Infected or not? Test right now!

Dvot

SARS-CoV-2 & RSV & MP & ADV & Flu A/B

Antigen Combo Test Kit

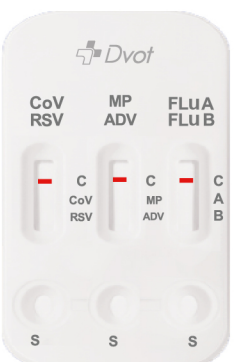
New Omicron EG.5、CH.1.1、JN.1 Detected

6 In 1

SARS -Cov-2	94.55% Sensitivity
Influenza A	90.48% Sensitivity
Influenza B	91.67% Sensitivity
RSV	93.62% Sensitivity
MP	90.82% Sensitivity
ADV	91.18% Sensitivity

CE CERTIFIED ISO 13485 MEDICAL DEVICES • QUALITY MANAGEMENT · ISO 9001:2015 CERTIFIED QUALITY MANAGEMENT SYSTEM · GOOD MANUFACTURING PRACTICE GMP CERTIFIED

Anterior **Nasal** Swab
Anteriorer Nasenabstrich



About the Antigen Combo Test Kit

During the first few days of a Covid-19 illness, symptoms tend to be nonspecific and may include cough, fever and sore throat. These symptoms can be indistinguishable from other viral infections, such as influenza, respiratory syncytial virus (RSV), or viruses associated with the common cold. Because of this, combo diagnostic testing is needed and important, not only to determine the cause of the illness, but also to determine whether treatment is appropriate.

DVOT® SARS-CoV-2 & RSV & MP & ADV & Flu A/B Antigen Combo Test Kit is an easy and rapid way to identify which infections cause the symptoms. It can be used anywhere and anytime by yourself.

Get result at home

Easy self-testing

8 Minutes
Time-saving

Anytime, Anywhere, Test by yourself !

Hospital · Test Site · Airport · Station · Hotel · Corporation · Mass Screening

HAVE YOU EVER HAD SUCH CONCERNS?

Worried about inconvenient to test

- No hospitals or test site available nearby.
- Physical discomfort, queue for a long time to test.

Worried about can not get result immediately

- Long time waiting for a PCR test result.
- Want to know the result immediately.

Worried about the family

- Anyone in my family been infected?
- How to test elder and infants?

Worried about infection

- Infection risk in crowded hospitals or test site.
- If there are close contacts around you?

Let us **SOLVE** your troubles!

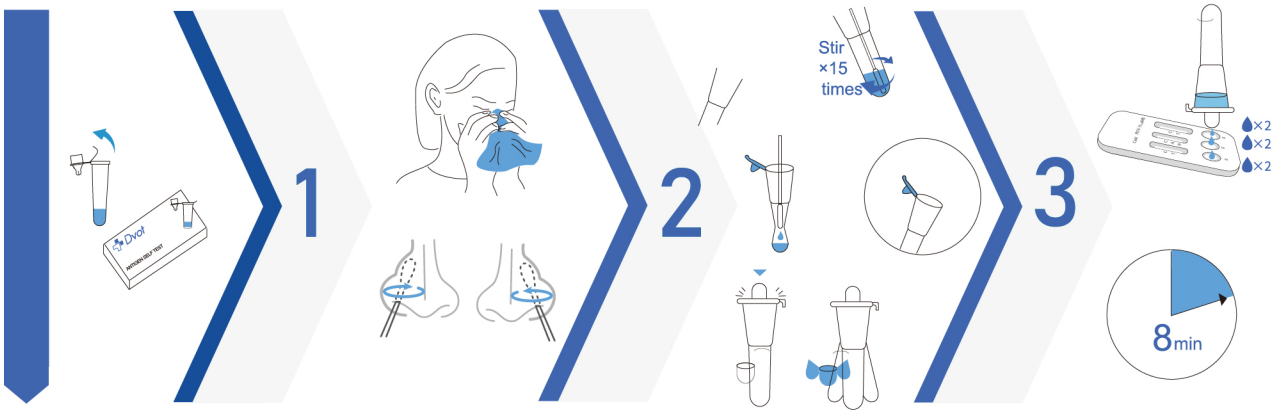
It can detect mutated virus

High accuracy detection of 97.65%

- Test result is available in 8 minutes.
- Self-testing is convenient at home, or anywhere else.
- Risk control for easy life and working.
- Shelf-life of 1.5 years, you can store for a long time.

