SARS-CoV-2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP Antigen Rapid Test Kit (Immunochromatographic Assay) USER INSTRUCTION



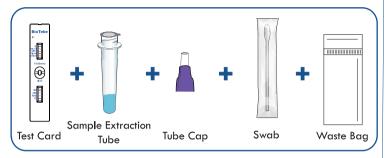


- 1. Read this instruction guide carefully.
- 2. Have ready a watch (or a clock/timer), tissues and either hand sanitizer or soap and warm water.
- 3. Check the test kit contents to make sure that nothing is damaged or broken.

- -For oropharyngeal swabs.
- -Please read the instructions carefully before you begin testing.







Note: Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.

Note: Materials required but not provided.

- (1) Watch (or a clock/timer),
- (2) Tissues.
- (3) Hand sanitizer / soap.



Wash your hands thoroughly for at least 20 seconds before the test.







Put the tube into the kit box holder and gently peel off the aluminum foil seal.



Either of the anterior nasal swab collection and the oropharyngeal swab collection can be chosen. Once the collection is complete, the later test steps are the same.

Remove the swab from its wrapper and take out the swab by holding the handle. Do not touch the fabric tip of the swab with your hands.









Oropharynaeal swabs collection:

Oropharyngeal swab collection: Insert the swab in the mouth completely into the pharynx, centering on the red swelling of the pharynx wall and upper anterior tonsils. Wipe both sides of pharyngeal tonsils and pharynx posterior wall with moderate force, avoid touching the tongue, and remove the swab.



Insert the swab into the sample tube. Touch the bottom of the sample tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by fingers 5 times.



Remove the swab by rotating against the sample tube while squeezing the sides of the tube to release the liquid from the swab. Remove and discard



Screw the purple tube cap onto the sample tube and then unscrew the top white cap.





Open the pouch and take out the Test Card. Place it on a flat, dry and clean surface. Turn the tube integrated dropper cap upside down and vertically at 90 degrees, gently squeeze to slowly and evenly drip 3 or 4 drops of liquid from the dropper into the sample hole of the detection card.

(Note: Improper operation may cause too much or too little liquid to drip into the sample hole, which can affect the detection results.)













IMPORTANT

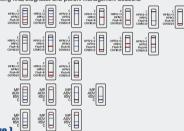
(Positive)

Two colored (C) lines appear in two separate windows, If the other line appears, the corresponding pathogen is positive

Special Flu A+B with red color representing influenza A virus and blue color representing

Note: A positive result means that you are likely to be infected with SARS-CoV-2/Influenza A virus/ Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus 1+3/ Respiratory syncytial

Note: Test results should always be interpreted in the context of clinical observations and epidemiological

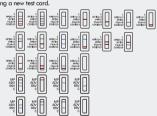


Two colored (C) lines appear in each window, and if no other lines appear, the corresponding pathogen is negative. However, a negative result does not exclude the absence of SARS-CoV-2/Influenza A virus/Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus 1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae infection and should not be used as the sole basis fo

treatment or patient management decisions. Negative results should be considered in the context of the individual's recent exposure history medical history and the presence of clinical signs and symptoms consistent with SARS-CoV-2/Influenza A virus/Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza

virus1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae and confirmed by nucleic acid testing as necessary for patient management. f Invalid)

If any of the control (C) lines do not appear, the test must be interpreted as invalid. An invalid test result means that your test has encountered an error and the results cannot be interpreted You will need to retest using a new test card.





All used test components should be disposed of in your household waste. After completing all sampling and testing steps, wash hands or use hand sanitizer.







BioTeke



USER INSTRUCTION

For oropharyngeal swabs.

SARS-CoV-2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP Antigen Rapid Test Kit (Immunochromatographic Assay)

PRODUCT NAME

SARS-CoV-2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP Antigen Rapid Test Kit

PACKAGE SPECIFICATION

1 Test/Kit; 20 Tests/Kit

INTENDED USE

This kit is only used for the in vitro qualitative detection of respiratory multipathogen antigen SARS-CoV-2/Influenza A virus/Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae from human oropharyngeal swab specimens.

