Lumigenex

CE

PocRoc® SARS-CoV-2 / Influenza A+B Antigen Combo Rapid Test Kit

PLEASE READ ALL OF THE INFORMATION IN THE INSTRUCTIONS FOR USE CAREFULLY BEFORE USING THE TEST

For self-testing.
For use with nasal swab samples.
For in vitro diagnostic use only.

NAME

PocRoc® SARS-CoV-2 / Influenza A+B Antigen Combo Rapid Test Kit

INTENDED USE

The PocRoc® SARS-CoV-2 / Influenza A+B Antigen Combo Rapid Test Kit is a lateral flow immunoassay intended for in vitro rapid, simultaneous qualitative detection and differentiation of nucleocapsid antigen from SARS-CoV-2 (including the Delta and Omicron variant), Influenza A (H1N1, H3N2) and/or Influenza B (Victoria and Yamagata) directly from nasal swab specimens.The detection of SARS-CoV-2 nucleocapsid protein antigen can be used to assist the diagnosis of the patients with symptoms of COVID-19 and of seasonal influenza within the first 7 days of symptom onset.This kit is intended for self-test as a rapid test for novel coronavirus (SARS-CoV-2), Influenza A and/or Influenza B infection by laypersons.A nasal swab sample can be self-collected by an individual aged 15-70 years. People between the ages of 15 and 70 who are unable to collect samples by themselves and the children who are 2-15 years may be assisted by other adults.

REAGENTS AND MATERIALS

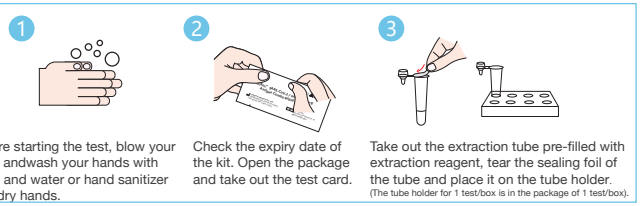
Number	Packing Specification	Test card	Nasal swab	Extraction Reagent	Tube Holder	Waste bag	IFU
1	1 test / box	1	1	1	/	1	1
2	5 tests / box	5	5	5	1	5	1
3	25 tests / box	25	25	25	1	25	25
4	50 tests / box	50	50	50	1	50	50

1. For components not included in the test kit, but necessary for the experiment: Timer.
2. The main components of the extraction reagent are PBS buffer, C12-14-Alkyldimethyl betaines and proclin300. Don't contact the extraction reagent.
3. Do not mix components with different batch numbers.

WARNINGS AND PRECAUTIONS

1. Read the Instructions for Use completely before using the test kit. Follow the instructions carefully, safely and appropriately use the kit components and prevent possible misuse. Failure to do so may result in an inaccurate result.
2. The test kit is for single use only, do not reuse any components of the test kit.
3. For seasonal influenza, the test kit should be suggested to do within the first 4 days of symptom onset. If testing is not performed within the first 7 days of symptom onset, it is possible for causing the risk of false negative results.
4. False positive results may be occur when the laypersons were infected by other pathogens.
5. The detection of this test kit is preferably done at 20 °C - 30 °C, and the humidity is not more than 80%, so as to avoid abnormal test results caused by supercooling, overheating or excessive humidity.
6. Do not use it if the aluminum foil bag is damaged or the test device is damp.
7. Do not use this test kit beyond the expiration date printed on the outer package. Always check expiry date before testing.
8. Wear appropriate personal protection equipment and gloves when performing the test, collecting and handling specimens for another individual who need help.
9. Do not insert the swab too deep. please stop the test if you feel strong resistance or pain.
10. Do not touch the reaction area of the test card. Do not touch the soft end of the swab .
11. Do not dilute the specimen for testing, otherwise you may get inaccurate results.
12. Apply the drops of test specimen only to the specimen well (S) on the test card.
13. Too many or too few drops of test specimen may result in invalid or incorrect test result.
14. Do NOT swallow the extraction solution. Avoid getting the extraction solution into the eyes or skins. If accidentally touch the skin, eyes or mucous membranes, please rinse with water immediately. Please consult a doctor without delay if you feel discomfort.
15. Keep out of reach of pet and children. And the children using the test should be supervised and help by the adults.
16. Dispose of all used test devices and potentially contaminated materials in the waste bag according to applicable local laws and regulations.

