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ARTG ID: 531589
English

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

INTENDED USE

The COVID-19/hMPV/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit is a lateral flow immunoassay designed to qualitatively detect antigens of SARS-CoV-2 (COVID-19)(nucleocapsid protein), Human metapneumovirus (hMPV)(Matrix protein),Influenza A (Flu A)(nucleocapsid protein), Influenza B (Flu B)(nucleocapsid protein), Adenovirus (ADV)(Hexon Protein), and Respiratory Syncytial Virus (RSV) (nucleocapsid protein) in human nasal swab samples. Respiratory infections caused by SARS-CoV-2,Human metapneumovirus, influenza, respiratory syncytial virus , and adenovirus can present with similar symptoms. 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 Human metapneumovirus, Influenza A/B, Adenovirus or Respiratory syncytial virus(within the first 4 days of the onset of symptoms).

This kit is designed for home use by laypersons in non-laboratory settings. Individuals aged 15 years and older may perform the test independently. For users under 15 years of age, the test should be conducted or supervised by an adult.

Test results of this kit are for clinical reference only. It is recommended that a comprehensive analysis of the disease be conducted based on clinical manifestations of patients and other laboratory tests.

PRINCIPLE

The COVID-19/hMPV/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 COVID-19/hMPV/RSV/ADV/Flu A&B antibody conjugated with colored microparticles and sprayed onto the conjugation pad is used as a detector. During the test, the COVID-19/hMPV/RSV/ADV/Flu A&B Antigen 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 COVID-19/hMPV/RSV/ADV/Flu A&B antibody. A colored test line would be visible in each result window if COVID-19/hMPV/RSV/ADV/Flu A&B Antigen 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.

MATERIALS

REF / Components	IRV-565-E010	IRV-565-E020	IRV-565-E040	IRV-565-E050	IRV-565-E060	IRV-565-E070	IRV-565-E100
1. Test Cassette	1T	2T	4T	5T	6T	7T	10T
2. Extraction Buffer Tube	1x	2x	4x	5x	6x	7x	10x
3. Disposable Swab	1x	2x	4x	5x	6x	7x	10x
4. Instructions for Use	1x	1x	1x	1x	2x	2x	2x

Materials required but not provided : Timer

For the sterilized swab
CE 0197 MDR 2017/745 EU Hangzhou Yiguoren Biotechnology Co., Ltd.
CE 0197 MDR 2017/745 EU Jiangsu Rongye Technology Co., Ltd.
CE 0197 MDR 2017/745 EU Jiangsu HXRT MD Co., Ltd.

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.

LIMITATIONS

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/hMPV/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 Human metapneumovirus/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.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.
3.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.

PERFORMANCE CHARACTERISTICS

For COVID-19 test

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

Clinical sensitivity = 97.10% (503/518 known confirmed Positives, 95%CI* 95.28% to 98.24%)

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

*:95% confidence interval

For hMPV test

The clinical performance of the COVID-19/hMPV/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 = 97.09% (100/103 known confirmed Positives, 95%CI* 91.78% to 99.00%)

Clinical specificity =98.18% (108/110 known confirmed Negatives, 95%CI* 93.61% to 99.50%)

*:95% confidence interval

For RSV test

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

Clinical sensitivity = 96.00% (120/125 known confirmed Positives, 95%CI* 90.98% to 98.28%)

Clinical specificity =99.09% (109/110 known confirmed Negatives, 95%CI* 95.03% to 99.84%)

*:95% confidence interval

For Adenovirus test

The clinical performance of the COVID-19/hMPV/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 = 96.36% (106/110 known confirmed Positives, 95%CI* 91.02% to 98.58%)

Clinical specificity =98.31% (116/118 known confirmed Negatives, 95%CI* 94.03% to 99.53%)

*:95% confidence interval

For influenza A test

The clinical performance of the COVID-19/hMPV/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 = 95.38% (124/130 known confirmed Positives, 95%CI* 90.30% to 97.87%)

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

*:95% confidence interval

For influenza B test

The clinical performance of the COVID-19/hMPV/RSV/ADV/FluA&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 =98.21% (165/168 known confirmed Negatives, 95%CI* 94.88% to 99.39%)

*:95% confidence interval

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 97.50% (39/40) and specificity of 100% (70/70).

For hMPV, the results were compared to an RT-PCR with a sensitivity of 100% (35/35) and specificity of 100% (70/70).

For Influenza A, the results were compared to an RT-PCR with a sensitivity of 97.22% (35/36) and specificity of 100% (74/74).

For Influenza B, the results were compared to an RT-PCR with a sensitivity of 97.14% (34/35) and specificity of 100% (74/74).

For ADV, the results were compared to an RT-PCR with a sensitivity of 100.00% (37/37) and specificity of 98.61% (71/72).

For RSV, the results were compared to an RT-PCR with a sensitivity of 97.06% (33/34) and specificity of 98.57% (69/70).

LIMIT OF DETECTION (ANALYTICAL SENSITIVITY)

Virus Lines	LoD Titer
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/Beijing/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
hMPV A1 (IA3-2002)	1.24×10^{4} $TCID_{50}$/mL
hMPV A2 (IA27-2004)	1.16×10^{4} $TCID_{50}$/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, Human metapneumovirus, respiratory syncytial, Adenovirus, Influenza A and B negative and positive samples using the COVID-19/hMPV/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit. No cross-reactivity results was observed.

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

2.Does these substances interfere with the test ?

The following substances were spiked into samples and tested with the COVID-19/hMPV/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
Beclomethasone 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/hMPV/RSV/ADV/Flu A&B Antigen Combo Rapid Test Kit: Alpha, Beta, Gamma, Delta and Omicron.