Easy detection will make you feel ease, people around you also feel comfortable.

Simple steps, easy-handling for anybody!



Result Reading

For Cov &Rsv

Cov &Rsv Positive	Rsv Positive	Cov Positive	Negative
Invalid	Invalid	Invalid	Invalid

For MP &ADV

MP&ADV Positive	ADV Positive	MP Positive	Negative
Invalid	Invalid	Invalid	Invalid

For Flu A/B

Flu A&B Positive	Flu B Positive	Flu A Positive	Negative
Invalid	Invalid	Invalid	Invalid

CERTIFICATE

IVD NOTIFICATION

EC Certificate No. 1058-IVDD-179/2022
EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Feng Chun Yuan Medical Equipment (Shenzhen) Co., Ltd.
Room.1304&Room.504,No.48,Xinyu Road,
Xiangshan Community, Xinqiao Street,
Baoan District, Shenzhen, Guangdong, CN, 518000, China

in vitro diagnostic medical devices
for Professional Testing

SARS-CoV-2 & RSV & MP &
ADV & Flu A/B
Antigen Combo Test Kit

Ref. No.: ACT01 (1 test/kit)
ACT05 (5tests/kit)
ACT25 (25 tests/kit)

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as ame ded)
implemented into Polish law,
as evidenced by the audit conducted by Share info Consulant Service LLC.

Validity of the Certificate: from 12.04.2022 to 13.04.2025

The date of issue of the Certificate: 12.04.2022

The date of the first issue of the Certificate: 12.04.2022

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

IFU

EN

Dvot

Anterior nasal swab
Lateral Flow Immunoassay
Self-Testing

SARS-CoV-2 & RSV & MP & ADV & Flu A/B

Antigen Combo Test Kit

- SARS-Cov-2
- Adenovirus (ADV)
- Influenza A
- Respiratory Syncytial Virus (RSV)
- Influenza B
- Mycoplasma Pneumoniae(MP)

You must follow the test instructions carefully to get an accurate result.

Call Feng Chun Yuan Medical Equipment (Shenzhen) Co., Ltd at +86 755 2790 0876

Or visit www.fcy-medical.com to obtain the complete instructions for use.

BEFORE THE TEST

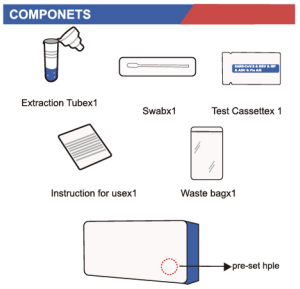
Wash your Hands

Before starting the test, wash your hands thoroughly for 20 seconds with soap or hand sanitizer, and dry your hands before testing.

Get a Timer

Not provided with the kit

COMPONETS



Package Keep the package for later use
Unpack the test skit and take all the components out.

STEP BY STEP GUIDANCE

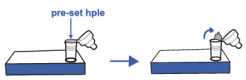
Self-Testing	Test by adult
14 ≤ Age	Self-Test
Disabled, elderlies, or who need assistance	Test by another adult

STEP 1: Prepare Your Test

1.Open Test Cassette

Unpack the test cassette and put it on a flat surface. Must start the test within 30 minutes after unpacking.

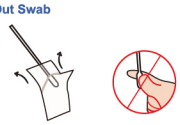
2.Place The Tube



Insert the extraction tube straight into the pre-set hole on the package box. Carefully peel off the aluminum foil seal, and do not spill the liquid out of the tube.

