloured band on the control line (C) is uneven or faint or if both occur.

NEGATIVE Coloured band appears only on the control line (C) in the result window, even if the coloured band is uneven or faint.

INVALID If the coloured band does not appear on the control line (C) in the result window, the result is considered invalid.

WHAT TO DO AFTER TEST

POSITIVE Test Result
A positive test result means that SARS-CoV-2 antigens were found in the swab sample. It is likely that you have COVID-19 and are contagious. However, a positive test result is presumptive only, meaning that it is not certain that you have COVID-19.
You should follow the current guidance on the website of the Commonwealth Department of Health and Aged Care here: https://www.health.gov.au/topics/covid-19/testing-positive.
Also see "POSITIVE TEST RESULT" on next page.

NEGATIVE Test Result
A negative test result means that SARS-CoV-2 antigens were not in the swab sample. However, a negative test result is presumptive only, meaning that it does not completely rule out the possibility of infection by the SARS-CoV-2 virus. Incorrect sampling or low viral load at the time of testing can cause a false negative result. If you feel unwell, seek medical assistance.

INVALID Test Result
If you get an invalid test result, it means that the test has not functioned correctly or that you have not used it correctly. You should take another test using a new test device, assay buffer tube, nozzle cap and sterile swab and using a freshly collected swab sample. Read the instructions for use carefully and repeat the test. If repeated tests also produce invalid results, please report the details to the sponsor.

SAFETY DISPOSAL
After you complete the test, put all of the used test kit components into a biohazard bag, then seal that biohazard bag and dispose of that sealed biohazard bag in your normal household waste. Wash your hands thoroughly using soap and warm water, or hand sanitiser, after disposing of used test kit components.

LUCA NK COVID-19 Ag Nasal LLB Self-Test

COVID-19 Self-Test for Self-Test use.

INTENDED USE

LUCA NK COVID-19 Ag Nasal LLB Self-Test is a testing device that uses an immunochromatographic assay technique to qualitatively detect the presence of the nucleocapsid protein antigen of the SARS-CoV-2 virus (the virus that causes COVID-19 disease) in human nasal swab specimens collected from symptomatic persons within 7 days of symptom onset. The test is used as an aid in the diagnosis of SARS-CoV-2 viral infections. The test is intended to be used in the home or similar environment by a lay person.

WHEN TO USE THE TEST KIT

Use LUCA NK COVID-19 Ag Nasal LLB Self-Test if you have one or more symptoms of COVID-19 including fever, headache, coughing, sore throat, loss of sense of smell or taste or shortness of breath.

TEST PRINCIPLE

LUCA NK COVID-19 Ag Nasal LLB Self-Test is an immunoassay for the qualitative detection of the SARS-CoV-2 antigen in human nasal swab specimens. The test device has a gold conjugation pad with a colouring material and a membrane which has a Test Line (T) coated with a Detection Antibody. If SARS-CoV-2 antigen is present in the nasal swab specimen, it binds with the Detection Antibody and a visible coloured band appears on the Test Line (T).

VARIANTS THAT THE TEST CAN DETECT

LUCA NK COVID-19 Ag Nasal LLB Self-Test can detect the following variants of SARS-CoV-2: Alpha(α), Beta(β), Gamma(γ), Delta(δ), Eta(η), Iota(ι), Kappa(κ), Lambda(λ), Mu(μ) and Omicron(ο). The manufacturer will carry out further clinical testing on new variants.

MATERIALS PROVIDED

Pack size (Ref No)	**20 Tests** (RD02-01D20)	**5 Tests** (RD02-01D05)	**2 Tests** (RD02-01D02)	**1 Test** (RD02-01D01)
Test devices	20	5	2	1
Sterile swabs	20	5	2	1
Assay buffer tube	20	5	2	1
Nozzle caps	20	5	2	1
Instructions for use	4	1	1	1
Tube stand	1			
Biohazard bag	20	5	2	1

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer, stopwatch, or clock

STORAGE AND STABILITY

1. Store the kit between 2°C to 30°C and away from direct sunlight, moisture and heat. Do not freeze the kit.
2. Do not use the test after the expiry date printed on the outer box.
3. Use the test immediately after removing the test device from the foil pouch.

