NK Nature-inspired Kit
LLB LUCA LIPID BILAYER

QR code to access the instructional video

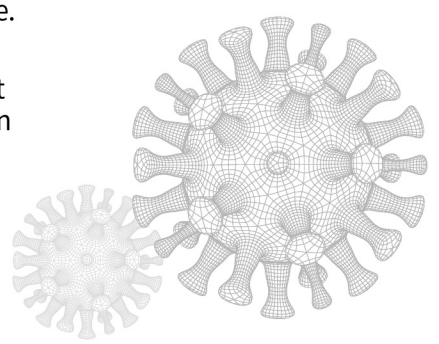
IVD

LUCA NK COVID-19 Ag Saliva LLB

INSTRUCTIONS FOR USE
Point-of-Care Testing only. Not for Self-Test use.

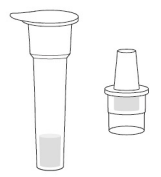
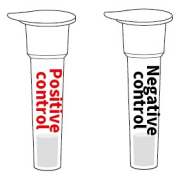
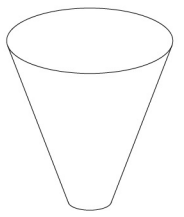
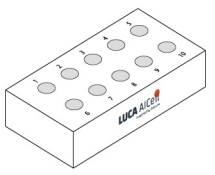
One step, rapid, immunochromatographic test for detection of the COVID-19 antigen in human saliva specimen.

LUCA AICell
Inspired by Nature



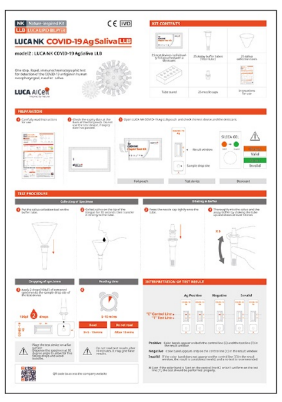
KIT CONTENTS

See the "MATERIALS PROVIDED" Table on the next page for the number of each item below which is included in each 25 Tests / Kit, 5 Tests / Kit and 1 Test / Kit.

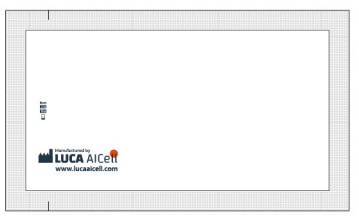
			
Test device individually foil pouched with a desiccant	Assay buffer tube and Nozzle cap	LUCA NK CONTROL (Positive & Negative)	
			
Tube stand	Biohazard bag	Instructions for use	Saliva collection tool

PREPARATION

1. Bring the test kit components to room temperature (15°C to 25°C) prior to use. Carefully read this document, which is the instructions for use for this test kit.



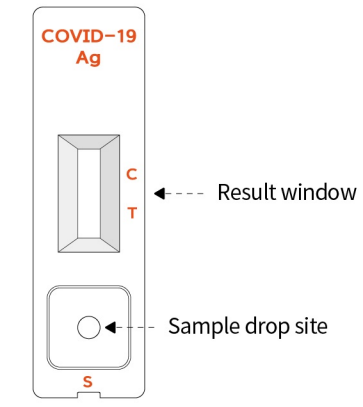
2. Check the expiry date at the back of the foil pouch. Do not use the test device if the date is after the expiry date.



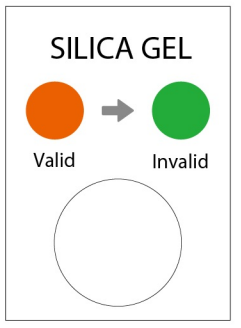
3. Open the LUCA NK COVID-19 Ag Saliva LLB pouch and check the test device and the desiccant.

Use the test device when the temperature is between 2-30°C and when the humidity is less than 90%. In those conditions, once the pouch is opened, the test device should be used within 40 minutes.

Foil pouch



Test device



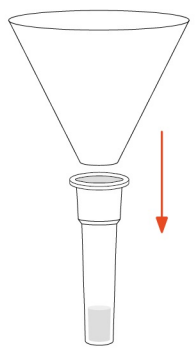
Check the colour. If the colour is green, do not use this test. Use another test.

