Influenza A/B/Corona Virus (COVID-19)/RSV Antigen Rapid Test (Colloidal Gold) for self-testing use Instructions for use

INTENDED USE

This product is intended to be used for in-vitro qualitative detection of nucleocapsid antigen for Influenza A/B/Corona Virus (COVID-19)/RSV in human nasal swab samples. This test kit provides only a preliminary result as an aid diagnosis of Influenza A/B/Corona Virus (COVID-19)/RSV.
The test is intended for home use with nasal swab specimens from individuals who have experienced COVID-19-like symptoms within the last 7 days or Influenza/RSV-like symptoms within the last 4 days.

TEST PRINCIPLES

The product is based on the principle of sandwich and colloidal gold immunochromatography, the nitrocellulose membrane Test Zone is pre-coated with mouse anti-Influenza A/B/Corona Virus (COVID-19)/RSV monoclonal antibody, the Control Zone is pre-coated with goat anti-mouse polyclonal antibody, the gold conjugation pad is pre-coated with colloidal gold labelled mouse anti-Influenza A/B/Corona Virus (COVID-19)/RSV monoclonal antibody.When testing positive samples, immune complexes agglutination, test line and control line appears in color. When testing negative samples, there's no Influenza A/B/COVID-19/RSV Antigen in the samples, no immune complexes will be formed and color only appears in the Control line.

MATERIALS PROVIDED

Components	Packing Specifications		
	1 test/kit	5 tests/kit	30 tests/kit
Test Card	1	5	30
Extraction tube with buffer	0.5mL ×1	0.5mL ×5	0.5mL ×30
Swab	1	5	30
Tube rack	1 (packaging)	1	1
Instructions for use	1	1	1
Biohazard specimen bag	1	5	30

STORAGE CONDITIONS AND SHELF LIFE

- If stored as specified, the product shelf life is 24 months.
- The product should be stored in dry condition under 2~30°C and kept away from light.
- Production date and validity period are shown on box label.

LIMITATIONS

1.The kit is a qualitative test that cannot quantify the concentration of Influenza A/B or Corona Virus (COVID-19)/RSV antigen.
2.A false negative result may be displayed, particularly if testing not performed within the first 4 days of symptoms onset for Influenza/RSV within the first 7 days of symptoms onset for COVID-19.
3.The test is less reliable in the later phase of infection and in asymptomatic individuals.
4.Negative results may not mean that a person is not infectious. If you are experiencing any Flu, RSV or COVID-19-like symptoms you should consult a medical practitioner for follow-up clinical care.
5.This product can only be used to detect Influenza A/B/COVID-19/RSV. A negative result does not rule our the other types of viral or bacterial infections.
6. A positive result cannot necessarily determine whether a person is infectious. If unwell seek medical assistance. If you are positive for Influenza A/B, RSV, consult a medical practitioner for follow-up clinical care.
7.Repeat testing is recommended (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.
8.Even if your test result is negative, continue to observe all applicable hygiene and safety measures.
9.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.
10.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.
11.If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.

PRECAUTIONS

1.The kit is intended for in-vitro diagnostic use only. Please read the instructions for use carefully before doing the test.
2.To obtain accurate results, operation should be done strictly according to the instructions.
3.People under 18 years old and people with any disability should be supervised or assisted by adult. This test is not intended for children under 2 years old.
4.Observe the storage conditions. Do not use this kit after expiry date printed on the label. Use only undamaged test kit. All components in this test kit should remain sealed until ready for use.
5.Under the condition of 2 ~30°C, where the humidity is below 60%, use within 1 hour after opening. Where the humidity is above 60%, it should be used immediately.
6.All kit components are single use only. Do not re-use.
7.Please use the swab and sample extraction buffer included in this kit. Do not replace the sample extraction in this kit with components from other kits.
8.Do not drink the extraction liquid. If buffer solution comes into contact with eyes and/or skin, flush abundantly with water. If you feel unwell, please consult a doctor immediately.
9.Wash hands thoroughly before and after the operation.
10.Do not touch the test strip in the test card.
11.Proceed with the test immediately after the swab sampling. Too many or insufficient droplets of the sample diluent may lead to incorrect or invalid results.
12.Read test result at 13-20minutes, DO NOT read the result after 20minutes.
13.Waste samples and used test components should be treated as potential infectious agents. Place in the biohazard plastic bag provided, discard in a closed bin and wash your hands.14.The test may cause sneezing or bruising. All these effects are temporary.