PREPARE FOR TEST

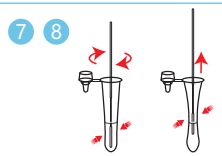


1. Before starting the test, blow your nose andwash your hands with soap and water or hand sanitizer and dry hands.
2. Check the expiry date of the kit. Open the package and take out the test card.
3. Take out the extraction tube pre-filled with extraction reagent, tear the sealing foil of the tube and place it on the tube holder. (The tube holder for 1 test/box is in the package of 1 test/box).

SAMPLE COLLECTION

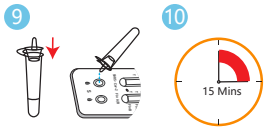
4. Remove the swab from its package,being careful not to touch the tip of the swab.
5. 6. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the person. The swab tip should be inserted up to nostril up to 2.5cm until resistance is met.
Rub the swab around the inside wall of each nostril at least 5 times. Take approximately 15 seconds to collect the sample. This is done with the same swab in the other nostril.

SAMPLE TREATMENT



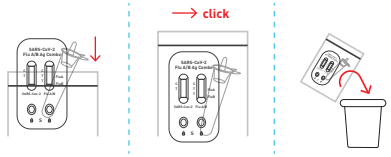
7. 8. Put the swab sample into the extraction tube with extraction reagent, rotate the swab for about 10s.Press the swab head 5 times against the tube wall to release the antigen in the swab as possibleas can. Squeeze liquid from the swab as much as possible when it is withdrawn from the tube. Discard the swab into the waste bag.

TEST



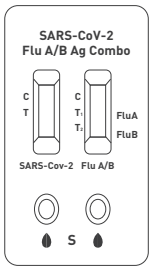
9. 10. Install the cap on the extraction tube, drop three drops into each sample well of the test card.
Please set the timer for 15 minutes, and start the timer. Read the result after 15 minutes.The result is considered inaccurate and invalid after 30 minutes.

DISPOSE THE TEST KIT

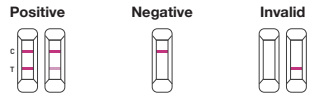


After test, put them into the waste bag, and seal the waste bag tightly, dispose of them in normal trash to comply with local regulations.

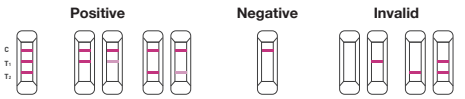
INTERPRETATION OF RESULT



For SARS-CoV-2 Antigen rapid test (Left side)



For Flu A/B rapid test (Right side)



Positive: if both the quality control line C and the test line (T or/and T1 or/and T2) appear, SARS-CoV-2 N antigen (or/and Flu A or/and Flu B) have been detected and the results are positive.
If the test result of COVID-19 is positive:
- There is a (suspected) infection of COVID-19. follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Negative: if there is only a quality control line C, the test lines are colorless, indicating that SARS-CoV-2 N antigen or Flu A or Flu B has not been detected and the results are negative.
If the test result of COVID-19 is negative:
continue to comply with all applicable rules regarding contacts and protective measures.
Even if the test is negative, there may be an infection. In case of doubt, repeat the test after 1-2 days, if symptoms persist, please seek medical attention and further testing if required.

Invalid: if the quality control line C is colorless, it will be invalid regardless of whether there is color line in the test lines (T or/and T1 or/and T2), and the test should be done again.
If the test result is invalid:
it may be caused by incorrect test operation. Please repeat the test with a new test card.

NOTE:
1. The color band in the test line (T) can show the depth of color, even a very weak/faint color should be judged as a positive result.
2. Do not read the results in dim or too bright light.