Desiccant

TEST PROCEDURE

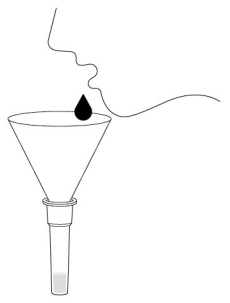
Collecting of specimen

1. Put the saliva collection tool on the assay buffer tube.



Use the assay buffer tube when the temperature is between 2-30°C and when the humidity is less than 90%. In those conditions, once the assay buffer tube is opened, the assay buffer tube should be used within 24 hours.

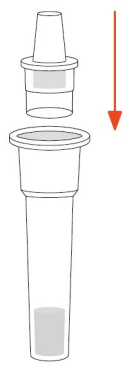
2. Collect saliva in your mouth for about 30 seconds. Then spit enough saliva (with no sputum) into the saliva collection tool so that the assay buffer tube contains about 50% assay buffer liquid and about 50% saliva.



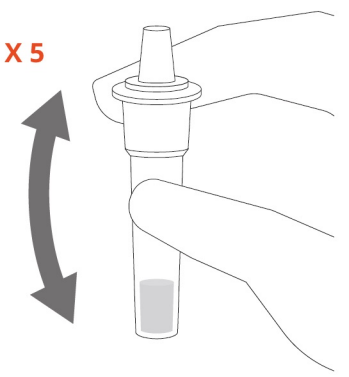
Samples should be tested immediately after collection. The sample is stable for up to 10 minutes. Test results in laboratory conditions showed that samples are stable for up to 3 days when stored at 2-8°C.

Diluting in buffer

3. Press the nozzle cap tightly onto the assay buffer tube.

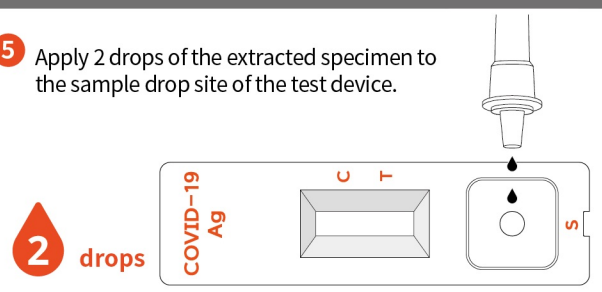


4. Thoroughly mix the saliva and the assay buffer by shaking the tube up-and-down 5 times.



Dropping of specimen

5. Apply 2 drops of the extracted specimen to the sample drop site of the test device.



⚠
- Place the test device on a flat surface.
- Dispense the specimen at a 90 degree angle to allow for freefalling drops and to avoid bubbles.

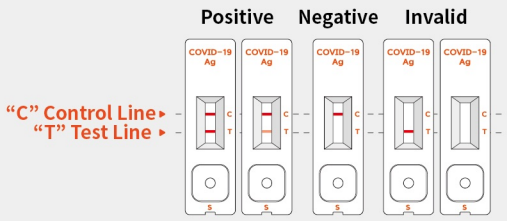
Reading time

6

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

⚠
- Do not read test results after 10 minutes. It may give false results.

INTERPRETATION OF TEST RESULT



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 the Nucleocapsid protein antigen of SARS-CoV-2 was found in the specimen. The person tested likely has COVID-19 and is contagious. A positive test result is presumptive only, meaning that it is not certain that the tested person has COVID-19. The person tested should check their local State or Territory Health Department guidelines for reporting positive results and for confirmation testing if necessary, and if unwell should seek medical assistance.

NEGATIVE Test Result
A negative test result means that the Nucleocapsid protein antigen of SARS-CoV-2 was not found in the specimen.
A negative test result also is presumptive only, meaning that it is not certain that the tested person does not have COVID-19. The tested person may still have COVID-19 and may be contagious. Follow the guidance from your local State or Territory Health Department for what to do if a negative result is obtained, and if unwell seek medical assistance.