DIAGNOSTIC PERFORMANCE

1.Limit of Detection (LoD):

Virus	LOD
SARS-CoV-2 virus(BetaCoV/Wuhan/IPBCAMS-WH-01/2019)	$2x10^2$TCID$_{50}$/mL
SARS-CoV-2 virus culture (Omicron Variants)	$4x10^3$TCID$_{50}$/mL
Influenza A H1N1 Sydney/5/2021	$2x10^3$TCID$_{50}$/mL
Influenza A H3N2 Darwin/9/2021	$5x10^2$TCID$_{50}$/mL
Influenza B/Yamagata Phuket/3073/2013	$3x10^3$TCID$_{50}$/mL
Influenza B/Victoria/Australia/1359417/2021	$1.5x10^3$TCID$_{50}$/mL
RSV(A-2)	$8x10^2$TCID$_{50}$/mL
RSV(B-1 wild type)	$1.5x10^3$TCID$_{50}$/mL

2.Clinical performance:
The kit was used to examine nasal sample from individuals either infected or not with COVID-19/Influenza A/Influenza B/RSV, and results compared with Nucleic Acid Diagnostic Kit (Multiplex PCR-Fluorescence Probing). The clinical results are as follows:

Corona Virus(COVID-19)	PCR Comparator		Sub total
	Positive	Negative	
Positive	250	4	254
Negative	10	271	281
Sub total	260	275	535
Positive Percent Agreement (PPA)=250/260(96.15%) (93.04%～98.14%) Negative Percent Agreement (NPA)=271/275(98.55%) (96.32%～99.60%) Clinical Study Results of 7 days post symptoms onset for COVID-19			

Influenza A	PCR Comparator		Sub total
	Positive	Negative	
Positive	102	4	106
Negative	3	271	274
Sub total	105	275	380
Positive Percent Agreement (PPA)=102/105(97.14%) (91.88%～99.41%) Negative Percent Agreement (NPA)=271/275(98.55%) (96.32%～99.60%) Clinical Study Results of 4 days post symptoms onset for Influenza A			

Influenza B	PCR Comparator		Sub total
	Positive	Negative	
Positive	101	4	105
Negative	4	271	275
Sub total	105	275	380
Positive Percent Agreement (PPA)=101/105(96.19%) (90.53%～98.95%) Negative Percent Agreement (NPA)=271/275(98.55%) (96.32%～99.60%) Clinical Study Results of 4 days post symptoms onset for Influenza B			

RSV	PCR Comparator		Subtotal
	Positive	Negative	
Positive	102	4	106
Negative	3	271	274
Subtotal	105	275	380
Positive Percent Agreement (PPA)=102/105(97.14%) (99.88%~99.41) Negative Percent Agreement(NPA)=271/275(98.55%) (96.32%~99.60%) Clinical Study Results of 4 days post symptoms onset for RSV			

3.Inclusivity (Variants)
Influenza A/B/Corona Virus (COVID-19)/RSV Antigen Rapid Test (Colloidal Gold) can detect Alpha, Beta, Gamma, Delta and Omicron COVID-19 mutants based on the studies conducted. The following Influenza strains could also be detected out by the device:

Influenza A strains	Influenza B strains
A/Victoria(Australia)/2570/2019	B/Victoria/27/2020(Yamagata)
A/Darwin(Australia)/6/2021	B/Phuket/3073/2013 (Victoria)
A/South Australia/34/2019	B/Colorado/06/2017 (Victoria)
A/Brisbane(Australia)/02/2018	B/Brisbane/5/2020(Victoria)
A/Sydney/1297/2022	B/Austria/1359417/2021 (Victoria)
A/South Australia/333/2022	B/Sydney/701/2019(Yamagata)
A/Tasmania/309/2022	B/Brisbane/37/2018(Yamagata)
A/Perth/179/2022	B/Victoria/28/2020(Victoria)
A/Victoria/4144/2022	B/Darwin/11/2021(Victoria)
A/Darwin/24/2021	
A/Tasmania/503/2020	
A/Darwin/726/2019	
A/Darwin/6/2018	
A/Victoria/2455/2019	

