ARTG ID: 524286

English

COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit Instruction for Use

INTENDED USE

The COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit is a lateral flow immunoassay for the qualitative detection of SARS-CoV-2 (nucleocapsid protein), Respiratory Syncytial Virus (nucleocapsid protein), Adenovirus (Hexon Protein), Influenza A (nucleocapsid protein) and Influenza B (nucleocapsid protein) in nasal swabs from subjects. The symptoms of respiratory viral infection due to SARS-CoV-2, respiratory syncytial, Adenovirus, influenza can be similar. The test is intended as an aid in diagnosis of symptomatic individual meeting respiratory infection for SARS-CoV-2 (within the first 7 days of the onset of symptoms) and influenza A/B, Adenovirus or Respiratory syncytial virus (RSV) (within the first 4 days of the onset of symptoms). This kit is intended for layperson's home use in a non-laboratory environment.

PRINCIPLE

The COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit is a lateral flow immunoassay based on the principle of the double antibody sandwich technique. A monoclonal SARS-CoV-2/RSV/ADV/Influenza A&B antibody conjugated with colored microparticles and sprayed onto the conjugation pad is used as a detector. During the test, the SARS-CoV-2/RSV/ADV/Influenza A&B antigen in the sample interacts with the SARS-CoV-2/RSV/ADV/Influenza A&B antibody conjugated with colored microparticles, creating an antigen-antibody labeled complex. This complex migrates on the membrane by capillary action up to the Test line where it is captured by the pre-coated monoclonal SARS-CoV-2/RSV/ADV/Influenza A&B antibodies. A colored test line (T) would be visible in the each result window if SARS-CoV-2/RSV/ADV/Influenza A&B antigens are present in the sample. The absence of the T line indicates a negative result. The control line (C) is for procedural control and should appear whenever the test procedure is being performed properly.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use after the expiration date.
3. Perform the test at room temperature 15 to 30°C.
4. The test cassette should remain in the sealed pouch until use.
5. Please read all information in this leaflet before performing the test.
6. Components from difference lots must not be mixed or used together.
7. Positive result cannot necessarily determine whether a person is infectious.

STORAGE AND STABILITY

Store the test kit in the original packaging at 2°C - 30°C. Do not freeze. Test kit contents remain stable until the expiration date printed on the outer packaging.

After opening the pouch, the test should be used within one hour. Prolonged contact with hot and humid environment will cause the product to deteriorate.

LIMITATION

1. A negative result does not rule out infection with another type of respiratory virus. And a positive result cannot necessarily determine whether a person is infectious.
2. The test can only be used once.
3. Test can only be performed by person over 15 years age. Any persons or children under 15 years will require adult supervision or assistance. Not to be performed on children under 2 years of age.
4. The performance of COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
5. In particular, false negative results may occur if the testing is not performed within the first 7 days of the onset of COVID-19 or within the first 4 days of influenza A&B/Adenovirus/RSV symptoms or if the antigen level in the sample is below the detection limit.
6. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
7. Recommend repeat testing 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. Negative results may not mean that a person is not infectious and if symptoms persist, please seek medical advice.

SAFETY INFORMATION

1. Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.
2. Follow the directions of your local state or territory government health department to protect yourself.
3. Test kit solutions should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and pets before and after use.
4. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical center.

CLINICAL PERFORMANCE

For COVID-19

The clinical performance of the COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit for professional use has been evaluated against RT-PCR, and the results are as follows:

Clinical sensitivity = 97.08% (498/513 known confirmed Positives, 95%CI* 95.23% to 98.22%)

Clinical specificity = 99.07% (743/750 known confirmed Negatives, 95%CI* 98.09% to 99.55%)

*:95% confidence interval

Sensitivity Result according to the date of onset

Days after symptom onset	RT-PCR	ACRT	Sensitivity
0	13	11	84.62%
1	22	22	100.00%
2	19	18	94.74%
3	17	17	100.00%
4	13	13	100.00%
5	22	21	95.45%
6	15	15	100.00%
7	14	12	85.71%

Sensitivity Result stratified by age group

Age	RT-PCR	ACRT	Sensitivity
0-5	13	12	92.31%
6-21	34	34	100.00%
22-59	71	67	94.37%
≥60	17	16	94.12%