ASSISTANCE

Customer Support Helpline
Phone: 1800 952 915– Hours are: 9am-7pm (AEST), 7 days
Email: info@lumigenex.co
Website: www.lumigenex.co
The instrution for use and operation video link:
https://www.lumigenex.com/product/107.html

LOCAL HEALTH CONTACT

Australian Capital Territory Department of Health	☎ 02 6207 7244	*health.act.gov.au/*
New South Wales Department of Health	☎ 137 788	*health.nsw.gov.au/*
Northern Territory Department of Health	☎ 1800 020 080	*health.nt.gov.au/*
Queensland Department of Health	☎ 134 268	*health.qld.gov.au/*
South Australian Department of Health	☎ 1800 253 787	*sahealth.sa.gov.au/*
Tasmanian Department of Health	☎ 1800 671 738	*health.tas.gov.au/*
Victorian Department of Health	☎ 1800 675 398	*dhhs.vic.gov.au/*
Western Australian Department of Health	☎ 1800 595 206	*healthywa.wa.gov.au/*

TGA Contact Information for Reporting Poor Performance and Usability Issues:
Call 1800 809 361 or email iris@health.gov.au

TEST PRINCIPLES

The PocRoc® SARS-CoV-2 / Influenza A+B Antigen Combo Rapid Test Kit is a lateral flow immunoassay. The test strip contains membranes which are pre-coated with mouse anti-SARS-CoV N protein monoclonal antibodies on the test lines. Another mouse anti-SARS-CoV N protein monoclonal antibody which can specifically bind to SARS-CoV-2 N protein, are bound to gold particles and sprayed on conjugation pads. When the sample is added into the sample well, SARS-CoV N protein and labeled antibody complexes are formed and travel up the strip. The labeled reagent is used to form a visible red line. The presence of SARS-CoV-2 will be indicated by a visible red test line (T) in the result window. Membrane is pre-coated with Chicken IgY on the control line (C). Control line (C) appears in each result window when sample has flowed through the strip. The Control Line (C) is used as a procedural control. The control line (C) should always appear when the test procedure is performed properly and the reagents are working as intended. If influenza A and/or B viral antigens are present in the sample, it will form a complex with mouse monoclonal IgG antibodies to influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex will then be bound by another mouse anti-influenza A and/or B antibody coated on the nitrocellulose membrane. A pink to purple control line (C) must appear in the control region for results to be valid. The appearance of a second and possibly a third light pink to purple line will appear in the test line (T) indicating an A, B or A and B positive result.

LIMITATIONS

1. The test kit is for use as an aid for in vitro diagnosis only and individuals with a positive result are advised to follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
2. The test kit is only used to detect human nasal swab specimens, and the results with other specimen tests may be incorrect.
3. The test kit is only used for qualitative testing and does not indicate the number of SARS-CoV, influenza A or B virus antigen in the specimens.
4. Failure to follow the instructions or interpretation of test results may adversely affect test performance and/or invalidate the test results.
5. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.And do not identify specific influenza A or B virus subtypes.
6. A positive result cannot necessarily determine whether a person is infected with SARS-CoV and/or Influenza A/B.
7. False positive results may be occur when the laypersons were infected by other pathogens
8. A negative result does not mean a person is not infectious with SARS-CoV-2 or does not have influenza. If symptoms persist the person should seek medical attention and further testing if required
9. A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test.
10. False negative results will occur If testing is not performed within the first 7 days of symptom onset of seasonal influenza.
11. The tests are less reliable in the later phase of infection and in asymptomatic individuals.

QUALITY CONTROL

Internal procedural control is included in the test. A colored line appearing at the control line (C) is an internal control. It indicates that sufficient specimen is added and correct procedural technique is applied.

KIT STORAGE AND STABILITY

All reagents are ready to use as supplied. Unopened reagent kits are stable at 4°C~30°C for 24 months tentatively. It should be used within 1 hour under the room temperature 20°C - 30°C and the humidity ≤80% once the pouch is opened. Do not freeze the kit or expose the kit above 37°C during storage.Don't use beyond the expiry date. For home use, the swabs must be tested immediately after collection.

PERFORMANCE CHARACTERISTICS

1. Clinical Evaluation:

For SARS-CoV-2 Antigen rapid test

Clinical evaluation was performed to compare the results obtained by PocRoc® SARS-CoV-2 / Influenza A+B Antigen Combo Rapid Test Kit.