INVALID Test Result
An invalid test result means that the test has not functioned correctly or has not been used correctly.
Conduct a new test with a new test device, assay buffer tube, saliva collection tool and saliva sample. If repeated tests also produce invalid results, please report the details to the sponsor.

Rapid test kit for COVID - 19 Antigen

LUCA NK COVID-19 Ag Saliva LLB

LUCA AICell
Inspired by Nature

For *in vitro* diagnostics use only

INTENDED USE

LUCA NK COVID-19 Ag Saliva LLB is an in vitro diagnostic test device that helps diagnose SARS-CoV-2 virus (the virus that causes COVID-19 disease) infection in symptomatic persons within 7 days of symptom onset when viral load is at its highest. The test uses immunochromatography to qualitatively detect the presence of the Nucleocapsid protein antigen of SARS-CoV-2 in saliva specimens. The test is for Point-of-Care Testing by trained laboratory staff or healthcare professionals only as an aid in the diagnosis of SARS-CoV-2 infection. It is not for Self-Test use.

WHEN TO USE THE TEST KIT

Use LUCA NK COVID-19 Ag Saliva LLB:

1. If the person to be tested has one or more symptoms of COVID-19 including fever, headache, coughing, sore throat, loss of sense of smell or taste, shortness of breath.
2. If the person to be tested is concerned about being exposed to a person with COVID-19.

TEST PRINCIPLE

LUCA NK COVID-19 Ag Saliva LLB is an in vitro diagnostic medical device using an immunochromatography assay technique, intended for the qualitative detection of the Nucleocapsid protein antigen of SARS-CoV-2 in a human Saliva. LUCA NK COVID-19 Ag Saliva LLB consists of a gold conjugation pad containing a colouring material and a membrane which has a control line (C) coated with Goat anti-mouse IgG (polyclonal Ab.) and a test line (T) coated with Anti-SARS-CoV-2 Nucleocapsid protein (NP) Antibody. If there is antigen of SARS-CoV-2 in the sample, an antibody-antigen-antibody complex is formed, and a coloured band appears on the test line (T) of the test device.
LUCA NK COVID-19 Ag Saliva LLB 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), Omicron(ο)

MATERIALS PROVIDED

Pack size (Cat. No)	25 Tests / Kit (RD02-02C)	5 Tests / Kit (RD02-02C05)	1 Test / Kit (RD02-02C01)
Test devices	25	5	1
Saliva Collection tool	25	5	1
Assay buffer tube	25	5	1
Nozzle caps	25	5	1
Instructions for use	1	1	1
Tube stand	1		
Biohazard bag		5	1
LUCA NK CONTROL	2 (1 Pos & 1 Neg)		

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Biohazard container
- Timer, stopwatch, or clock
- Personal protective equipment

STORAGE AND STABILITY

1. Store the kit between 2°C to 30°C. As the efficacy of the test kit may decrease when exposed to moisture and heat, store the kit away from direct sunlight, moisture and heat.
2. The kit's components can be used until the expiration date printed on the outer box.
3. Do not freeze the kit.
4. Use the test immediately after removing the test device from the foil pouch because the test device is sensitive to humidity and temperature.

PERFORMANCE CHARACTERISTICS

(1) Clinical evaluation

Two comparison studies between the test device (LUCA NK COVID-19 Ag Saliva LLB) and a PCR-based test authorised by the relevant Korean Government regulatory agency (MFDS) were conducted by lab professionals, the first using 50 specimens and the second using 220 specimens. The sensitivity and specificity percentages (positive and negative percent agreement) for the first comparison study were 95% and 100%, respectively, and for the second comparison study were 86.37% and 98.19%, respectively. The information in the Tables below was extracted from the second comparison study.