TEST PRINCIPLE

The kit is immunochromatographic and uses double-antibody sandwich method to detect SARS-CoV-2/Influenza A virus/Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae antigen, During detection, the treated specimens are loaded into the sample wells of the test card. When the concentration of SARS-CoV-2/Influenza A virus/Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus1+3/ Respiratory syncytial virus/ Adenovirus /Mycoplasma pneumoniae antigen in specimen is higher than the minimum detection limit, the viral antigen will form complexes with labeled antibodies first. Under chromatography, antigen-antibody complexes move forward along the nitrocellulose membrane till captured by pre-coated monoclonal antibody of SARS-CoV-2/Influenza A virus/Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus 1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae in the detection zone on the nitrocellulose film to form a red or blue reaction line on the detection zone indicating the test result is positive. Conversely, if there is no viral antigen or the concentration of antigen in specimen is below the minimum detection limit, no red/blue reaction line appears in the detection zone, and the test result is negative. Regardless of whether the sample contains viral antigens or not, a dark blue/purple reaction line will appear in the quality control zone (C). This is the relevant criterion for determining the chromato graphy process as "normal"

MATERIALS PROVIDED

The test kit consists of test card, sample extraction tube, tube cap, swab and waste bag.

	Main	Loading quanti	ty (Specification)
Components	Ingredients	1 Test/Kit	20 Tests/Kit
Test card	Test strip containing specific SARS-CoV-2/Influenza A virus/ Influenza B virus / Human Parainfluenza virus 1-2/ Human Parainfluenza virus 1-3/ Respiratory syncytial virus/ Adenovirus / Mycoplasma pneumoniae monoclonal antibody, Anti-mouse IgG polyclonal antibody	1pc	20pcs
San	ple extraction tube	1pc	20pcs
	Tube cap	1pc	20pcs
	swab	1pc	20pcs
	Waste bag	1pc	20pcs

 Test cards are sealed together with desiccant in an aluminum foil pouch. Do not use different batches of test cards and sample extraction tubes.

STORAGE CONDITIONS AND SHELF LIFE

The test card and sample extraction tube should be stored at 2°C~30°C, to be valid for 24 months. Test cards should be used as soon as possible (maximum time: within 1 hour after opening the foil pouch. The bottle of the sample extraction tube should be capped immediately after use and stored at 2°C~30°C. Only use it within the validity period. Date of manufacture and expiration: See package label for details.

SPECIMEN REQUIREMENTS

The swab specimen should be tested immediately after collection.

LIMITATIONS OF THE TEST

 The test results of this kit can only serves reference for clinicians and should not be used as the sole basis for a clinical diagnosis and treatment. Clinical management of patients should be included the context of their signs and symptoms, their medical historyother laboratory tests, and response to treatment

2. The quality of the sampling technique and the specimen processing have a greater impact on the detection of pathogens included in this test kit. Thus, a negative test result does not exclude the possibility of a viral infection.

3. Due to methodological limitations of antigen-based test, the analytical sensitivity of immunochromatographic tests is generally lower than that of nucleic acid-based test. Therefore, any test interpretation should pay high attention to negative results and make a comprehensive judgment based on other test results. If cinically necessary, negative results in should be checked by nucleic acid test or virus culture identification. 4. When the test result is positive, it is recommended to apply other methods such as PCR or viral culture for further confirmation if clinically relevant. if necessary or mandated by authorities, please also consult with your local public health office appropriate action.

5. Secifically, false-negative results may occur, if:

(i) Improper sample collection, transport and processing, or low viral titers in the sample

(ii) samples were taken too early or too late after infection, so that peak viral titers were missed. Multiple samplings at multiple sites in the same patient may help avoid false negative results.efore, multiple sampling at multiple sites in the same patient may avoid

PERFORMANCE CHARACTERISTICS

- . The width of the membrane strip of this kit is not less than 2.5 mm, and the liquid migration speed is not less than 10 mm/min.
- 2. Negative/positive reference coincidence rate

All the positive references are positive for the corresponding pathogens, which is consistent with the known results of the reference. All the negative references are negative for the corresponding pathogen

3. Repeatability

Repeated testing was conducted for national or enterprise repeatable reference products for 10 times. The test results were consistent with the known results of the reference products and were uniform in color.

