This product is for in vitro diagnostic use only and should not be used for any other purposes.
Please read these instructions carefully before use.

SARS-CoV-2 & INFLUENZA A+B & RSV & ADV ANTIGEN COMBO TEST KIT (COLLOIDAL GOLD)

REF CFRA1ST-1

CE 3018

HKMD No. 252753

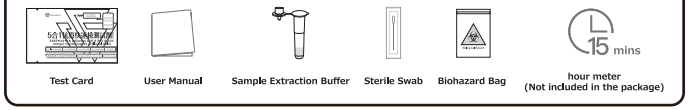
USER MANUAL

Latest update:20250908

INTENDED USE

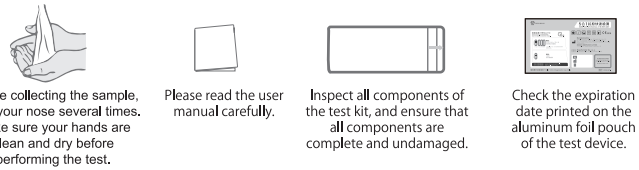
This product is used for the qualitative detection of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus antigen in human nasal swab specimens. It is a non-automated rapid test method for infection. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals. Individuals who test positive should seek follow up care with their physician or healthcare provider as additional testing may be necessary. Users under the age of 15 should complete the test with supervision of an adult. Both symptomatic and asymptomatic infections can be tested.

PACKAGE CONTENTS



Test Card | User Manual | Sample Extraction Buffer | Sterile Swab | Biohazard Bag | hour meter (Not included in the package)

PREPARATION BEFORE INSPECTION



Before collecting the sample, blow your nose several times. Make sure your hands are clean and dry before performing the test.

Please read the user manual carefully.

Inspect all components of the test kit, and ensure that all components are complete and undamaged.

Check the expiration date printed on the aluminum foil pouch of the test device.

INTRODUCTION

Acute respiratory infection is a common and frequently occurring disease worldwide. Respiratory virus is an important pathogen of acute respiratory infection. Its clinical manifestations are mainly rhinitis, pharyngitis, laryngitis, Tonsillitis and other symptoms. Severe cases can cause tracheitis, bronchitis and pneumonia. It is the main cause of morbidity and mortality in winter and spring for young children, the elderly and the infirm, and those with low immune function. It has been proven that 80% of acute upper respiratory diseases and most lower respiratory diseases are caused by pathogens outside of bacteria, with respiratory viruses being the most common.

PRINCIPLE

This kit uses the double antibody-sandwich method to detect antigens. When an appropriate amount of specimen is added to the specimen well(s) of the test device, the specimen will move forward along the test device. If the specimen contains an antigen, the antigen binds to the antibody labeled with colloidal gold on the binding pad, and the immune complex forms a sandwich complex with another coated antibody which was coated on the test line, a visible colored line will show up, which indicates that the antigen is positive. The test device also contains a quality control line, regardless of whether there is a test line, the red quality control line should appear. If the quality control line does not appear, it indicates that the test result is invalid and need to do the test again.

QUALITY CONTROL

Program control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient volume of the specimen.

WARNINGS AND PRECAUTIONS

- This test kit is for in vitro diagnostic use only.
- This test kit is intended for persons aged 15 and over. Users under the age of 15 should complete the test with supervision of an adult.
- Bring the contents of the kit to room temperature before testing.
- Appropriate protection should be worn while performing the test to avoid splashes when adding the sample.
- If the SARS-CoV-2 testis positive, there is a suspicion of a COVID-19 infection, contact your doctor/GP immediately or the local health department, follow local guidelines Self-isolate and perform a confirmatory PCR test.
- If the result of the influenza A/B, RSV, ADV test is positive: There is currently the Suspected influenza A/B, RSV, ADV infection and what to do next be undertaken according to local guidelines.
- Do not reuse the test kit.
- Do not use the test kit if the pouch breaks the seal broken or the test cassette is wet or dirty.
- Do not use the contents of the test kit after the expiry date on the expiry date printed on the outside of the packaging.

STORAGE INSTRUCTIONS

- The test kit should be protected from direct sunlight at 2 to 30℃, with the shelf life stated on the packaging.
- This test kit should be used within 1 hour of opening the foil bags.

⚠ Keep out of reach of children

DIRECTIONS FOR USE

⚠ Allow the test device, sample extraction buffer to equilibrate to room temperature (15- 30°C) prior to testing, blowing the nose before taking a nasal swab .

Nasal Swab Specimen Collection :

BEFORE STARTING: Wash and sanitise your hands, then clean the nostrils.

1. Remove the swab from the package.

2. While gently rotating the swab, insert swab about 2cm into nostril until resistance is met at turbinates.

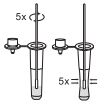
3. Rotate the swab several times against nasal wall and repeat in other nostril using the same swab.