Saliva specimens		RT-PCR		
		Positive	Negative	Total
LUCA NK COVID-19 Ag Saliva LLB	Positive	95	2	97
	Negative	15	108	123
	Total	110	110	220

- Sensitivity (Positive percent agreement): 86.37% (95/110, 95% CI: 0.7871 to 0.9156)
- Specificity (Negative percent agreement): 98.19% (108/100, 95% CI: 0.9361 to 0.995)

Clinical sensitivity according to days after symptom onset

Days after symptom onset	Positive	Negative	Sensitivity	95% CI
Day 0-3	69	6	92%	0.8363 to 0.9628
Day 4-7	22	4	84.62%	0.6647 to 0.9385
> Day 7	4	5	44.45%	0.1888 to 0.7333
Total	95	15	86.37%	0.7871 to 0.9156

Clinical sensitivity according to Ct value of RdRp gene

Ct Value (RdRp gene)	Positive	Negative	Sensitivity	95% CI
Ct<20	54	0	100.0%	0.9336 to 1.0000
20≤Ct<25	18	1	94.74%	0.7536 to 0.9906
25≤Ct<30	11	3	78.58%	0.5241 to 0.9243
Ct≥30	12	11	52.18%	0.3296 to 0.7076
Total	95	15	86.37%	0.7871 to 0.9156

(2) Analytical Performance

1. **Limit of Detection(LoD)**:
The LoD for the LUCA NK COVID-19 Ag Saliva LLB to detect SARS-CoV-2 (NCCP 43326 Human corona virus BetaCoV/Korea KCDC03/2020)) was confirmed to be 1 X $10^{1.59}$ $TCID_{50}$/ml by 2 ng/ml (Ct value of RdRp gene 28.62). The sensitivity below the Ct value of 25 was 95%.

2. **Cross-Reactivity study**:
The product has been tested for potential cross-reactivity with the 21 items listed in the table below and no cross-reactivity was detected, except with the related SARS-CoV Human SARS coronavirus (His Tag).

No.	Pathogens	Test Conc.
1	Human Adenovirus 1	4.0X10^{10} pfu/mL
2	Human Coronavirus OC43	4.2X10^{7} pfu/mL
3	Human Coronavirus 229E	6.0X10^{6} pfu/mL
4	Japanese encephalitis virus	2.0X10^{5} pfu/mL
5	Dengue virus type 2	3.0X10^{8} pfu/mL
6	Human Influenza B virus	1.0X10^{7} pfu/mL
7	Human Rhinovirus 21	4.0X10^{7} pfu/mL
8	Human parainfluenza virus 1	4.0X10^{8} pfu/mL
9	Human parainfluenza virus 2	2.0X10^{10} pfu/mL
10	Human parainfluenza virus 3	4.0X10^{8} pfu/mL
11	Human Influenza A virus H1N1	1.2X10^{5} pfu/mL
12	Human hepatitis A virus	1.0X10^{5} pfu/mL
13	Human Influenza A virus H3N2	2.0X10^{6} pfu/mL
14	Human metapneumovirus	3.0X10^{5} pfu/mL
15	Human Coronavirus NL63	4.0X10^{5} pfu/mL
16	Human coronavirus HCoV-HKU-1 (Nucleoprotein)	1 ug/mL
17	SARS-CoV-1 (SARS Coronavirus) (Nucleocapsid protein (His Tag))	1 ng/ml
18	Mycrobacterium pneumonia(Strain FH)	4.5X10^{8} pfu/mL
19	MERS-CoV Nucleocapsid protein (His Tag)	0.25 mg/ml
20	Respiratory Syncytial Virus A	1.2X10^{6} pfu/mL
21	Respiratory Syncytial Virus B	4.6X10^{5} pfu/mL

3. **Interference study**:
Interference studies showed that test results of this product are not interfered with or affected by:
a. Food/Beverage: mouth wash, toothpaste, alcohol, chewing gum, orange juice, cigarette, vaping, black tea, coffee, energy drinks or soft drinks
b. Other substances: any of the 28 items listed in the Table below:

