Influenza A/B/Corona Virus (COVID-19) 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) 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).
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-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) monoclonal antibody, the Control Zone is pre-coated with goat anti-mouse polyclonal antibody, the gold conjugation pad is pre-coated with colloidal gold labeled mouse anti-Influenza A/B/Corona Virus (COVID-19) monoclonal antibody.When testing positive samples, immune complexes agglutination, test line and control line appears color. When testing negative samples, there's no Influenza A/B/COVID-19 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℃ and kept away from light.
- Production date and validity period are shown on the label.

LIMITATIONS

1.The kit is a qualitative test that cannot quantify the concentration of Influenza A/B or SARS-CoV-2 antigen.
2.A false negative result might be received, particularly if testing not performed within the first 4 days of symptoms on set for Influenza or within the first 7 days of symptoms on set 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 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.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, 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 test components should be treated as potential infectious agents. Place in the plastic bag provided, discard in a closed bin and wash your hands.

DIAGNOSTIC PERFORMANCE

1.Limit of Detection (LoD):
The LOD of SARS-CoV-2 virus (BetaCoV/Wuhan/IPBCAMS-WH-01/2019) is 2×10^2 $TCID_{50}$/mL; The LOD of SARS-CoV-2 virus culture (Omicron Variants) is 4×10^2 $TCID_{50}$/mL; The LOD of Influenza A H1N1 Sydney/5/2021 virus is 2×10^3 $TCID_{50}$/mL; The LOD of Influenza A H3N2 Darwin/9/2021 virus is 5×10^2 $TCID_{50}$/mL; The LOD of Influenza B/Yamagata Phuket/3073/2013 virus is 3×10^3 $TCID_{50}$/mL; The LOD of Influenza B/Victoria/Australia /1359417/2021 virus is 1.5×10^3 $TCID_{50}$/mL.

2.Clinical performance:
The kit was examined with nasal sample from individuals either infected with or uninfected COVID-19/ Influenza A/ Influenza B, 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			

3.Inclusivity (Variants)
Influenza A/B/Corona Virus (COVID-19) 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) Antigen 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)
Human coronavirus 229E	No	No	No
Human coronavirus OC43	No	No	No
Human coronavirus NL63	No	No	No
Human coronavirus HKU1	No	No	No
Adenovirus	No	No	No
Human Metapneumovirus	No	No	No
Parainfluenza virus 1	No	No	No
Parainfluenza virus 2	No	No	No
Parainfluenza virus 3	No	No	No
Parainfluenza virus 4	No	No	No
Influenza A	No	N/A	No
Influenza B	No	No	N/A
Enterovirus	No	No	No
Respiratory syncytial virus A	No	No	No
Respiratory syncytial virus B	No	No	No
Rhinovirus	No	No	No
MERS-CoV	No	No	No
Haemophilus influenza	No	No	No
Streptococcus pneumoniae	No	No	No
Streptococcus pyogenes	No	No	No
SARS-CoV-1	Yes	No	No
SARS-CoV-2	N/A	No	No
Candida albicans	No	No	No
Bordetella pertussis	No	No	No
Mycoplasma pneumoniae	No	No	No
Chlamydia pneumoniae	No	No	No
Staphylococcus epidermidis	No	No	No
Legionella pneumophila	No	No	No
Mycobacterium tuberculosis	No	No	No
Pneumocystis jirovecii (PJP)	No	No	No
Pooled human nasal wash–representative of normal respiratory microbialflora	No	No	No

5.Interference experiment
The following substances were tested at the concentration shown, and no interference was found with Whole Blood, Mupirocin, Mucin, Fluticasone Propionate, Pus, Tamiflu (Oseltamivir Phosphate), Chloraseptic (Menthol/Benzocaine), Dexametazoline, Naso GEL (NeilMed), Sulfur, CVS Nasal Drops (Phenylephrine), Zanamivir, Afrin (Oxymetazoline, Zicam (Nasal Congestion Relief Gel), CVS Nasal Spray (Cromolyn), Tobramycin.