PERFORMANCE CHARACTERISTICS

(1) Clinical evaluation

A comparison study between LUCA NK COVID-19 Ag Nasal LLB Self-Test and a PCR-based test authorised by the Korean Government's Ministry of Food and Drug Safety was conducted by lab professionals using 222 nasal swab specimens.

The results showed that 211 of 222 test results were correct so that the **Overall Percent Agreement (Accuracy)** was **95.05%** (95% CI: 92.19% to 97.90%).

Nasal specimens		RT-PCR		
		Positive	Negative	Total
LUCA NK COVID-19 Ag Nasal LLB Self-Test	Positive	103	2	105
	Negative	9	108	117
	Total	112	110	222

The positive percent agreement (sensitivity) and negative percent agreement (specificity) were 91.97% (95% CI: 85.43 to 95.71%) and 98.19% (95% CI: 93.61 to 99.50%), respectively. More than 20% of the positive nasal swab specimens used in the study had a low viral load (Ct > 30) which are more difficult to detect as positive due to the low viral load.

(2) Analytical Performance

1. **Limit of Detection**: The Limit of Detection (LoD) for LUCA NK COVID-19 Ag Nasal LLB Self-Test was confirmed to be 1 X 101.59 $TCID_{50}$/ml.
2. **Cross-Reactivity study**: The following 20 microorganisms had no impact on the performance of the LUCA NK COVID-19 Ag Nasal LLB Self-Test: Human Adenovirus 1, Human Coronavirus OC43, Human Coronavirus 229E, Japanese encephalitis virus, Dengue virus type 2, Human Influenza B virus, Human Rhinovirus 21, Human parainfluenza virus 1 & Human parainfluenza virus 2 & Human parainfluenza virus 3, Human Influenza A virus H1N1, Human hepatitis A virus, Human Influenza A virus H3N2, Human metapneumovirus, Human Coronavirus NL63, Human coronavirus HCoV-HKU-1 (Nucleoprotein), Mycrobacterium pneumonia(Strain FH), MERS-CoV Nucleocapsid protein (His Tag), Respiratory Syncytial Virus A & Respiratory Syncytial Virus B. SARS-CoV-1 (SARS Coronavirus) has reactivity with the test and affects the test results because the test cannot differentiate between SARS-CoV-2 and SARS-CoV-1 due to their high homology.
3. **Interference study**: An interference study showed that the following potentially interfering substances did not affect the test performance of LUCA NK COVID-19 Ag NASAL LLB Self-Test: Mucin (from porcine stomach), Human Hemoglobin, Glucose, L-Ascorbic acid, Human Albumin, Sodium citrate tribasic, Acetaminophen, Sodium chloride, Heparin sodium salt from porcine intestinal mucosa, Doxycycline hyclate, Erythromycin, Tobramycin, EDTA (Ethylenediaminetetraacetic acid), Ibuprofen, Olopatadine hydrochloride, Co & Cool Nasal Spray of Hanmi Pharm (Chlorpheniramine Maleate 250mg/100mL, Xylometazoline Hydrochloride 0.1g/100mL), Nosecare Nasal Spray of Bukwang Pharm (Chlorpheniramine Maleate...2.5mg/mL, Dipotassium Glycyrrhizinate...3mg/mL, Naphazoline Hydrochloride...0.5mg/mL), Oseltamivir, Biotin, Lamivudine, quinine, Bilirubin Conjugate, Mupirocin, Acetylsalicylic acid, Ciprofloxacin, Cromoglycate, Zanamivir, Human Whole blood.
4. **Usability Study**: A Clinical Performance Study involved 343 laypersons who carried out a self-test using the test. The results were that the **Overall Percent Agreement (Accuracy)** was **97.4%** and the sensitivity and specificity were 92.6% and 99.2%, respectively. The overall feedback from a Usability Study involving 100 of those 343 laypersons was that the test was user-friendly and easy to use.