No.	Substance name	Test concentration
1	Mucin (from porcine stomach)	0.2 mg/mL
2	Human Hemoglobin	10 mg/mL
3	Glucose	1 mg/mL
4	L-Ascorbic acid	1 mg/mL
5	Albumin, Human	60 mg/mL
6	Sodium citrate tribasic	50 mg/mL
7	Acetaminophen	0.4 mM
8	Sodium chloride	40 mM
9	Heparin sodium salt from porcine intestinal mucosa	200 U/mL
10	Doxycycline hyclate	140 uM
11	Erythromycin	163.2 uM
12	Tobramycin	10 ug/mL
13	EDTA (Ethylenediaminetetraacetic acid)	20 mM
14	Ibuprofen	5 mM
15	Olopatadine hydrochloride	10 mg/mL
16	Co & Cool Nasal Spray of Hanmi Pharm. Chlorpheniramine Maleate 250mg/100mL, Xylometazoline Hydrochloride 0.1g/100mL	20%(v/v)
17	Nosecare Nasal Spray of Bukwang Pharm. Chlorpheniramine Maleate...2.5mg/mL, Dipotassium Glycyrrhizinate...3mg/mL, Naphazoline Hydrochloride...0.5mg/mL	20%(v/v)
18	Oseltamivir	20 mg/mL
19	Biotin	100 ug/mL
20	Lamivudine	2 mg/mL
21	Quinine	300 uM
22	Bilirubin Conjugate	1 mM
23	Mupirocin	20 mg/mL
24	Acetylsalicylic acid	7.24 mM
25	Ciprofloxacin	30.2 umol/L
26	Cromoglycate	10 mg/mL
27	Zanamivir	5 mg/ml
28	Human Whole blood	5 % (v/v)

4. **High-Dose Hook Effect**:
No hook effect was observed up to the concentration of 1x$10^{5.301}$ $TCID_{50}$/mL using coronavirus NCCP43326/ 2020/Korea). No hook effect was observed up to the concentration of 2 ug/mL for SARS-CoV-2 nucleocapsid protein.

5. **Precision**:
Repeatability and reproducibility test results satisfy 100% of the acceptance criteria.

LIMITATION OF TEST

1. If the concentration of the SARS-Cov-2 antigen in the sample is below the detection limit of the test, or if it is collected or transported improperly, false negative results may result, so SARS-CoV-2 infection cannot be excluded even if the result is negative.
2. This product only verifies the existence of SARS-CoV-2 antigens. The colour intensity of the control line (C) and the test line (T) and the concentration of SARS-CoV-2 antigen are not correlated.
3. If there is a mutation in the binding site of the monoclonal antibody contained in this product, the sensitivity may be lowered.

QUALITY CONTROL

An internal procedural control is included in the test kit. In order to be a valid test result, a test must produce a coloured band on the control line (C) even if it is faint. If a coloured band on the control line (C) does not appear within the 5-10 minute test result period, the test result is invalid and another test should be carried out.

EXTERNAL QUALITY CONTROL PROCEDURE

LUCA NK CONTROL are control solutions (one positive and one negative) that comprise an additional external control that is supplied with each 25 Test/Kit to test whether the test reagents work properly. To use, pour a minimum of 50% of the liquid in the positive LUCA NK CONTROL tube into a new assay buffer tube taking care not to spill any of the liquid in the process. Then complete the "TEST PROCEDURE" section on the previous page starting with Step (3) in the "Diluting in buffer" section. Then perform the same process using a new assay buffer tube and new test device with the negative LUCA NK CONTROL tube. These controls are for verifying proper test performance in accordance with good laboratory practice. LUCA AICELL, INC. recommends using the controls for each new Lot Number of test kits, each new operator, each new shipment of test kits, to investigate repeated invalid results or at periodic intervals required by your organisation. If the control solutions do not perform as expected, please report the details to the sponsor.