4. Analytical specificity

2) Cross-reactivity

SARA-CoV-2		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total	Influenza A		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total	
		Positive	Negative				Positive	Negative		
SARS-CoV-2/Hu A+B/ HPIV2/HPIV1+3/RSV/	Positive	131	0	131	SARS-CoV-2/Flu A+B/ HPIV2/HPIV1+3/RSV/	Positive	123	0	123	
ADV/MP Antigen Rapid Test Kit	Negative	8	901	909	ADV/MP Antigen Rapid Test Kit	Negative	11	906	917	
Total		139	901	1040	Total		134	906	1040	
Statistic	Value	,	95%CI		Statistic	Value		95%CI		
Sensitivity	94.249	6 (88.	97%~97.4	8%)	Sensitivity	91.79	% (85.	79%~95.8	3%)	
Specificity	100.00	% (99.5	59% ~10 0.	00%)	Specificity	100.00	% (99.5	59%~100.	00%)	
Total coincidence rate	99.23%	6 (98.	49%~99.6	996)	Total coincidence rate	98.949	% (98.	12%~99.4	7%)	
Influenza B		Respi SARS-Co	QIAstat-Dx Respiratory ARS-CoV-2 Panel Tot		Human Parainfluenza virus2		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total	
		Positive	Negative				Positive	Negative		
SARS-CoV-2/Flu A+B/ HPIV2/HPIV1+3/RSV/ ADV/MP Antigen	Positive	119	0	119	SARS-CoV-2/Flu A+B/ HPIV2/HPIV1+3/RSV/ ADV/MP Antigen	Positive	109	0	109	
Rapid Test Kit	Negative		909	921	Rapid Test Kit	Negative	11	920	931	
Total		131	909	1040	Total		120	920	1040	
Statistic	Value		95%CI		Statistic	tic Value		95%CI		
Sensitivity	90.849	% (84.	(84.55%~95.18%)		Sensitivity	90.839	6 (84.19%~95.33%)			
Specificity	100.00	% (99.6	(99.60%~100.00%)		Specificity	100.00	% (99.60%~100.00%)			
Total coincidence rate	98.859	% (97.	99%~99.4	0%)	Total coincidence rate	coincidence rate 98.94		% (98.12%~99.47%)		
Human Parainfluenza virus1+3		QIAstat-Dx Respiratory SARS-CoV-2 Panel Tot		Total	Respiratop		Resp	QIAstat-Dx Respiratory SARS-CoV-2 Panel		
		Positive	Negative		Syncytial Vi	rus	Positive	Negative		
SARS-CoV-2/Flu A+B/ HPIV2/HPIV1+3/RSV/	Positive	105	0	105	SARS-CoV-2/Flu A+B/ HPIV2/HPIV1+3/RSV/	Positive	101	0	101	
ADV/MP Antigen Rapid Test Kit	Negative	12	923	935	ADV/MP Antigen Rapid Test Kit	Negative	13	926	939	
Total		117	923	1040	Total		114	926	1040	
Statistic	Value	,	95%CI		Statistic	Value	95%CI			
Sensitivity	89.749	% (82.	77%~94.5	i9%)	Sensitivity 88.609		% (81.29%~93.79%)			
Specificity	100.00	% (99.6	60%~100.	00%)	Specificity 100.00		0% (99.60%~100.00%)			
Total coincidence rate	98.859	6 (97.	99%~99.4	10%)	Total coincidence rate	98.75	% (97.87%~99.33%)		3%)	
Adenoviru	ıs	Respi	QIAstat-Dx Respiratory ARS-CoV-2 Panel Total		Mycoplasmal Pneumonia		QIAstat-Dx Respiratory SARS-CoV-2 Panel T		Total	
		Positive	Negative		Fileumon	ıa	Positive	Negative		
SARS-CoV-2/Flu A+B/ HPIV2/HPIV1+3/RSV/	Positive	113	0	113	SARS-CoV-2/Flu A+B/ HPIV2/HPIV1+3/RSV/	Positive	101	0	101	
ADV/MP Antigen Rapid Test Kit	Negative	10	917	927	ADV/MP Antigen Rapid Test Kit	Negative	11	928	939	
Total		123	917	1040	Total		112	928	1040	
Statistic	Value		95%CI		Statistic	Value		95%CI		
Sensitivity	91.879	% (85.	56%~96.0	3%)	Sensitivity	90.189	6 (83.	11%~94.9	9%)	
	100.00	c (00 f	00/ - 100			100.00	N /00 0		1,000	
Specificity	100.00	90 (99.0	i0%~100.	00%)	Specificity	100.00	90 (99.0	60%~100.0	1050]	

	o cross-reactivity with the	following pathogens:	
No.	Virus/ Bacteria name	Strain	Concentration / CT value
1	Coronavirus HKU I	GZ/1804-138	CT:23