6.Usability Research
To evaluate the usability of this product, 150 enrolled laypersons were provided a kit and instructions for use to test themselves. 98% (147/150) of participants can perform the test correctly without professional assistance.The interpretation results of non-professional participants were compared with those of professionals, and the results were 100% (150/150) consistent.
The relative sensitivity consistency rate was 93.33% (28/30) for detection of COVID-19 virus, 96.7% (29/30) for the detection of Influenza A virus, 93.33% (28/30) for the detection of Influenza B virus. The relative specificity consistency rate was 96.67% (58/60) for detection of COVID-19 virus, 98.33% (59/60) for the detection of Influenza A virus, 96.67% (58/60) for the detection of Influenza B virus.

INDEX OF SYMBOL

	Do not re-use	IVD	For in vitro diagnostic use only	REF	Catalogue number
2℃ 30℃	Store between 2-30℃		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@epicmh.com.au.

Hoyotek Biomedical Co., Ltd.
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Instructions for Use
Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
For self-testing use

COMPONENTS

The Influenza A/B/Corona Virus (COVID-19) Antigen Rapid Test contains the following items to perform the test:

1. Test card
2. Instructions for use
3. Extraction tube with buffer
4. Sampling swab
5. Tube rack
6. Biohazard specimen bag

1.PREPARATIONS BEFORE TEST

❶ Read the Instructions for Use carefully.

❷ Clean and dry a flat surface in preparation for the test. Blow your nose with tissue and throw it away in a bin.

❸Wash or sanitize your hands, and dry completely to avoid contaminating the test kit.

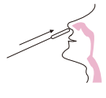
❹ Check the components to make sure nothing is damaged.

❺ Please scan the QR code to watch the operation video.

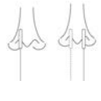
2.COLLECT AND PREPARE SAMPLE

❶Remove the foil of the extraction tube and put it on the tube rack. (The tube rack can be found on the packaging for single-test)

❷Take out the swab from its package and **DO NOT** touch the fabric soft tip of the swab.



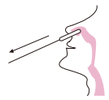
❸ Carefully insert the entire soft end of the swab into one nostril, about up to 2.5 cm (1 inch) from the edge of the nostril. **DO NOT** insert the swab any deeper if you feel strong resistance or pain.



❹ Slowly rotate the swab 5 times inside the nostril tissue. **Repeat this process with the same swa**b for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

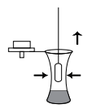
REF
HYTCG02S01 (1Test/Kit)
HYTCG02S05 (5Tests/Kit)
HYTCG02S30 (30Tests/Kit)

Please scan the QR code to access the operation video.
For assistance regarding the use of the product or for reporting any issues associated with the performance of the test, call 1300 999 668.
This service is available between 9 am and 7 pm (AEST), Monday-Sunday.



❺ Slowly remove the swab from the nostril while rotating. Do not touch the soft tip, to avoid contamination.

❻ Insert the swab in the extraction tube and **swirl** the swab at least 10 times while pressing the swab against the bottom and side of the extraction tube.



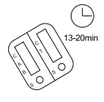
❼ **Gently pinch/squeeze** the tube with your fingers, stir the swab head against the inside of the extraction tube. Pinch the extraction tube against swab, to release as much liquid as possible.

❽ **Insert** a dropper tip into the extraction tube tightly.

3.TEST THE SAMPLE

❶ Open the pouch and remove the test card. Lay it on the clean, flat surface.

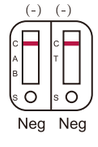
❷Add **four drops** of the solution into each well. Keep the tube vertical.



❸ **Immediately** start timing and wait. Read test result at 13-20 minutes, DO NOT read the result after 20 minutes.