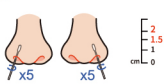
STEP 2: Collect Sample

3.Take Out Swab



Unpack the swab, DO NOT touch the swab tip!

4.Collect Sample from Both Nostrils

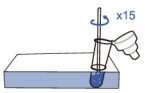


Gently insert the soft end of the swab about 1.5 to 2 cm into a nostril, slowly rotate against the nasal wall 5 times for approximately 15 seconds, repeat in the other nostril using the same swab.

Note: If you are testing a child, please make sure the child's head is kept steady during the swabbing. The depth of swabbing should be less than when adults are tested.
It is necessity to use protective equipment (gloves, mask) when you test others.

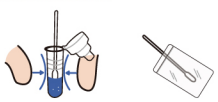
STEP 3: Process Sample

5.Rotate Swab Against Tube



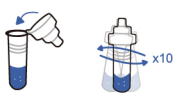
Withdraw the swab from your nostril, and insert the swab tip into the bottom of the tube. Slowly rotate the swab against the inside wall of the tube for 15 times.

6.Squeeze/Take out Swab



Gently squeeze the swab tip against the inside wall of the extraction tube. Withdraw the swab. Dispose it into the waste bag.

7.Shake/ Mix sample

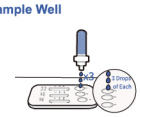


Close the dripper firmly. Gently shake the extraction tube 10 times.

STEP 4: Testing

8.Drop 3 Drops to Each Sample Well

Note:
If there isn't enough for 3 drops, please use a new kit, and re-do the previous steps.



Drip three drops of sample vertically into the each sample well on the cassette. and start timing.

9.Read Result After 8 Minutes

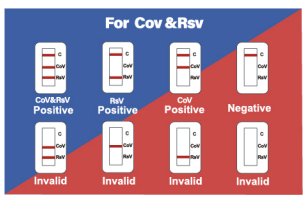
Read the result between 8 to 30 minutes. Result becomes INVALID after 30 minutes.

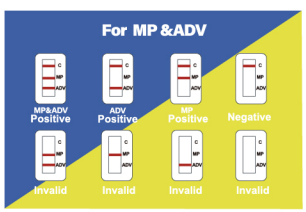
10.Dispose The Waste

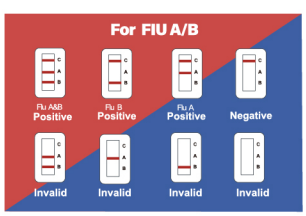
Place all test pieces in the waste bag, then throw the waste bag away. The disposal of used test components according to the local regulations.

Reading Result

Please share test results with your healthcare provider.







Intended Use

The SARS-CoV-2 & RSV & MP & ADV & Flu A/B Antigen Combo Test Kit is a lateral flow immunoassay intended for the vitro diagnostic qualitative rapid detection of nucleocapsid protein antigen from swab samples from individuals who are suspected of COVID-19 and / or Influenza A+B and / or RSV or MP or ADV within the first seven (7) days of symptom onset. Children of 2-13 years old should be tested by adult.Disabled,elderlies or who need assistance should be tested by another adult.

Test Principle

Antigen Combo Test Kit is based on the principle of Lateral Flow Immunoassay, which is intended for the qualitative rapid detection of nucleocapsid protein from SARS-CoV-2, Influenza A ,Influenza B,RSV,MP and ADV virus in bilateral anterior nasal (AN) swab specimens from patients who are suspected of COVID-19 within the first seven (7) days of symptom onsets.

When the sample is added to the sample well, the nucleocapsid protein in the sample reacts with the gold dye-labeled antibody.It forms an immuno-complex,which flows onto the nitrocellulose membrane. When the immuno-complex reaches the T Line (Test band), it bind to the immobilized capture antibody line on the nitrocellulose membrane then develops color on the T Line (Test band), which indicates a positive result. Regardless of whether the sample contains nucleocapsid protein, the gold dye-labeled quality control antigen will bind to the coated antibody at the C band and develop color.

