SARS-CoV-2 Antigen Test Kit (LFIA)

Self-testing

FOR IN VITRO DIAGNOSTIC USE ONLY.
FOR SELF-TESTING.
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST.

EN

Scan this **QR code** to access the instructional video

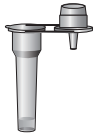
To access instructions, please visit website:
www.palebluemedical.com.au

REF	Specification
1031-14-01	1 pc/Box
1031-24-01	2 pcs/Box
1031-34-01	5 pcs/Box
1031-54-01	20 pcs/Box

Display of the anterior nasal swab in original size.

KIT CONTENTS

Test Cassette (individually in a foil pouch with desiccant)



Lysis Buffer and Dropper

Anterior Nasal Swab (CE 0197)

Instructions For Use (20pcs/Box,4*IFU)

Bio-Safety Bag

PREPARATION

1. • Keep the detection environment clean
   • Check the product on the validation period
   • Take out the contents and identify them correctly
   • Clear the nasal cavity
   • Wash and dry the hands

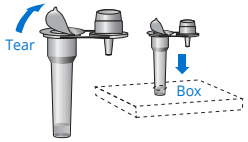
2. Carefully read IFU.

3. Check the expiry date on the foil pouch. Open it and take out the test cassette, place it on a flat surface.

This test kit should be used within 1 hour after opening the foil pouch.

ANTERIOR NASAL SECRETION TEST PROCEDURE

1. Tear the seal of the lysis buffer and place it on the test-tube rack.

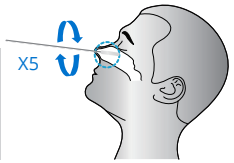


For specification of 1 pc/box, 2 pcs/box and 5 pcs/box, the package box can be used as test-tube rack by pushing the dotted holes on the box
For 20 pcs/box, please use the provided test-tube rack in the box

2. Insert the swab (stick with larger absorbent tip) into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present.

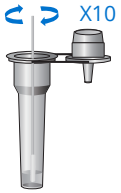
   Carefully rotate the swab in a circular path against the inside of the nostril at least 5 times.

   Using the same swab repeat the procedure in the other nostril.



Sample should be treated with lysis buffer provided in this kit as soon as possible after collection.

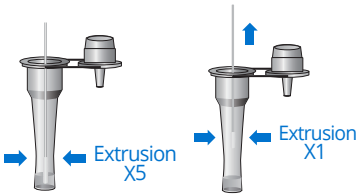
3. Insert the swab into the lysis buffer and rotate the swab against the inner tube wall 10 times.



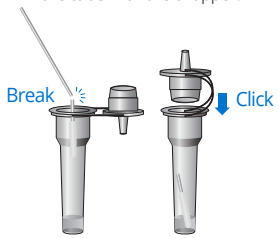
SARS-CoV-2 Antigen Test Kit (LFIA)

Self-testing

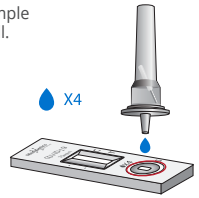
4. Squeeze the swab from the outer tube wall 5 times.
   Lift the swab above the buffer solution, squeeze the swab from the outer tube wall one time to leave the sample in the tube as much as possible.



5. Break the swab and cover the tube with the dropper.



6. Add 4 drops processed sample extract into the sample well.



Lay the test cassette on a clean flat surface

7. Read the results within 15-20 mins.

Result observed after 20 mins is invalid

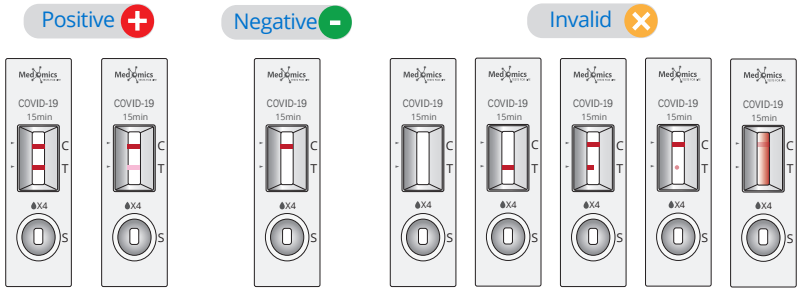
Remark: Additional required but not provided equipment: Timer
Dispose of all those used materials into Bio-safety bag and seal well and dispose into a household waste bin.

DISPLAY OF THE RESULT / EXPECTED VALUES

"C": Quality Control Line

"T": Detection Line

"S": Sample Well



• **Positive result:** If both the quality control C line and the detection T line appear, then the SARS-CoV-2 antigens have been detected and the result is positive.