	Virus/		Concentration
No.	Virus/ Bacteria name	Strain	/CT value
2	Coronavirus OC43	VR-1558, OC43	4.2×10 ⁵ TCID ₅₀ /mL
3	Coronavirus NL63	NL63	1.6×10 ³ TCID ₅₀ /mL
4	Coronavirus 229E	229E/GZ/1801-3	5.6×10 ⁶ TCID ₅₀ /mL
5	Rhinovirus (group A)	A30/GZ/1710-89	4.2×10 ⁶ TCID ₅₀ /mL
6	Rhinovirus (group B)	70/F02-2547	1.0×10 ⁶ TCID ₅₀ /mL
7	Enterovirus (CA16)	CA16 /Guangzhou/0302/2011	1.8×10 ⁷ TCID ₅₀ /mL
8	Enterovirus (Echo)	ATCC VR-39, HILL	1.0×10 ⁶ TCID ₅₀ /mL
9	Enterovirus (EV71)	EV71/Guangzhou/0402/2 012	5.6×10 ⁶ TCID ₅₀ /mL
10	Epstein-barr virus capsid antigen	B95-8	CT: 17
11	Measles virus	Edmonston	1.0×10 ⁷ TCID ₅₀ /mL
12	Human cytomegalovirus	RC256	3.2×10 ³ TCID ₅₀ /mL
13	Rotavirus	VR-2018	CT: 20
14	Norovirus	ATCC VR-3234SD	3.6×10 ⁵ Copies/μL
15	Mumps virus	Jones	1.0×10 ⁷ TCID ₅₀ /mL
16	Varicella zoster virus	VR-1367	CT: 13
17	MERS-coronavirus	EMC/2012	1.6×10 ⁵ TCID ₅₀ /mL
18	Human metapneumovirus	GZ/1803-107	1.0×10 ⁵ TCID ₅₀ /mL
19	Haemophilus influenzue	GIM 1.961.	4.8×10 ⁷ CFU/mL
20	Chlamydia pneumoniae	ATTC VRJ-2282, TW183	4.2×10 ² TCID ₅₀ /mL
21	Streptococcus pyogenes	ATCC 19615	1.6×10 ⁸ CFU/mL
22	Pooled human pharyngeal washes	N/A	100%
23	Bordetella pertussis	GDM 1.952	2.6×10 ⁹ CFU/mL
24	Legionella pnuemophila	Philadelphial, Brenner	1.9×10 ⁶ CFU/mL
25	Staphylococcusaureus aureus	CMCC(B) 26003	2.6×10 ⁹ CFU/mL
26	Staphylococcus epidermidis	191 (Winslow and Winslow) Evans	7.7x10 ⁵ CFU/mL
27	Candida albicans	CMCC(F) 129002	1.3x10 ⁸ CFU/mL
28	Streptococcus pneumoniae	(Klein) Chester	1.0×10 ⁶ CFU/mL
Bioteke t	est detects all the path	ogens listed below: SARS-0	oV-2/Influenza A virus/

Bioteke test detects all the pathogens listed below: SARS-CoV-2/Influenza A virus/ Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus 1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae

No.	Virus/Bacteria name	Strain	Concentration/ CT value
1	Influenza A virus 2009HIN1	L19-A1/Si chuan/SWL1/2009	4.2×10 ⁶ TC I D ₅₀ /mL
2	Influenza A virus seasonal HINI	L6-A1/ Liaoning huanggu /1183/2007	5.6×10 ⁵ TCID ₅₀ /mL
3	Influenza A virus H3N2	L8-A3/ Brisbane/10/2007	1.0×10 ⁶ TC I D ₅₀ /mL
4	Influenza A virus H5N1	A/Chicken/Liaoning/SD007/ 2017(H5N1)	CT: 20
5	Influenza A virus H7N9	A/Guangd/17SF003/2016(H7 N9)	CT: 20