Specimen Transport and Storage :

After swabbing, process the swab in the extraction buffer as soon as possible. Do not place the swab back into the swab packaging sleeve after specimen collection.
Specimens should be tested within 30 minutes. Do not freeze or transport the sample for later testing.

Testing Procedure :

1. Peel off the aluminum foil seal from a sample extraction buffer.



2. Immerse the sampled swab into the sample extraction buffer to make the sample extraction buffer completely penetrate the swab, rotate and squeeze the swab 5 times, take out and discard the swab.

3. Insert the tube cap firmly on the sample extraction tube.Gently shake the extraction tube for about 10 seconds to make sure sample mix well with extraction buffer.

4. Transfer 2 drops of mixed sample into the test card vertically, start the timer. Read the result at 15 minutes. Don't interpret the result after 30 minutes.
**Read the result at 15 minutes. Result after 30 mins will not be valid.

⚠ Put used product components in the biohazard bag. Close the bag and put it in medical waste recycling bin.

INTERPRETATION OF RESULTS

POSITIVE (+)

- Flu A Positive: Two red bands appear in the Flu A/Flu B detection zone. One is in the test zone (A), and the other is in the control zone (C).
- Flu B Positive: Two red bands appear in the Flu A/Flu B detection zone. One is in the test zone (B), and the other is in the control zone (C).
- Flu A/Flu B Positive: Three red bands appear in the Flu A/Flu B detection zone. One is in the test zone (A), one is in the test zone (B), and the other is in the control zone (C).
- SARS-CoV-2 Positive: Two red bands appear in COVID-19 detection zone. One is in the test zone (T), and the other is in the control zone (C).
- RSV Positive: Two red bands appear in RSV detection zone. One is in the test zone (T), and the other is in the control zone (C).
- ADV Positive: Two red bands appear in ADV detection zone. One is in the test zone (T), and the other is in the control zone (C).

**Note:The red line in the test line (T) can show different shades of color. However, even a very weak ribbon should be judged as a positive result during the specified observation period, regardless of the color of the ribbon.

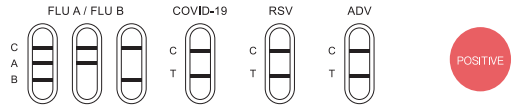


Fig.1 Positive Result

NEGATIVE (-)

If only quality control line C, test line T or test line A or test line B are colorless, it means that no antigen of corresponding pathogen is detected, and the result is negative.

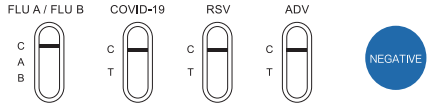


Fig.2 Negative Result

INVALID

If the quality control line C is not observed, it will be invalid regardless of whether there is test line T or test line A or test line B, and the test shall be conducted again.

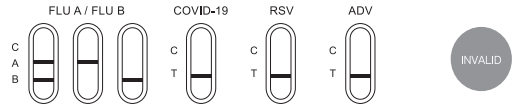


Fig.3 Invalid Result

TEST METHOD LIMITATIONS

- The accuracy of the test depends on the quality of the sample. Improper sampling or storage, use of expired samples or repeatedly frozen and thawed samples can do this affect the test result. The test results can also by temperature and humidity are affected.
- Low levels of Flu A & B,COVID-19, RSV, ADV antigens in the sample can produce negative results, so that an infection cannot be completely ruled out.
- Some medications (such as high levels of over-the-counter or prescription drugs such as nasal spray) in the samples taken may affect the test result. Please perform the test again if the result is doubtful.
- This product is for qualitative testing only. The specific concentration of each indicator must be related to other quantitative methods are measured.
- The results of this test are for clinical reference only and should be used not be the only basis for the diagnosis. The results should be in combination with clinical observations and other test methods be used.

CLINICAL PERFORMANCE

1.COVID-19 test

A total of 420 samples were collected in this study, of which 220 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
COVID-19 Test		POS	NEG	Total	PPA	96.82%	93.58%	98.45%
	POS	213	0	213	NPA	>99.9%	98.12%	100%
	NEG	7	200	207	Total compliance rate			98.33%
	TOTAL	220	200	420				

Sensitivity: 96.82%
Specificity: >99.9%
Accuracy: 98.33%

2.Influenza A test

A total of 305 samples were collected in this study, of which 105 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
Influenza A Test		POS	NEG	Total	PPA	>99.9%	96.47%	100%
	POS	105	0	105	NPA	>99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			>99.9%
	TOTAL	105	200	305				

Sensitivity: >99.9%
Specificity: >99.9%
Accuracy: >99.9%

3.Influenza B test

A total of 305 samples were collected in this study, of which 100 were positive and 205 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
Influenza B Test		POS	NEG	Total	PPA	>99.9%	96.30%	100%
	POS	100	0	100	NPA	>99.9%	98.16%	100%
	NEG	0	205	205	Total compliance rate			>99.9%
	TOTAL	100	205	305				