STEP BY STEP GUIDANCE

Reagents and Materials	1 test/kit	5 tests/kit	25 tests/kit
Test cassette	1	5	25
Specimen collection swab	1	5	25
Extraction tube with buffer	1	5	25
Waste bag	1	5	25
Instruction of use	1	1	1

Materials Required but not Provided

Timer, Personal Protective Equipment

Storage and Stability

Store at temperature of 2-30°C(35.6-86°F) in a dry shady place. Avoid direct sunlight. Do not freeze the kit or its components, 12months of shelf life (Production date to expiration date).

After the pouch is unsealed, the device should be used as soon as possible within 30 minutes

Test Limitations

1. The test results of this product are for diagnostic aid only and cannot be used as the sole basis for confirming or excluding the diagnosis. To achieve diagnostic purposes, the results should always be assessed in combination with clinical examination, medical history, and other laboratory data.
2. This product is only indicate the presence of SARS-CoV-2 and / or Influenza A/Influenza B antigens in the anterior nasal specimen. Other specimen types may lead to incorrect results and must not be used.
3. Subject to the limitations of the assay methodology, the questionable results should be verified with other test methodologies.
4. Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test
5. Positive test results do not rule out co-infections with other pathogens.
6. False-negative test results may occur if a specimen is improperly collected transported, or handled.
7. False-negative test results may occur if the level of an antigen in a sample is below the detection limit of the test.
8. False negative results are more likely after eight days or longer of symptoms.
9. False positive results may occur if contamination.
10. Negative results don't preclude SARS- CoV-2 and Influenza A or Influenza B infection and they cannot be used as the sole basis for treatment or other management decisions. Should be confirmed with a molecular assay.
11. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result, avoid touching any bleeding areas when collecting specimens.

Warnings and Precautions

1. Do not re-use the items.
2. If you have problems with your hands or vision, you may need someone to assist you with the swabbing and testing process.
3. Do not eat or drink for at least 30 minutes before doing the test to reduce the risk of spoiling the test.
4. Do not use the kit if opened, damaged, or expired, keep test card sealed in its foil pouch before use.
5. Avoid splashing or aerosol formation of specimen and buffer.
6. Do not dilute the collected swab with any solution except for the provided extraction buffer.
7. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
8. Samples with invalid results must be retested.
9. Do not store the test kit in direct sunlight.
10. Use the specimen collection swab in the kit, use of alternative swabs may result in false negative results.
11. Collect samples as soon as possible within 7 days of sympto monset.
12. The reagent solution contains harmful chemicals (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, please seek help from healthcare professional.

Hazardous ingredients for Reagent Solution

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
ProCline TM 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.03%

Diagnostic Sensitivity/Specificity

The SARS-Cov-2 & Influenza A+B Antigen Combo Test Kit has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method. One anterior nasal swab sample and one nasopharyngeal swab sample (for RT-PCR comparator test) were collected from each individual.

SARS-CoV-2 Antigen	PCR Test		
	Positive	Negative	Total
Positive	104	0	104
Negative	6	450	456
Total	110	450	560
PPA	104/110, 94.55% (95% CI, 88.61% to 97.48%)		
NPA	450/450, >99% (95% CI, 99.15% to 100%)		
TPA	554/560, 98.93% (95% CI, 97.68% to 99.51%)		

Influenza A Antigen	PCR Test		
	Positive	Negative	Total
Positive	57	0	57
Negative	6	104	110
Total	63	104	167
PPA	57/63, 90.48%(95% CI, 80.74% to 95.56%)		
NPA	104/104, >99% (95%CI, 96.44%% to 100%)		
TPA	161/167, 96.41% (95%CI, 92.38% to 98.34%)		