Note: The color intensity of the T line is related to the concentration of SARS-CoV-2 antigens contained in the sample. The result should be determined by whether the T line is colored or not, regardless of the color intensity. Even a faint T line should be interpreted as positive.

What you need to do:
· There is currently a suspicion of a COVID-19 infection.
• If you test positive, you should not visit high-risk settings like hospitals and aged and disability care settings for at least 7 days or until symptoms have gone, unless seeking immediate medical care.
• To help protect those around you, We recommend to avoiding contact with people who are at higher risk of severe disease, wearing a mask outside the home, working from home where possible, avoiding going to school, public areas, or travel on public transport, in taxis or ride-share services, practicing good hygiene, and following your local health department's advice when leaving home.
• If you have any appointments you cannot miss (visit to a doctor, family violence service or police), let them know in advance that you have COVID-19.
• If you have a Covid-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.
• If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222.
• If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.
• Most people with COVID-19 experience only mild symptoms, or no symptoms at all (asymptomatic). You can manage these symptoms with over-the-counter medication
•Try to get plenty of rest, drink lots of water and eat well. You can still do moderate exercise if you feel well enough, within your home and/or garden if you have one. If you are eligible, your GP can prescribe COVID-19 oral treatments to reduce your chance of severe illness or hospitalisation. Seek urgent medical attention (call 000) if you develop severe symptoms, such as difficulty breathing, an oxygen level of less than 92% when tested with a pulse oximeter, blue lips or blue lips or face,pain or pressure in the chest, cold and clammy, or pale and mottled, skin, fainting or collapsing, being confused, difficultly waking up, little or no urine output, and coughing up blood.
• Severe COVID-19 in children is rare. Most children will have no, or only mild symptoms. If you are worried about your child's symptoms, contact your GP as soon as possible. A GP or nurse will treat your child based on their age, symptoms and past medical history. If they are showing severe symptoms, call 000 immediately.
• Most people who test positive for COVID-19 recover completely, but some people may develop long COVID. COVID-19 vaccinations, including boosters, reduce your risk of re-infection and gives the best protection against severe illness from COVID-19. After testing positive, you should wait 6 months before making a booster dose appointment.

• **Negative result:** If only the quality control C line appears and the detection T line is not visible, the sample contains no SARS-CoV-2 antigens or the SARS-CoV-2 antigens concentration is lower than the limit of detection and the result is negative.

What you need to do:
· If it is suspected, repeat the test after 1 - 3 days, as the coronavirus cannot be precisely detected in all phases of infection.

• **Invalid result:** If C line does not appear, T line is not complete, or a reddish-purple background affects the interpretation, the result is invalid.

What you need to do:
· Repeat the test.
· If the result is remains invalid, contact the sponsor hotline for further guidance.

Please DO NOT take any decision of medical relevance without consulting your doctor/general practitioner.

Keep out of reach of children

MedOmics TESTS FOR LIFE

Do Not Re-use | Do not use if package is damaged | REF Catalogue Number | IVD In Vitro Diagnostic Medical Device | LOT Batch code | Consult instructions for use | STERILE EO Sterilized using ethylene oxide

Caution | Use-by date | Contains sufficient for <n> tests | Temperature limit | Keep dry | Keep away from sunlight | Date of manufacture | Manufacturer

Customer Support For assistance regarding to the use of the test kit and interpretation of test results, call **1800 517 206**
The service is available between 9 am to 7 pm (AEST), or 9 am to 8 pm (AEDT), 7 days per week.

SARS-CoV-2 Antigen Test Kit (LFIA)

Self-testing

Introduction

Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera: α, β, γ and δ. The α and β genera are only pathogenic to mammals, while γ and δ genera mainly cause bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting fecal-oral transmission.
7 kinds of human coronaviruses (HCoV) that cause human respiratory diseases have been identified so far, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 is one of the most contagious viral pathogens that cause human respiratory tract infections (RTI). Currently, the patients infected by novel coronavirus are the main source of infection.Asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The clinical manifestations include fever, fatigue, cough and other symptoms, accompanied by dyspnea, which can rapidly develop into life-threatening severe pneumonia, respiratory failure, acute respiratory vesicle syndrome, septic shock, multiple organ failure, and severe metabolic acid-base imbalance.

Intended Use

SARS-CoV-2 Antigen Test Kit (LFIA) is a colloidal gold immunochromatography for the rapid qualitative detection of SARS-CoV-2 nucleocapsid antigens present in human anterior nasal samples in vitro. It is intended to aid in the diagnosis of an active SARS-CoV-2 infection for people having symptom within 7 days. The test kit is single use only and intended for self-testing by people aged 18 or older. People aged under 18 should be supported by an adult.