LIMITATIONS OF TEST

1. The test is for the qualitative detection of SARS-CoV-2 antigen in human nasal swab specimens. It does not indicate the quantification of the virus.
2. The test is for in vitro diagnostic use only and for self-test use only.
3. A negative test result does not completely rule out SARS-CoV-2 infection, particularly if you have been in contact with the virus and/or if you have symptoms.
4. A negative test result does not mean that a person is not infectious and does not rule out infection with another type of respiratory virus.
5. A positive result cannot necessarily determine whether a person is infectious.
6. The SARS-CoV-1 virus (SARS Coronavirus) may cause a false positive test result. See "Cross-Reactivity study"
7. The test should be performed within the first 7 days of symptom onset when viral shedding / viral load is highest.
8. If the test is performed more than 7 days after symptom onset, false negative results may occur.
9. The test is less reliable in the later phase of infection and in asymptomatic persons.

QUALITY CONTROL

The test includes an internal quality control which confirms adequate specimen volume and correct procedure technique when a coloured band appears in the Control Line "C" area of the test device.

WARNINGS AND PRECAUTIONS

1. Before using test, carefully read instructions for use.
2. Remove any piercings from the nose before testing.
3. Keep test kit and kit components out of the reach of children and pets before and after use.
4. Do not use the test if you are prone to nose bleeds.
5. If samples are not taken in accordance with the instructions, it can have a significant impact on the test results.
6. Do not wear coloured lens (glasses or contact lens) when interpreting the test result, as coloured lens can affect the interpretation of the test result.
7. Do not use if the Test kit package is damaged.
8. Do not reuse any kit components or mix components from different kit lots or different products.
9. Keep test kit components sealed prior to use.
10. When handling this test kit, do not let your hands or other foreign objects directly touch the result window of the device or the membrane of the strip.
11. If the assay buffer liquid gets into your mouth, eyes or comes into contact with your skin, immediately gargle water in your mouth several times (if it got into your mouth) or rinse the affected area with plenty of running water (if it got into your eyes or came into contact with your skin). If unwell, seek medical assistance.
12. Repeat testing within 1 to 3 days is recommended if ongoing suspicion of infection, high risk setting or occupational or other requirement.
13. Use test on persons aged 2 years or older. Do not use test on persons under 2 years old. An adult should carry out the test on persons aged 2 to 12 years.
14. Do not smoke, eat or drink while carrying out the test.
15. If you have problems with your hands or vision, an adult without those problems should assist you with the swabbing and testing process.

POSITIVE TEST RESULT

1. If you get a positive result, staying at home protects your community. You should not visit high risk settings such as hospitals, aged care or disability care centres.
2. If you are unwell or need COVID-19 advice for you or someone in your care, talk to your health provider or speak to a nurse by calling the healthdirect helpline on 1800 022 222.
3. If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately and tell the operator and paramedics if you tested positive.

FURTHER INFORMATION

1. If you are experiencing problems with the test or for customer support, please contact the Involution Healthcare Pty Ltd Customer Support Number 1800 960 593 8:45am to 5:15pm AEST/AEDT Monday to Friday (excluding public holidays).
2. You can also contact the TGA to report poor performance or usability issues via the Users Medical Device Incident Report, email (iris@health.gov.au) or call (1800 809 361)

REFERENCES

1. Gannon Ck Mak et al., Evaluation of rapid antigen test for detection of SARS-CoV-2 virus. J Clin Virol. (2020), 129, 104500.
2. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays, WHO/2019-CoV/Antigen_Detection/2020.1

INDEX OF SYMBOLS		
Temperature limitation	Lot Number	Manufacturer
For in vitro diagnostic use only	Catalog Number	Contains sufficient for X tests
Do not reuse	Consult instructions for use	Do not use if package is damaged
Use By	Keep dry	Caution
Biological risks		

Manufactured by LUCA AICELL, INC.

LUCA AICell
Inspired by Nature

11-35, Simin-daero 327beon-gil, 3rd Fl, Dongan-gu,
Anyang-si, Gyeonggi-do, 14055, Republic of Korea
Tel: +82-31-8091-1000, Fax: +82-31-8091-0010
Email: contact@lucaaicell.com
Website: www.lucaaicell.com

AUSTRALIAN SPONSOR & DISTRIBUTOR

INVOLUTION HEALTHCARE

Involution Healthcare Pty Ltd
Level 36 Gateway, 1 Macquarie Place,
Sydney NSW 2000, Australia
Email: support@involutionhc.com
Website: www.involutionhc.com
Customer Support Number: 1800 960 593
8:45am to 5:15pm AEST/AEDT Monday to Friday
(excluding public holidays).

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