Influenza B Antigen	PCR Test		
	Positive	Negative	Total
Positive	55	0	55
Negative	5	106	111
Total	60	106	166
PPA	55/60, 91.67%(95% CI, 81.93% to 96.39%)		
NPA	106/106, >99% (95%CI, 96.50% to 100%)		
TPA	161/166, 96.99% (95%CI, 93.14% to 98.71%)		

RSV Antigen	PCR Test		
	Positive	Negative	Total
Positive	44	3	47
Negative	3	168	171
Total	47	171	218
PPA	44/47, 93.62% (95% CI, 88.61% to 97.48%)		
NPA	167/171, 98.25% (95% CI, 99.15% to 100%)		
TPA	212/218, 97.24% (95% CI, 97.68% to 99.51%)		

Mycoplasma Pneumoniae(MP) Antigen	PCR Test		
	Positive	Negative	Total
Positive	89	1	90
Negative	9	185	194
Total	98	186	284
PPA	89/98, 90.82%(95% CI, 83.46% to 95.09%)		
NPA	185/186, >99.46% (95%CI, 97.05% to 99.9%)		
TPA	274/284, 96.48% (95%CI, 93.64% to 98.08%)		

Adenovirus (ADV) Antigen	PCR Test		
	Positive	Negative	Total
Positive	93	1	94
Negative	9	188	197
Total	102	189	291
PPA	93/102, 91.18%(95% CI, 84.08% to 95.29%)		
NPA	188/189, >99.47% (95%CI, 97.06%% to 99.91%)		
TPA	281/291, 96.56% (95%CI, 93.79% to 98.12%)		

Limit of Detection (Analytical Sensitivity)

The LoD for SARS-CoV-2/Influenza A/ Influenza B were as follows.

Virus Strains	LoD	#Positive/#Tot al
SARS-CoV-2	252 TCIDso/mL	20/20
Influenza A H1N1 A/Florida/3/2006	56 TCIDso/mL	20/20
Influenza A H3N2 A/Hong Kong/8/68	30 TCIDso/mL	20/20
Influenza B Victoria Lineage B/Florida/78/2015	84 TCIDso/mL	20/20
Influenza B Yamagata Lineage B/Florida/4/2006	15 TCIDso/mL	20/20

Cross-reactivity and Microbial Interference

In the cross-reactivity study and the microbial interference study, no cross-reactivity and microbial interference were observed for any microorganisms examined at the indicated concentrations.

For SARS-CoV-2:

Human coronavirus 229E	Influenza B Washington/02/19
Human coronavirus OC43	Enterovirus Type 68 Major Group
Human coronavirus NL63	Respiratory syncytial virus Type A
MERS-coronavirus	Rhinovirus Type 1A
SARS-coronavirus	*Haemophilus influenzae*, type b
Adenovirus 1	*Streptococcus pneumoniae*
Human Metapneumovirus 16 (hMPV-16) Type A1	*Streptococcus pyogenes*
Parainfluenza virus 1	*Candida albicans*
Parainfluenza virus 2	Pooled human nasal wash – *respiratory microbial flora*
Parainfluenza virus 3	*Bordetella pertussis*
Influenza A H1N1	*Mycoplasma pneumoniae*
Influenza A H3N2	*Chlamydia pneumoniae*
TFexas/50/12	*Legionella pneumophila*
Influenza A H1N1pdm California/07/2009	*Staphylococcus aureus*
Influenza B Colorado/6/17	*Staphylococcus epidermidis*
Influenza B Utah/5/14	

For Influenza A and Influenza B:

Human coronavirus 229E	Measles
Human coronavirus OC43	Human metapneumovirus
Human coronavirus NL63	Mumps virus
SARS-coronavirus	Respiratory syncytial virus
Adenovirus 1	*Bordetella pertussis*
Adenovirus 7	*Chlamydia trachomatis*
Parainfluenza virus 1	*Corynebacterium diphtheriae*
Parainfluenza virus 2	*Escherichia coli*
Parainfluenza virus 3	*Hemophilus influenzae*
Staphylococcus aureus	*Legionella pneumophila*
Streptococcus pneumoniae	Moraxella catarrhalis
Streptococcus pyogenes	*Mycobacterium tuberculosis (avirulent)*
Staphylococcus epidermidis	*Mycoplasma pneumoniae*
Streptococcus salivarius	*Neisseria meningitidis*
Cytomegalovirus	*Neisseria subflava*
Enterovirus	*Pseudomonas aeruginosa*
Epstein Barr Virus	

Interference Substances Studies

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. The performance of the SARS-Cov-2 & Influenza A+B Antigen Combo Test Kit was not affected by any of the potential interfering substances listed in the table below at the concentration tested.

Whole Blood	4% v/v	Biotin	1:10 dilution
Mucin	0.5% w/v	Homeopathic Nasal Wash	1:10 dilution
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	Sore Throat Phenol Spray	15% v/v
Naso GEL (NeilMed)	5% v/v	Tobramycin	4 µg/mL
CVS Nasal Drops (Phenylephrine)	15% v/v	Mupirocin	10 mg/mL
Afrin (Oxymetazoline)	15% v/v	Fluticasone Propionate Tamiflu (Oseltamivir Phosphate)	5% v/v
CVS Nasal Spray (Cromolyn)	15% v/v		5 mg/mL
Zicam	5% v/v		

Description of Symbols

Symbol	Illustration	Symbol	Illustration
	Temperature limitation		Use-by date
LOT	Batch code		Caution
	Manufacturer		Do not resterilize
IVD	In vitro diagnostic medical device		Keep dry
REF	Catalogue number		Consult instruction for use or consult electronic instructions for use
	Date of manufacture	EC REP	Authorized representative in the European Community / European Union
	Do not re-use		
	Keep away from sunlight		

FENG CHUN YUAN MEDICAL EQUIPMENT(SHENZHEN)CO., LTD
Room1304 & Room 504 , No.48, Xinyu Road, Xiangshan Community, Xinqiao Street, Baoan District, Shenzhen,Guangdong, China, 518 000
Tel: +86 (755) 2790 0876
Email: market@fcy-medical.com
Share Info Consultant Service LLC
EC REP Repräsentanzbüro
Address: Heerdter Lohweg 83, 40549 Düsseldorf

BUREAU VERITAS
Certification

Feng Chun Yuan Medical Equipment (ShenZhen) Co., Ltd.

Room 1304 & Room 504, No. 48, Xinyu Road, Xiangshan Community, Xinqiao Street, Baoan District Shenzhen City, Guangdong Province P.R.China

Certified site:

Room 1304 & Room 504, No. 48, Xinyu Road, Xiangshan Community, Xinqiao Street, Baoan District Shenzhen City, Guangdong Province P.R.China

Bureau Veritas Italia S.p.A. certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 13485:2016

Scope of certification

Design and Manufacture of immunoassay detection reagent, as an aid in clinical assessment of infectious diseases detection. Design and Manufacture of Sterile sample collection Swab, Disposable medical face masks.

Original cycle start date by another certification body:	**04/08/2020**
Expiry date of previous cycle:	**03/08/2023**
Certification / Recertification Audit date:	**10/06/2023**
Certification / Recertification cycle start date:	**26/07/2023**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **03/08/2026**

Certificate No. - Version: IT324652-1 Revision date: **26/07/2023**

GIORGIO LANZAFAME – Local Technical Manager

Certification body address:
Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 009A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC mutual Recognition Agreements

Shipping Details

CB	
QTY :	360 PCS
G.W :	14 KG
MEAS :	46X44X44CM

Manufacturer: Feng Chun Yuan Medical Equipment(Shenzhen)Co., Ltd
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