WARNINGS AND PRECAUTIONS

(1) Precautions

1. This product is for Point-of-Care Testing by trained laboratory staff or healthcare professionals only.
2. Do not reuse this product.
3. Read and follow the instructions of use to perform the test.
4. This test is not for Self-Test use.
5. Keep test kit and kit components out of the reach of children and pets before and after use.
6. Samples must be taken carefully by trained healthcare professionals only due to the risk of infection.
7. If samples are not taken in accordance with the instructions, it can have a significant impact on the test results. Please follow the instructions for taking the samples.
8. Samples should be tested immediately after collection. Test results in laboratory conditions showed that samples are stable for up to 3 days when stored at 2-8°C.
9. Use the test device and the assay buffer tube when the temperature is between 2-30°C and when the humidity is less than 90%. In those conditions, once the test device is opened, the test device should be used within 40 minutes and once the assay buffer tube is opened, the assay buffer tube should be used within 24 hours.
10. Do not wear glasses or contact lens with coloured lens when interpreting the test result, as coloured lens can affect the interpretation of the test result.
11. Wash hands thoroughly before and after performing the test with soap and water or hand sanitiser.
12. Drink a cup of water at least 60 minutes before saliva collection to maintain adequate hydration which improves saliva flow.
13. Do not drink, chew gum or tobacco, smoke or vape for at least 30 minutes before saliva collection.
14. Make sure that the assay buffer tube contains about 50% assay buffer liquid and about 50% saliva for the test, so that there is about the same quantity of saliva as assay buffer liquid. Too much or too little saliva in the assay buffer tube may affect the test result.
15. Collect saliva in your mouth for about 30 seconds. Then spit enough saliva (with no sputum) into the saliva collection tool so that the assay buffer tube contains about 50% assay buffer liquid and about 50% saliva.

(2) General safety and handling of biohazardous substances.

After testing, used testing devices and disposable sampling tools should be properly disposed of in accordance with applicable regulations.

(3) Warnings

1. Do not use if the Test kit package is damaged.
2. Do not reuse any kit components or mix components from different kit lots or different products.
3. All components in this test kit should remain sealed until ready for use.
4. Be careful handling the specimen as it may contain virus or bacterial infection and wear appropriate personal protective equipment during the test.
5. 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.
6. 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.
7. There is a risk of false negative results, particularly if testing is not performed within the first 7 days of symptom onset.
8. The test is less reliable in the later phase of infection and in asymptomatic individuals.
9. The test is for presumptive screening only. In the case of a positive result, the person tested should check their local State or Territory Health Department guidelines for reporting positive results and for confirmation testing if necessary, and if unwell should seek medical assistance.
10. A positive result cannot necessarily determine whether a person is infectious.
11. Repeat testing is recommended if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
12. A negative test result does not mean that a person is not infectious. Follow the guidance from your local State or Territory Health Department for what to do if a negative result is obtained, and if unwell seek medical assistance.
13. A negative result does not rule out bacterial infection or co-infection with another virus.

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 (9am-7pm (AEST) / 9am-8pm (AEDT) 7 days a week)**.
2. You can also contact the TGA to report poor performance or usability issues via the Users Medical Device Incident Report, email (iris@tga.gov.au) or call (1800 809 361).
3. Information regarding available support services can be obtained by contacting your local State or Territory Department of Health, as below:

Australian Capital Territory - Department of Health	Business hours: 02 5124 9213 Coronavirus helpline (8am to 8pm daily): 02 6207 7244 www.health.act.gov.au
New South Wales - Department of Health	General enquiries: 1300 066 055 Coronavirus hotline (24/7): 137 788 www.health.nsw.gov.au
Northern Territory - Department of Health	General enquiries: 08 8922 8044 Coronavirus hotline: 1800 020 080 www.health.nt.gov.au
Queensland - Department of Health	13HEALTH: 13 432 584 Coronavirus hotline: 134 268 www.health.qld.gov.au
South Australia - Department of Health	General enquiries: 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787 www.sahealth.sa.gov.au
Tasmania - Department of Health	General enquiries: 1300 135 513 Coronavirus hotline: 1800 671 738 www.health.tas.gov.au
Victoria - Department of Health	General enquiries: 1300 650 172 Coronavirus hotline (24/7): 1800 675 398 www.dhhs.vic.gov.au
Western Australia - Department of Health	General enquiries: 08 9222 4222 Coronavirus hotline (8am to 6pm Mon-Fri): 1800 595 206 www.healthywa.wa.gov.au

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 Lot Number	Manufacturer
IVD For in vitro diagnostic use only	REF 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		

Revision Date: 10 June 2024
Rev.2
RD0202C-AU002

Manufactured by LUCA AICELL, INC.

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Customer Support Number: 1800 960 593
(9am-7pm (AEST) / 9am-8pm (AEDT) 7 days a week)