4.The Cross-Reactivity of Influenza A/B/Corona Virus (COVID-19) /RSVAntigen Rapid Test was evaluated by testing a panel of pathogens that could potentially cross-react with the analyte detection reagents in the test device:

Potential Cross-Reactant	SARS-CoV-2 (Yes/No)	Influenza A (Yes/No)	Influenza B (Yes/No)	RSV (Yes/No)
Human coronavirus 229E	No	No	No	No
Human coronavirus OC43	No	No	No	No
Human coronavirus NL63	No	No	No	No
Human coronavirus HKU1	No	No	No	No
Adenovirus 71	No	No	No	No
Human Metapneumovirus	No	No	No	No
Parainfluenza virus 1	No	No	No	No
Parainfluenza virus 2	No	No	No	No
Parainfluenza virus 3	No	No	No	No
Parainfluenza virus 4	No	No	No	No
Influenza A	No	N/A	No	No
Influenza B	No	No	N/A	No
Enterovirus	No	No	No	No
Respiratory syncytial virus A	No	No	No	N/A
Respiratory syncytial virus B	No	No	No	N/A
Rhinovirus	No	No	No	No
MERS-CoV	No	No	No	No
Haemophilus influenza	No	No	No	No
Streptococcus pneumoniae	No	No	No	No
Streptococcus pyogenes	No	No	No	No
SARS-CoV-1	Yes	No	No	No
SARS-CoV-2	N/A	No	No	No
Candida albicans	No	No	No	No
Bordetella pertussis	No	No	No	No
Mycoplasma pneumoniae	No	No	No	No
Chlamydia pneumoniae	No	No	No	No
Staphylococcus epidermidis	No	No	No	No
Staphylococcus aureus	No	No	No	No
Legionella pneumophila	No	No	No	No
Mycobacterium tuberculosis	No	No	No	No
Pneumocystis jirovecii (PJP)	No	No	No	No
Pooled human nasal wash–representative of normal respiratory microbialflora	No	No	No	No

5.Interference Experiment
The following substances were tested at the concentration shown, and no interference was found.

Whole Blood	10% v/V
Pus	5% v/V
Naso GEL	10% v/V
CVS Nasal Drops (Phenylephrine)	30% v/V
Afrin (Oxymetazoline)	30% v/V
CVS Nasal Spray (Cromolyn)	30% v/V
Zicam (Nasal Congestion Relief Gel)	10% v/V
Fluticasone Propionate	10% v/V
Mucin	10 g/L
Chloraseptic (Menthol/Benzocaine)	3.0 mg/mL
Tobramycin	8 μg/mL
Mupirocin	20 mg/mL
Tamiflu (Oseltamivir Phosphate)	10 mg/mL
Dexametazoline	2.5 mg/mL
Sulfur	50 mg/mL
Zanamivir	2.5 mg/mL

6.Usability Research
To evaluate the usability of this product, 180 enrolled laypersons were provided a kit and instructions for use to test themselves. 98.33% (177/180) of participants could perform the test correctly without professional assistance.The interpretation results of non-professional participants were compared with those of professionals, and the results were 96.11% (173/180) consistent.
The relative sensitivity consistency rate was 93.33% (28/30) for detection of COVID-19 virus. 96.67% (29/30) for the detection of Influenza A virus,93.33% (28/30) for the detection of Influenza B virus, 90.00%(27/30)for the detection of RSV virus. The overall consistency rate was 95.83%(115/120). The user's age, experience, different education background, understanding of instructions, result reading and other factors may influence the operation process and result interpretation.

INDEX OF SYMBOL

	Do not re-use	IVD	For in vitro diagnostic use only	REF	Catalogue number
2-30°C	Store between 2-30 C		Consult instructions for use		Caution
	Do not use if package is damaged	LOT	Lot number		Keep dry
		Σ	Contains sufficient for <n> tests		Use by date
	Keep away from sunlight		Manufacturer		Manufacturing date

SUPPORT SERVICES

You can contact the Therapeutic Goods Administration (TGA) to report performance or usability issues via the online Users Medical Device Incident Report, emailing **iris@health.gov.au** or calling **1800 809 361**.
Information regarding available support services can also be obtained by contacting the local sponsor: calling **1300 999 668** at 9am-7pm，or emailing support@epicmedical.com.au

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