For influenza A test

The clinical performance of the COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit for professional use has been evaluated against RT-PCR, and the results are as follows:

Clinical sensitivity = 94.62% (123/130 known confirmed Positives, 95%CI* 89.30% to 97.37%)

Clinical specificity = 98.74% (157/159 known confirmed Negatives, 95%CI* 95.53% to 99.65%)

*:95% confidence interval

Sensitivity Result according to the date of onset

Days after symptom onset	RT-PCR	ACRT	Sensitivity
0	27	25	92.59%
1	19	18	94.74%
2	29	29	100.00%
3	30	29	96.67%
4	25	22	88.00%

Sensitivity Result stratified by age group

Age	RT-PCR	ACRT	Sensitivity
0-5	13	12	92.31%
6-21	15	14	93.33%
22-59	74	70	94.59%
≥60	28	27	96.43%

For influenza B test

The clinical performance of the COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit for professional use has been evaluated against RT-PCR, and the results are as follows:

Clinical sensitivity =92.31% (120/130 known confirmed Positives, 95%CI* 86.42% to 95.77%)

Clinical specificity =98.21% (165/168 known confirmed Negatives, 95%CI* 94.88% to 99.39%)

*:95% confidence interval

Sensitivity Result according to the date of onset

Days after symptom onset	RT-PCR	ACRT	Sensitivity
0	21	19	90.48%
1	29	26	89.66%
2	38	35	92.11%
3	23	21	91.30%
4	19	19	100.00%

Sensitivity Result stratified by age group

Age	RT-PCR	ACRT	Sensitivity
0-5	18	17	94.44%
6-21	22	20	90.91%
22-59	69	65	94.20%
≥60	21	18	85.71%

For RSV test

The clinical performance of the COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit for professional use has been evaluated against RT-PCR, and the results are as follows:

Clinical sensitivity = 95.56% (129/135 known confirmed Positives, 95%CI* 90.64% to 97.95%)

Clinical specificity =99.16% (118/119 known confirmed Negatives, 95%CI* 95.39% to 99.85%)

*:95% confidence interval

Sensitivity Result according to the date of onset

Days after symptom onset	RT-PCR	ACRT	Sensitivity
0	35	33	94.29%
1	38	36	94.74%
2	20	19	95.00%
3	20	19	95.00%
4	22	22	100.00%

Sensitivity Result stratified by age group

Age	RT-PCR	ACRT	Sensitivity
0-5	15	15	100.00%
6-21	33	32	96.97%
22-59	63	59	93.65%
≥60	24	23	95.83%

For Adenovirus test

The clinical performance of the COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit for professional use has been evaluated against RT-PCR, and the results are as follows:

Clinical sensitivity = 95.83% (115/120 known confirmed Positives, 95%CI* 90.62% to 98.21%)

Clinical specificity =98.36% (120/122 known confirmed Negatives, 95%CI* 94.22% to 99.55%)

*:95% confidence interval

Sensitivity Result according to the date of onset

Days after symptom onset	RT-PCR	ACRT	Sensitivity
0	26	24	92.31%
1	24	22	91.67%
2	22	21	95.45%
3	28	28	100.00%
4	20	20	100.00%

Sensitivity Result stratified by age group

Age	RT-PCR	ACRT	Sensitivity
0-5	10	10	100.00%
6-21	28	27	96.43%
22-59	64	60	93.75%
≥60	18	18	100.00%

USABILITY STUDY RESULTS

The usability study was conducted with lay persons who performed the test and interpreted the result. The test procedure and obtain consistent test results with professionals.

For SARS-CoV-2, The results were compared to an RT-PCR with a sensitivity of 94.29% (33/35) and specificity of 100% (65/65).

For Influenza A, The results were compared to an RT-PCR with a sensitivity of 94.44% (34/36) and specificity of 98.44% (63/64).

For Influenza B,The results were compared to an RT-PCR with a sensitivity of 90.63% (29/32) and specificity of 98.53% (67/68).

For ADV, The results were compared to an RT-PCR with a sensitivity of 94.12% (32/34) and specificity of 98.48% (65/66).