Sensitivity: >99.9%
Specificity: >99.9%
Accuracy: >99.9%

4.RSV test

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
RSV Test		POS	NEG	Total	PPA	>99.9%	96.30%	100%
	POS	100	0	100	NPA	>99.9%	98.12%	100%
	NEG	0	200	200	Total compliance rate			>99.9%
	TOTAL	100	200	300				

Sensitivity: >99.9%
Specificity: >99.9%
Accuracy: >99.9%

5.ADV test

A total of 300 samples were collected in this study, of which 100 were positive and 200 were negative. The statistics of the study results are shown in the following table:

Comparative Kit							95% Wilson Score CI	
							LCI	UCI
ADV Test		POS	NEG	Total	PPA	99.00%	94.55%	99.82%
	POS	99	0	99	NPA	>99.9%	98.12%	100%
	NEG	1	200	201	Total compliance rate			99.67%
	TOTAL	100	200	300				

Sensitivity: 99.00%
Specificity: >99.9%
Accuracy: 99.67%

Limit of detection (LOD)

Type		LOD
COVID-19		80 $TCID_{50}$/mL
Influenza A	Liao Ning/1183/2007 (H1N1)	$2.2x10^3$ $TCID_{50}$/mL
Influenza A	A/Victoria/3/75	$1.16x10^2$ $TCID_{50}$/mL
Influenza A	A/HongKong/8/68	$2.58x10^4$ $TCID_{50}$/mL
Influenza B	Jiang Xi/32/2000	$2.9x10^2$ $TCID_{50}$/mL
Influenza B	B/1704	$6.8x10^2$ $TCID_{50}$/mL
RSV		10ng/ml
ADV		10ng/ml

3. Cross reaction:

3.1. For COVID-19:
Do not cross react with Adenovirus 3, Parainfluenza virus Type 2, Human coronavirus NL63, MERS, coronavirus (Pseudovirus, part of ORFlab+N gene), Human coronavirus 229E, Human coronavirus OC43, Human Coronavirus HKU1, SARS-COV-2, Pseudovirus (N full-length gene), Enterovirus, Respiratory syncytial virus(A), Parainfluenza virus Type 3, Parainfluenza virus Type 4a, Influenza A H3N2 (Wisconsin/67/05), Influenza A H1N1, Influenza B, (VICRTORIA), Rhinovirus(HRVA30), Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii, Pseudomonas Aeruginosa, Human Metapneumovirus (hMPV), Parainfluenza virus Type 1, Staphylococcus Epidermidis, Streptococcus Salivarius, etc.
3.2. For Flu A+B:
Influenza A virus and influenza B virus do not cross each other.
Do not cross react with influenza C virus, parainfluenza virus, adenovirus, respiratory syncytial virus, herpes simplex virus, mumps virus, rhinovirus, respiratory chlamydia, mycoplasma, tuberculosis, bacillus pertussis, candida albicans, diphtheria, influenza Haemophilus, Legionella pneumophila, Mycobacterium tuberculosis, Staphylococcus aureus, gastrointestinal virus 71, coronavirus, etc.
3.3. For Flu RSV and ADV:
Do not cross react with SARS-CoV-2, Influenza A, Influenza B, etc.

4. Interfering substances

4.1. For COVID-19:
There is no interference with test results, such as Parainfluenza virus Type 1, Parainfluenza virus Type 2, Parainfluenza virus Type 3, Parainfluenza virus Type 4a, Adenovirus (e.g. C1 Ad. 71), Human Metapneumovirus (hMPV), Influenza A H3N2 (Wisconsin/67/05), Influenza A H1N1, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Influenza B (Malaysia/2506/04), Enterovirus, Respiratory syncytial virus, Rhinovirus, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii, Pseudomonas Aeruginosa, Candida albicans, Pooled human nasal wash, Bordetella pertussis, Mycoplasma pneumoniae, Staphylococcus Epidermidis, Streptococcus Salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS coronavirus, etc.
4.2. For Flu A+B, RSV and ADV:
Common interfering substances in the sample, such as blood, mucin, pus, etc., have no effect on the test results.

Symbol

Symbol	Meaning	Symbol	Meaning
IVD	In Vitro Diagnostic Medical Device	30°C 2°C	Storage Temperature Limit
	Manufacturer	EC REP	Authorized Representative In The European Community
	Date of Manufacture		Use By Date
	Do Not Reuse		Consult Instruction For Use
LOT	Batch Code	CE 3018	CE Conformity Marking
REF	Catalogue number	Σ	Contains Sufficient For <n> Tests
	This Way Up		Do Not Use If Package Is Damaged
	Keep Away From Sunlight		Keep Dry
	Keep out of reach of children		Biological Hazard

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