4.READ THE RESULTS

NEGATIVE RESULTS

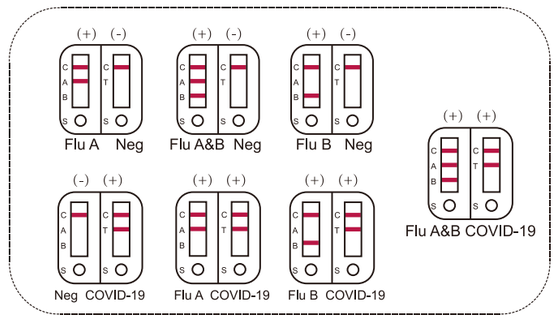


For Flu A/B on the left and for COVID-19 on the right:
The presence of only control line (C) indicates a negative result.

1. Read the instructions for use carefully before test and follow the steps in order.
2. The test results will be displayed in 13-20 minutes. A clock/timer required, to measure the time.
3. Store the test kit at room temperature and dry place (2~30℃), keep the kit away from direct sunlight.
4. Keep the test kit away from children.
5. Children and young people under the age of 18 should be supervised or assisted by an adult. This test is not intended for children under 2 years old.

You are likely not infectious with Flu A/B or COVID -19 at the time the test was taken, repeat the test after 24-48 hours if you have symptoms. A negative result may not mean that the person is not infectious. If symptoms persist or if unwell, please consult a medical practitioner for follow-up clinical care.

POSITIVE RESULTS



For Flu A/B Antigen Test
Refer to the the column on the left

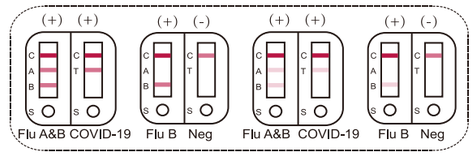
❶ Flu A Positive:
The presence of reddish purple control line (C) and A test line indicates a positive result for Influenza A viral antigen.
❷ Flu B Positive:
The presence of reddish purple control line (C) and B test line indicates a positive result for Influenza B viral antigen.
❸ Flu A+B Positive:
The presence of reddish purple control line (C), A test line and B test line indicates a positive result for Influenza A and Influenza B viral antigen.

A positive result means that you are very likely infected with Influenza A or/and B. If you are positive for Influenza A/B, consult a medical practitioner for follow-up clinical care.

For COVID-19 Antigen Test
Refer to the column on the right

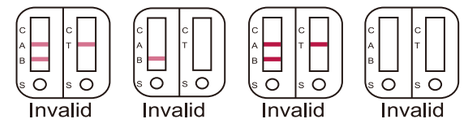
The presence of reddish purple control line (C) and T test line indicates a positive result for COVID-19 viral antigen.

If tested positive for COVID-19, staying at home protects your community. You should not visit high-risks settings such aged and disability care. If feeling unwell or needing COVID-19 advice, talk to your health care provider or talk to a nurse by calling 1800 022 222. If developing symptoms such severe shortness of breath or chest pain, call triple zero (000) immediately. Find detailed information: https://www.health.gov.au/topics/covid-19/testing-positive



The test line can be very faint. Any pink or purple line visible is a Positive Result.

INVALID RESULTS



For Flu A/B on the left and for COVID-19 on the right:
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

An invalid result can be caused by a possibly incorrect test operation. Please repeat the test with a new test kit according to the instructions for use. Do not use any components from the first test kit. Testing to be repeated using a new test kit and a freshly collected sample. If the second test result is invalid too but you are unwell, contact your healthcare provider for advice. Contact the Sponsor if more than one invalid result is obtained.

5.WASTE DISPOSAL

❶ After the test completion, place the contaminated materials, such as test card, extraction tube and swab into the Biohazard specimen bag. Dispose of the sealed bag in general household waste bins (not recycling) or according to your local regulations. DO NOT REUSE.

❷ Wash or sanitize hands again after disposal.

Epic Medical & Health Pty Ltd
Hotline 1300 999 668
Email: support@epicmh.com.au
Operating hours Monday-Sunday
(9am - 7pm, AEST)