Test Principle

SARS-CoV-2 Antigen Test Kit (LFIA) detects the SARS-CoV-2 nucleocapsid antigens with colloidal gold immunochromatography using a double antibody sandwich assay. The test cassette contains (1) colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein antibody, (2) one detection T line and one quality control C line fixed on a nitrocellulose membrane. T line is fixed with another anti-SARS-CoV-2 Nucleocapsid Protein antibody for detecting SARS-CoV-2. The quality control antibody is fixed on the C line. When the appropriate amount of test sample treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip via capillary action. If the sample contains SARS-CoV-2 nucleocapsid antigens and concentration is higher than the limit of detection, the antigens will bind to the colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein antibody.
The immune complex will be captured by another anti-SARS-CoV-2 Nucleocapsid Protein antibody immobilized on the membrane, forming a red T line and indicating a positive result for SARS-CoV-2. If the sample contains no SARS-CoV-2 nucleocapsid antigens or concentration is lower than the limit of detection, a negative result is displayed.

Internal Quality Control

The test cassette contains a quality control C line. Regardless of what nucleocapsid antigens are present the C line should appear to indicate that the sample has been transported properly through the membrane. If the C line does not appear, it indicates that the test result is invalid and the sample is required to be retested.

Kit Contents

Specification	Test Cassette	Anterior Nasal Swab	Lysis Buffer and Dropper	Bio-Safety Bag	Instructions For Use	Test-tube Rack
1 pc/Box	1	1	1	1	1	Please use the package box
2 pcs/Box	2	2	2	2	1	Please use the package box
5 pcs/Box	5	5	5	5	1	Please use the package box
20 pcs/Box	20	20	20	20	4	1

• Test cassette contains test strip, plastic cassette, desiccant. The test strip contains colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein antibody, nitrocellulose membrane (C line fixed with goat-anti-mouse IgG polyclonal antibody, and T line fixed with another anti-SARS-CoV-2 Nucleocapsid Protein antibody)

WARNINGS AND PRECAUTIONS

• This test kit is used for self-testing.
• This test kit is used for in vitro diagnosis only.
• This kit is intended for independent use over the age of 18. Under 18, use with adult help or supervision.
• Bring the kit contents to room temperature before testing.
• Negative results do not rule out SARS-CoV-2 infection,particularly in those who have been in contact with patients.
• A negative result does not rule out infection with another type of respiratory virus.
• If testing is not performed within the first 7days symptom onset, false negative results may occur.Test within the first 7 days of symptom onset when viral shedding/viral load is at its highest.
• Do not re-use.
• Do not drink buffer or use in the eye.
• Do not use the test kit if the pouch is damaged, the seal is broken or the test cassette is wet or polluted.
• Do not use the test kit contents expired.
• When collecting an anterior nasal swab sample, use only the Anterior Nasal Swab provided in the Kit.
• This test kit is used in the later phase of infection and in asymptomatic individuals, and these tests are less reliable.

Test Method Limitations

• The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples or repeated frozen-thawed samples can affect the test result. Test results can also be affected by temperature and humidity.
• Negative results may be caused by low concentration of SARS-CoV-2 antigens in the sample and therefore cannot completely rule out the possibility of infection.
• Recommend repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
• Some medication (e.g. high concentration of over-the-counter (OTC) or prescription medication such as nasal spray) in the collected samples may interfere with the test result. Please perform the test again if the result is in doubt.
• This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
• For the detection of novel coronavirus and possible subtypes (mutant strains), the changes of epitopes caused by mutation sites of Nucleocapsid Protein may reduce the analytical sensitivity of the reagent and lead to false negative results.

SARS-CoV-2 Antigen Test Kit (LFIA)

Self-testing

Disposal Instructions

Dispose of all those used materials into Bio-safety bag and seal well and dispose into a household waste bin.

Storage Instructions

• The test kit should be stored away from direct sunlight at 2˚C to 30˚C with a shelf-life of 24 months. Do not freeze.
• This test kit should be used within 1 hour after opening the foil pouch.

Product Performance

• Limit of Detection - LoD
The limit of detection for SARS-CoV-2 Antigen Test Kit (LFIA) was determined to be 10 TCID50/mL using inactivated SARS-CoV-2 Virus. TCID50 = Tissue Culture infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculate.