6.Which strains of influenza the test covers ?

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

Influenza B		
B/SichuanGaoxin/5311/2018	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

9.What to do if you test positive?

Anyone diagnosed with COVID-19 can pass the virus onto others.

While isolation is no longer a legal requirement, if you test positive for COVID-19, staying at home protects the people in your community.

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:

- 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
- 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 healthdirect 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.

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).

SYMBOLS

	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
	Contains sufficient for <n> tests	REF	Catalogue number

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Code: 1054047200
Version No.: 1.0
Effective Date: XXXXX

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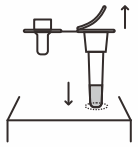
ARTG ID: 531589

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

Note: Use test only one time.

Scan the QR code or visit our website for instructional video, product information and IFU: https://www.biotop6.com/cellife-covid-19hmpvrsvinfluenza-ab-antigen-test-kit-product/

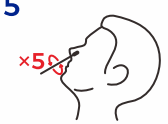
1 Wash your hands.

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 

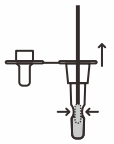
Tilt your head back slightly. Insert the swab about 1.5 to 2.5 cm into one nostril. Gently rotate the swab at least five times against the nasal wall.

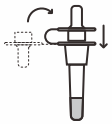
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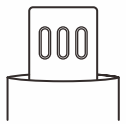
Insert the same swab about 1.5 to 2.5 cm into the second nostril. Again, gently rotate the swab at least five times against the nasal wall.

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.

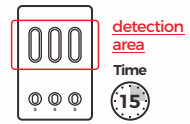
7 
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

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 three 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 and Swab samples and dispose in normal household waste.

Caution

For positive results: If you have a COVID-19 POSITIVE result, follow current Department of Health advice (Refer to FAQ #9). If you have a hMPV or Influenza or RSV or ADV POSITIVE result, individuals are advised to consult a medical practitioner forfollow-up clinical care.

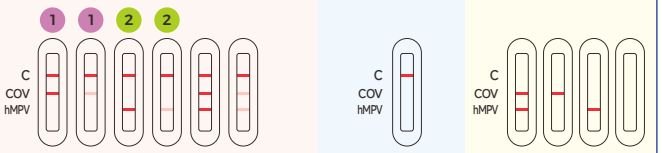
Note: Any faint/weak positive test line counts as a positive result, please follow the corresponding guidance above.

For negative results: If you have symptoms like fever, cough and/or shortness of breath. Please retest in 1-3 days. You must continue following the applicable hygiene and distancing rules even with a negative result. If symptoms persist or if unwell please consult a medical practitioner for follow-up clinical care.

For invalid results: Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

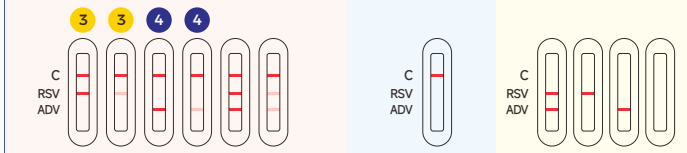
If an invalid result is produced, the user should review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test Cassette immediately and contact your local distributor.

COVID-19/hMPV



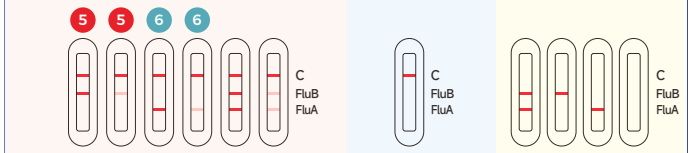
Positive | Negative | Invalid

RSV/ADV



Positive | Negative | Invalid

Flu B/Flu A



Positive | Negative | Invalid

POSITIVE (COVID-19/hMPV)

1 **COVID-19 POSITIVE:** Two colored lines appearon the membrane. One line appears in the control region(C) and the other line appears in the COVID-19 test line region.

2 **hMPV POSITIVE:** Two colored lines appear on themembrane. One line appears in the control region(C) and the other line appears in the hMPV test lineregion.

POSITIVE (RSV/ADV)

3 **RSV POSITIVE:** Two colored lines appear on themembrane. One line appears in the control region(C) and the other line appears in the RSV test lineregion.

4 **ADV POSITIVE:** Two colored lines appear on the membrane. One line appears in the control region(C) and the other line appears in the ADV test line region.

POSITIVE (Flu B/Flu A)

5 **Influenza B (Flu B) :** Two colored lines appear on the membrane. One line appears in the control region(C) and the other line appears in the Flu B test line region.

6 **Influenza A (Flu A) :** Two colored lines appear onthe membrane. One line appears in the control region(C) and the other line appears in the Flu A test line region.

Multiple POSITIVE: If the control (C) line appears and two or more test lines are visible in the detection area, this indicates the presence of multiple target pathogens (co-infection).

NEGATIVE (COVID-19/hMPV)

One colored line appears in the control region (C). No colored line appears in the COVID-19 and hMPV test region (T).

NEGATIVE (RSV/ADV)

One colored line appears in the control region (C). No colored line appears in the RSV and ADV test region (T).

NEGATIVE (Flu B/Flu A)

One colored line appears in the control region (C). No colored line appears in the Flu B and Flu A test region (T).

INVALID

Control line fails to appear.

INVALID

Control line fails to appear.

INVALID

Control line fails to appear.

Customer Support Line: 02 7908 9566 Customer Service hours: 9 AM ~ 8 PM, 7 Days. ~ UTC+10