The results were summarized as below:

Method		2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
PocRoc® SARS-CoV-2/ Influenza A+B Antigen Combo Rapid Test Kit	Results	Positive	Negative	
	Positive	150	0	150
	Negative	14	96	110
Total Results		164	96	260

Clinical sensitivity = 150/164*100%=91.46% (86.18%-94.85%)
Clinical specificity = 96/96*100%=100.00% (96.15%-100.00%)
Accuracy: (150+96)/(150+14+0+96)*100%=94.62% (91.17%-96.77%)
*Confidence Interval

For Flu A+B Antigen rapid test

Flu A Sensitivity and Specificity

Method		Nucleic Acid Test Kit (RT-PCR)		Total Results
PocRoc® SARS-CoV-2/ Influenza A+B Antigen Combo Rapid Test Kit	Results	Positive	Negative	
	Positive	163	16	179
	Negative	12	990	1002
Total Results		175	1006	1181

Clinical sensitivity =163/ (163+12) × 100% = 93.14% (95%CI* 88.40%~96.03%)
Clinical specificity = 990/ (990+16) × 100% = 98.40% (95%CI* 97.43%~99.02%)
Accuracy: (163+990) / 1181 × 100% = 97.62%
*Confidence Interval

Flu B Sensitivity and Specificity

Method		Nucleic Acid Test Kit (RT-PCR)		Total Results
PocRoc® SARS-CoV-2/ Influenza A+B Antigen Combo Rapid Test Kit	Results	Positive	Negative	
	Positive	195	15	210
	Negative	12	1050	1062
Total Results		207	1065	1272

Clinical sensitivity =195/ (195+12) × 100% = 94.20% (95%CI* 90.14%~96.65%)
Clinical specificity = 1050/ (1050+15) × 100% = 98.59% (95%CI* 97.69%~99.14%)
Accuracy: (195+1050) /1272 × 100% = 97.87%
*Confidence Interval

2. For usability study

Usability study was performed to evaluate the sensitivity and specificity of laypersons self-test, 110 laypersons participated in the study and the results is follow:

	Self-test results	RT-PCR results	Concordance rate
Negative	4	0	90%
Positive	36	40	

	Self-test results	RT-PCR results	Concordance rate
Negative	70	70	100%
Positive	0	0	

The sensitivity of laypersons self-test is 90%(36/40)
The specificity of laypersons self-test is 100%(70/70)
The accuracy of laypersons self-test is 96.36% (106/110)

3. The limit of detection

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2, Influenza A and Influenza B at which at least 95% of all (true positive) replicates test positive. The LoD for The PocRoc® SARS-CoV-2 / Influenza A+B Antigen Combo Rapid Test Kit was established using limiting dilutions of heat-inactived SARS-CoV-2 Viral culture, heat-inactived Influenza A, heat-inactived Influenza B clinical sample. Based on this testing the LoD for nasal swab specimens was confirmed as:
SARS-CoV-2: 121 $TCID_{50}$ /mL
Influenza A/Victoria/2570/2019 (H1N1)pdm09: 54.68 $TCID_{50}$ /mL;
Influenza A/Darwin/9/2021 (H3N2): 47.5 $TCID_{50}$ /mL;
Influenza A Liao Ning/1183/2007(H1NI): 65 $TCID_{50}$ /mL.
Influenza A /(H3N2)Brisbane /10/2007:62 $TCID_{50}$ /mL ;
Influenza B/Austria/1359417/2021-like (B/Victoria lineage) virus: 122 $TCID_{50}$/mL;
Influenza B/Phuket/3073/2013-like (B/Yamagata lineage) virus: 105 $TCID_{50}$ /mL;
Influenza B (Guang Dong/1512/2010): 130 TCID50 /mL ;
Influenza B (Jiang Xi/32/2000) :140 $TCID_{50}$ /mL

4. High dose hook effect:

Strong positive samples of heat-inactivated viruses of the specific virus strains were diluted in a gradient, and gradient samples from low concentration to high concentration were tested, and were repeated in 5 times. The concentration when the color depth decreased with increased concentration was used as the minimum concentration of the sample when the hook effect appeared. A testing up to 10^6 $TCID_{50}$ /mL for SARS-CoV-2 virus, and 10^5 $TCID_{50}$ /mL for Influenza A and Influenza B demonstrated that a high dose affect will not occur.