• Cross Reactivity
The following commensal and pathogenic microorganisms that may be present in the nasal cavity were tested on SARS-CoV-2 Antigen Test Kit (LFIA) for cross reactivity and potential interference. Cross-reactivity or interference caused by these microorganisms is unlikely to occur, including Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, MERS-coronavirus, SARS-coronavirus, Influenza A H1N1, Influenza A H3N2, Influenza A H5N1, Influenza A H7N9, Influenza B Victoria, Influenza B Yamagata, Parainfluenza virus Type 1, Respiratory syncytial virus, Enterovirus CA16e, Adenovirus, Mycoplasma pneumoniae, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella pertussis, Legionella pnuemophila, Streptococcus pneumoniae, Haemophilus influenzae, Mycobacterium tuberculosis and Sandida albicans.

• Interfering Substances Effect
The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were tested on SARS-CoV-2 Antigen Test Kit (LFIA). There is no interference were found to affect the test performance: endogenous substance (mucin, whole blood, icteric (bilirubin), rheumatoid factor, triglycerides, hemoglobin, anti-nuclear antibody, pregnant, total IgG, total IgM, total IgA and human anti-mouse antibody(HAMA)), exogenous substance (mupirocin, tamiflu (oseltamivir phosphate), fluticasone propionate, fluconazole, zincum gluconium (i.e., zicam), alkalol, phenol, phenylephrine hydrochloride, oxymetazolin hydrochloride, cromolyn, oxymetazoline, galphimia glauca, sabadilla, albuterol, acarbose, oseltamivir, chlorpheniramine, diphenhydramine, glimepiride (sulfonylureas), chlorothiazide, acetylsalicylic acid, moxicillin, ibuprofen, beclomethasone, indapamide, flunisolide, guaiacol glyceryl ether, biotin, zanamivir, tobramycin, sulfur, ribavirin, ephedrine, benzocaine, menthol, budesonide, tiamcinolone, dexamethasone, sodium chloride with preservatives, lopinavir, ritonavir, chloroquine phosphate and Ivermectin).

• Verification of Variants
The SARS-CoV-2 Antigen Test Kit (LFIA) has been tested and proven to detect Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1),Kappa(B.1.617.1), Delta (B.1.617.2),Iota (B.1.526),Epsilon (B.1.427/B.1.429) and Omicron(B.1.1.529) variants.

• Clinical Performance
The performance of Medomics SARS-CoV-2 Antigen Test Kit(LFIA) was established with 216 anterior nasal swabs collected from patients with COVID-19 symptoms within 7 days after onset of symptoms . Clinical samples were evaluated to be positive or negative using FDA EUA RT-PCR reference methods. Two copies of samples were collected from one patient. One copy was tested directly using Medomics SARS-CoV-2 antigen Test Kit(LFIA) and the other was tested by RT-PCR.

	RT-PCR		
Medomics COVID-19 Ag Test	Positive	Negative	Total
Positive	107	1	108
Negative	5	103	108
Total	112	104	216

*95% Confidence Interval

Sensitivity: 95.54%(89.89%~98.53%)
Specificity: 99.04%(94.76%~ 99.98%)
PPV: 99.07%(94.95%~99.98%)
NPV: 95.37%(89.53%~98.48%)
Accuracy: 97.22%(94.05%~98.97%)

• Usability Study
Usability study was conducted with 90 lay persons who performed the test and interpreted the result. The results were compared to an RT-PCR with a sensitivity of 93.33% (28/30) and specificity of 100% (60/60).
97.78% (88/90) of lay persons were able to use the SARS-CoV-2 Antigen Test Kit to complete the test procedure and obtain consistent test results with professionals.
99% (99/100) of lay persons were able to understand the instruction for use of SARS-CoV-2 Antigen Test Kit and interpret the interpret contrived results correctly.

[References]
1 | LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020, 35(3): 411-416.
2 | K Tugba, W Ralph, L Hakho. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges. IScience, 2020, 23 (8): Doi: 10.1016/j.isci.2020.101406

Report Performance or Usability Issues:
Contact TGA to report poor performance or usability issues in the self-test environment.
Report an issue via the Users Medical Device Incident Report, email: iris@health.gov.au

Jiangsu Medomics Medical Technology Co.,Ltd.
F3,BuildingC,No.3-1 Xinjinhu Road, Jiangbei New Area, Nanjing,Jiangsu, China
Tel: Tel: +86-25-58601060 Fax: +86-25-58601060
www.medomics-dx.com
E-mail: info@medomics-dx.com

Sponsor
Pale Blue Medical Trading Pty Ltd
5/44 Ellingworth Parade Box Hill, Vic 3128
https://www.palebluemedical.com.au/
info@palebluemedical.com.au

Customer Support For assistance regarding to the use of the test kit and interpretation of test results, call **1800 517 206**
The service is available between 9 am to 7 pm (AEST), or 9 am to 8 pm (AEDT), 7 days per week.

AU V7.3A
Effective date: 2024-09-09