For RSV, The results were compared to an RT-PCR with a sensitivity of 93.75% (30/32) and specificity of 98.53% (67/68).

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

Virus Lines	LoD Titer
SARS-CoV-2 B.1.1.529	1.1×10^2 $TCID_{50}$ /mL
SARS-CoV-2 BA.4	1.45×10^2 $TCID_{50}$ /mL
SARS-CoV-2 BA.5	1.3×10^2 $TCID_{50}$ /mL
SARS-CoV-2 wild type	1.0×10^2 $TCID_{50}$ /mL
Flu A H1N1/Wisconsin/588/2019	2.08×10^3 $TCID_{50}$ /mL
Flu A H3N2/SouthAustralia/34/2019	7.76×10^2 $TCID_{50}$ /mL
Flu B Austria/1359417/2021(Victoria lineage)	2.84×10^3 $TCID_{50}$ /mL
Flu B Phuket/3073/2013(Yamagata lineage)	1.08×10^4 $TCID_{50}$ /mL
Flu A H1N1/Bejing/262/95	3.105×10^2 $TCID_{50}$ /mL
Flu A H3N2/Shangdong/9/93	2.26×10^2 $TCID_{50}$ /mL
Flu B Victoria lineage/Shandong/7/97	1.825×10^3 $TCID_{50}$ /mL
Flu B Yamagata lineage/Jiangsu/10/03	2.44×10^3 $TCID_{50}$ /mL
RSV type A (A2)	2.75×10^3 PFU/mL
RSV type B (B WV-14617-85)	2.8×10^2 $TCID_{50}$ /mL
Adenovirus type 3	1.8×10^3 $TCID_{50}$ /mL
Adenovirus type 7	2.8×10^3 $TCID_{50}$ /mL

FREQUENTLY ASKED QUESTIONS

1.Will other diseases affect the result?

The potential cross-reactivity of the following pathogens was evaluated with SARS-CoV-2, respiratory syncytial, Adenovirus, Influenza A and B negative and positive samples using the COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit. No interference or competitive inhibition was observed.

Virus or organisms		
SARS-CoV	Influenza A H5N1 virus	Coxsackie virus CA16e
Human coronavirus NL63	Influenza B Yamagata	Coxsackie virus B5
Human coronavirus HKU1	Influenza B Victoria	Coxsackie virus A24
Human coronavirus Oc43	Haemophilus influenzae	Candida albicans
Human coronavirus 229E	Adenovirus 1	Human Metapneumovirus A2
MERS	Adenovirus 2	Legionella pneumophila
Respiratory syncytial virus Type A	Adenovirus 3	Mycobacterium tuberculosis
Respiratory syncytial virus Type B	Adenovirus 4	Mycoplasma pneumoniae
Parainfluenza virus 1	Adenovirus 5	Pneumocystis jiroveci
Parainfluenza virus 2	Adenovirus 7	Streptococcus pneumoniae
Parainfluenza virus 3	Adenovirus 55	Staphylococcus aureus
Parainfluenza virus 4	Enterovirus EV70	Rhinovirus A2
Seasonal influenza A H1N1 virus	Bordetella pertussis	Rhinovirus B52
Influenza A H3N2 virus	Chlamydia pneumoniae	Streptococcus pyogenes

2.Does these substances interfere with the test ?

The following substances were spiked into samples and tested with the COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit. No interference results was observed.

Substances		
Mucin	Phenylephrine Hydrochloride	Histamine hydrochloride
Human blood (EDTA anticoagulated)	Arbidol	Alpha interferon
Bedomethasone dipropionate nasal aerosol	Zanamivir	Azithromycin
physiological seawater nasal spray	Ribavirin	Oseltamivir phosphate
Triamcinolone acetonide nasal spray	Peramivir	Meropenem
Mometasone furoate nasal spray	Lopinavir	Tobramycin
Fluticasone propionate nasal spray	Ritonavir	Hexadecadrol
Budesonide nasal spray	Levofloxacin	Flunisolide
Oxymetazoline hydrochloride spray	Ceftriaxone	

3.Will this test hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

4.I have a nosebleed after swabbing my nose. What should I do ?