5. Cross-Reactivity:

Cross-reactivity of the PocRoc® SARS-CoV-2 / Influenza A+B Antigen Combo Rapid Test Kit was evaluated by testing various viruses as below, the final results show that the kit does not cross react with any other viruses and microorganisms except SARS-CoV (2003).
SARS-CoV-2 : There is no interference in studies on the following microorganisms or pathogens.
Substances:

Coronavirus HKU1	SARS-coronavirus	Human Metapneumovirus (hMPV)	Legionella pneumophila
Coronavirus OC43	Respiratory syncytial	Parainfluenza virus 1	Mycoplasma pneumoniae
Coronavirus NL63	Rhinovirus A16	Parainfluenza virus 2	Streptococcus pneumoniae
Coronavirus 229E	Adenovirus C1	Parainfluenza virus 3	
MERS-coronavirus	Adenovirus 71	Parainfluenza virus 4	

Influenza A and B : There is no interference in studies on the following microorganisms or pathogens.
Substances:

Coronavirus OC43	Influenza B	Parainfluenza virus 2	Adenovirus 71
Coronavirus NL63	SARS-coronavirus	Parainfluenza virus 3	Rhinovirus A16
Coronavirus 229E	MERS-coronavirus	Parainfluenza virus 4	Streptococcus pneumoniae
Coronavirus HKU1	Respiratory syncytial virus	Human Metapneumovirus (hMPV)	Legionella pneumophila
Influenza A	Parainfluenza virus 1	Adenovirus C1	Mycoplasma pneumoniae

6. Interference Substances Studies:

The potential interference of endogenous substances with the antibodies used for the detection of SARS-CoV-2, Influenza virus type A and Influenza virus type B was examined by testing below substances in a negative clinical matrix, in the absence or presence of each virus, at 1 x LOD concentrations for SARS-CoV-2, Influenza virus type A and Influenza virus type B. The interference study was conducted using medically relevant concentrations of the potentially interfering substances listed below to assess the potential interference of the substances on the performance of the PocRoc®SARS-CoV-2/ Influenza A+B Antigen Combo Rapid Test Kit. No interference was observed with the listed substances when tested at the concentration presented in the table below.
Interference Substances:

Whole Blood	CVS Nasal Drops (Phenylephrine)	Sore Throat Phenol Spray
Mucin	Afrin (Oxymetazoline)	Tobramycin
HAMA Serum	CVS Nasal Spray (Cromolyn)	Mupirocin
Chloraseptic (Menthol/Benzocaine)	Zicam	Fluticasone Propionate
Naso GEL (NeilMed)	Homeopathic (Alkalol)	Tamiflu (Oseltamivir Phosphate)

Symbols:

	Consult Instructions for Use	LOT	Batch Code
	Do not reuse		Manufacturer
IVD	In-vitro diagnostic device		Do not use if package damaged
	Temperature limitation		Expiry date
EC REP	European Representative		Fragile. Handle with care
	Set up		Protect from moisture
	Caution, consult accompanying documents		Date of manufacture

ASSITANCE

Customer Support Helpline
Phone: 1800 952 915– Hours are: 9am-7pm (AEST), 7 days
Email: info@lumigenex.co
Website: www.lumigenex.co
The instrution for use and operation video link:
https://www.lumigenex.com/product/107.html

LOCAL HEALTH CONTACT

Australian Capital Territory Department of Health	☎ 02 6207 7244	*health.act.gov.au/*
New South Wales Department of Health	☎ 137 788	*health.nsw.gov.au/*
Northern Territory Department of Health	☎ 1800 020 080	*health.nt.gov.au/*
Queensland Department of Health	☎ 134 268	*health.qld.gov.au/*
South Australian Department of Health	☎ 1800 253 787	*sahealth.sa.gov.au/*
Tasmanian Department of Health	☎ 1800 671 738	*health.tas.gov.au/*
Victorian Department of Health	☎ 1800 675 398	*dhhs.vic.gov.au/*
Western Australian Department of Health	☎ 1800 595 206	*healthywa.wa.gov.au/*

TGA Contact Information for Reporting Poor Performance and Usability Issues:
Call 1800 809 361 or email iris@health.gov.au

Manufacturer
Lumigenex (Suzhou) Co., Ltd.
Address: Building C24, 218 Xing Hu Street, SIP, Suzhou, P.R. China 215123
Tel: +86 512-80988088
E-mail: lumi@lumigenex.com

Distributed and Sponsored by
Kept Pty Ltd
Level 1, 5 George St,
North Strathfield, NSW 2137
info@lumigenex.co
1800 952 915

Version: 1.0 Date of Issue: Aug 15, 2022