In the unlikely event your nose starts bleeding, apply pressure to your nose until the bleeding stops and consult a healthcare professional. Do not insert the Swab again.

5.Can the test detect various variants of COVID-19 ?

Yes, the following SARS-CoV-2 variants can be detected with the COVID-19 (SARS-CoV-2) Antigen Test Kit: Alpha, Beta, Gamma, Delta and Omicron.

6.Which strains of influenza the test covers ?

Influenza A		
A/Vietnam/HN31242/2007	A/Victoria/2570/2019	A/Hong Kong/2671/2019
A/Shanghai/2/2013	A/Switzerland/8060/2017	A/Victoria/4897/2022
A/RR/8/34	A/Hong Kong/45/2019	A/Wisconsin/67/2022
A/California/04/2009	A/Wisconsin/588/2019	A/Massachusetts/18/2022
A/Darwin/9/2021	A/Darwin/6/2021	A/Croatia/10136RV/2023
A/SouthAustralia/34/2019	A/Singapore/INFMH-16-0019/2016	A/District of Columbia/27/2023
A/Guizhou/54/89	A/Brisbane/02/2018	
A/Bean Goose/Hubei/chenhu XVI35-1/2016	A/Michigan/45/2015	

Influenza B		
B/SichuanGaoxin/531/2018	B/Austria/1359417/2021	B/Brisbane/60/2008
B/Hong Kong/3417/2014	B/Washington/02/2019	B/Brisbane/9/2014
B/Phuket/3073/2013	B/Colorado/06/2017	B/Singapore/WUH4618/2021

7.Which strains of RSV the test covers ?

RSV Type A/A2	RSV Type B/GZ/1704-8	RSV Type B/B WV-14617-85
RSV Type A/Long	RSV Type B/18537	

8.Which strains of Adenovirus the test cover ?

Adenovirus 1/GZ/1608-21	Adenovirus 4/GZ/1611-72	Adenovirus 7/Gomen
Adenovirus 2/GZ/1705-34	Adenovirus 5 /GZ/1801-54	Adenovirus 7/GZ0201/2010
Adenovirus 3/GZ/0101/2011	Adenovirus 3/G.B.	Adenovirus 55/GZ/1612-129

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the online Users Medical Device Incident Report , emailing iris@health.gov.au or calling 1800 809 361 (08 : 30am to 5 : 00pm Monday to Friday).

ARTG ID: 524286

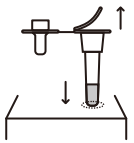
COVID-19/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit

Note: Use test only one time.

1

Wash your hands.

2



Tear the aluminum foil on the extraction buffer tube. Place extraction tube into box tube stand.

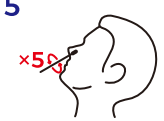
3

Open the swab package and take out the swab.
Note : Do not touch the swab tip with finger.

4

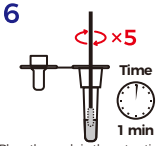
Tilt your head back slightly. Insert the swab about 1.5 to 2.5 cm into one nostril. Gently rotate the swab at least five times against the nasal wall.

5



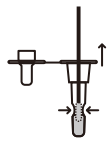
Insert the same swab about 1.5 to 2.5 cm into the second nostril. Again, gently rotate the swab at least five times against the nasal wall.

6



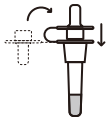
Place the swab in the extraction tube and rotate the swab against the walls of the tube 5 times. Allow the swab to stand in the extraction buffer tube for 1 minute.

7



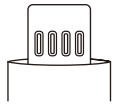
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

8



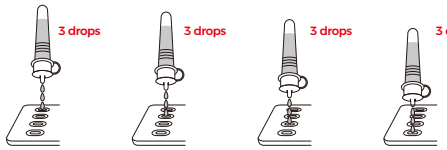
Press the nozzle cap tightly onto the tube.

9



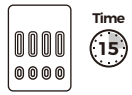
Open the foil pouch and take out the test device.

10



3 drops must be added to the four specimen wells.

11



Read the result at 15 minutes. Do not interpret the result after 20 minutes.

12

Carefully wrap the used test kit components andSwab samples and dispose in normal household waste.

Scan the QR code or visit our website for instructional video, product information and IFU:
https://www.ahpcpharmacyoutlet.com.au/products/ahpc-5-in-1-antigen-test-kit-single-pack-pending-tga

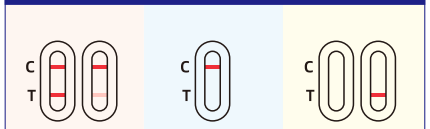
Components \ REF	ICRAF-555-F010	ICRAF-555-F040	ICRAF-555-F050	ICRAF-555-F060	ICRAF-555-F100	ICRAF-555-F250
	1 T	4 T	5 T	6 T	10 T	25 T
1. Test Cassette	1 x	4 x	5 x	6 x	10 x	25 x
2. Extraction Buffer Tube	1 x	4 x	5 x	6 x	10 x	25 x
3. Disposable Swab	1 x	4 x	5 x	6 x	10 x	25 x
4. Instruction for Use	1 x	1 x	1 x	1 x	1 x	25 x

Materials required but not provided : Timer

For the sterilized swab

CE 0197 MDR 2017/745 EU Hangzhou Yiguoren Biotechnology Co., Ltd.
CE 0197 MDD 93/42/EEC Jiangsu HanHeng Medical Technology Co., Ltd.

COVID-19 / RSV / ADV



Influenza A&B

NOTE

The intensity of color that the test line area (COVID-19/Flu A/Flu B/ADV/RSV) shows will vary according to the concentration of SARS-CoV-2 antigen, Influenza A antigen and Influenza B antigen, ADV antigen, RSV antigen. The result should be determined on whether the test line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (COVID-19/Flu A/Flu B/ADV/RSV) should be considered positive.

Positive result:

• SARS-CoV-2 positive result: If both the control line (C line) and the test line (T line) appearat the same time, it means that SARS-CoV-2 antigen has been detected and the result is positive. 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 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.

• Influenza A positive result: If both the control line (C line) and the Influenza A test line (Flu A line) appear at the same time, it means that Influenza A antigen has been detected in the sample and the result of Influenza A is positive.

• Influenza B positive result : If both the control line (C line) and the Influenza B test line (Flu B line) appear at the same time, it means that Influenza B antigen has been detected in the sample and the result of Influenza B is positive.

• ADV positive result: If both the control line (C line) and the test line (T line) appear at the same time, it means that ADV antigen has been detected in the sample and the result of ADV is positive.

• RSV positive result: If both the control line (C line) and the test line (T line) appear at the same time, it means that RSV antigen has been detected in the sample and the result of RSV is positive.

If the quality control C line appears, and more red lines appear in the detection line area, indicating that the sample contains one or more pathogenic microorganisms.

Negative result: If only the quality control C line appears and the detection line is not visible, the sample contains no SARS-CoV-2, Influenza A, Influenza B, ADV, RSV or the concentration is lower than the limit of detection and the result is negative.

Invalid result: If the C line does not appear, the result is invalid and a new test must be performed again.

Customer Support help line:
02 8054 5535
Customer Service hours:
9 AM ~ 8 PM, 7 Days. ~ UTC+10

2	Do not re-use		Use-by date
IVD	In vitro diagnostic medical device		Keep away from sunlight
2°C 30°C	Store between 2-30°C		Keep dry
	Consult instructions for use		Do not use if package is damaged and consult instructions for use
LOT	Batch code		Manufacturer
n	Contains sufficient for <n> tests	REF	Catalogue number

Hangzhou Fanttest Biotech Co.,Ltd.
Room 201, Building 1, No. 37-3, Futang Road, Tangqi Town,
Linping District, Hangzhou City, Zhejiang Province,311106,P.R.China.
E-mail: info@fanttest.com Tel: +86 571 86337555

Australia Sponsor
Australia Health Products Central Pty Ltd
604 / 3 Waverley St Bondi Junction Sydney NSW 2022
Customer Support help line: **02 8054 5535**
Customer Service hours: **9 AM ~ 8 PM, 7 Days. ~ UTC+10**
Web: www.cellifehealthcare.com.au

Code: 1054033900
Version No.: 2.0
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