<u> </u>		
Influenza B virus Yamagata	GZ/174/201803	5.6×10 ⁶ TCID ₅₀ /mL
Influenza B virus Victoria	GZ/133/201712	1.0×10 ⁶ TCID ₅₀ /mL
Respiratory syncytial virus A	RSVA/GZ/Hecin1705-74	1.3×10 ⁵ TCID ₅₀ /mL
Respiratory adenovirus type I	ADVI IGZ/Hecin1608-21	2.4×10 ⁸ TCID ₅₀ /mL
Respiratory adenovirus type 2	GZ/1705-34/2017	5.6×10 ⁵ TCID ₅₀ /mL
Respiratory adenovirus type 3	ADV3/GZ/0101/2011	1.0×10 ⁶ TCID ₅₀ /mL
Respiratory adenovirus type 4	ADV4/GZ/Hecin1611-72/2016	5.6×10 ⁵ TCID ₅₀ /mL
Respiratory adenovirus type 5	ADV/GZ/1801-54	1.0×10 ⁷ TCID ₅₀ /mL
Respiratory adenovirus type 7	ADV7/GZ/1706-198	3.2×10 ⁷ TCID ₅₀ /mL
Respiratory adenovirus type 55	ADV55/GZ/1612-129	3.2×10 ⁸ TCID ₅₀ /mL
SARS-CoV-2	Wild Type	2.8×10 ⁶ TCID ₅₀ /mL
Mycoplasma pneumoniae	ATCC 15531	1.0×10 ⁹ Copies/mL
Human Parainfluenza virus 1	PIV1/Guangzhou/07011	1.3×10 ⁷ TCID ₅₀ /mL
Human Parainfluenza virus 2	PIV2/GZ/Hecin171134/20 17	5.6×10 ⁷ TC I D ₅₀ /mL
Human Parainfluenza	PIV3/Guangzhou/0903/2 012	3.2×10 ⁵ TCID ₅₀ /mL
Human Parainfluenza virus 4a	ATCC VR-1378, M-25	4.5×10 ⁵ TC I D ₅₀ /mL
Human Parainfluenza	ATCC VR-1377, CHI 9503	1.3×10 ⁷ TC I D ₅₀ /mL
	Yamagata Influenza B virus Victoria Respiratory syncytial virus A Respiratory adenovirus type1 Respiratory adenovirus type2 Respiratory adenovirus type3 Respiratory adenovirus type4 Respiratory adenovirus type5 Respiratory adenovirus type5 Respiratory adenovirus type7 Respiratory adenovirus type7 Respiratory adenovirus type5 SARS-CoV-2 Mycoplasma pneumoniae Human Parainfluenza virus 1 Human Parainfluenza virus 2 Human Parainfluenza virus 3 Human Parainfluenza virus 4a Human Parainfluenza	Yamagata GZ/174/201803 Influenza Bvirus Victoria GZ/333/201712 Respiratory syncytial virus A RSVA/GZ/Hecin1705-74 Respiratory adenovirus type 1 ADVI IGZ/Hecin1608-21 Respiratory adenovirus type 2 GZ/1705-34/2017 Respiratory adenovirus type 3 ADV3/GZ/0101/2011 Respiratory adenovirus type 4 ADV4/GZ/Hecin1611-72/2016 Respiratory adenovirus type 5 ADV/GZ/1801-54 Respiratory adenovirus type 5 ADV7/GZ/1706-198 Respiratory adenovirus type 5 ADV55/GZ/1612-129 Mycoplasma pneumoniae Human Parainffuenza virus 1 ATCC 15531 Human Parainffuenza virus 3 PIV1/Guangzhou/07011 Human Parainffuenza virus 3 PIV3/Guangzhou/0903/2 Human Parainfluenza virus 4 ATCC VR-1378, M-25 Human Parainfluenza virus 4 ATCC VR-1377, CH19503

PRECAUTIONS

- This is a single-use in vitro diagnostic reagent, do not reuse and do not use expired products 2. All test specimens must be considered potentially infectious, and during collection, processing, storage, mixing of specimens appropriate protective measures should be applied. For example, gloves and masks should be used as appropriate and waste (like used swabs, test cards, extraction tubes) should be handled as potentially biohazardous items. 3. Use the swab and sample extraction tube provided with this reagent for sampling, and do
- not use different batches of test cards and sample extraction tubes.
- 4. Use only fresh specimens for testing, do not use repeated freeze-thawn samples. 5. Operate at room temperature. Test cards kept at lower temperatures should be brought to room temperature before opening to avoid moisture absorption.
- 6. Do not use reagent kits with obvious damage or after their expiration date.
- 7. The aluminum foil pouch contains desiccant and must not be ingested.
- 8. Improper sample collection or processing may result in fals e-negative results.
- 9. Ensure proper sample loading volume, results may not be valid if too much or too little sample loading volume was applied to the test card.
- 10. In case of a positive result, please adhere to local rules, regulations and practices for reporting to your local public health agency.
- 11. For any test result, a final diagnosis should only be made by a physician by combining individual information from the medical history, physical examination, signs and symptoms with other test results, as appropriate,
- 12. If you have any questions or suggestions on the use of this kit, please contact the manufacturer. 13. For unknown reasons, long-term use of some drugs may lead to false positive results of the test,
- which are not covered by the interfering substances.

 14.If the test result is negative but the patient is still symptomatic or suspected of having an infection, serial testing is recommended over the next few days.

SYMBOLS





Contains sufficient

Date of



limit



Use-by









if package is diagnostic device



(SQ) CE mark of conformity

Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain

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Edition: A1



EC REP

C€

MedUnion S.L.

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图纸名称	呼吸道八联检说明书-英文	文件号	RD2114-15-04-001-A1	材质	双胶纸
尺寸	A4	颜色	见图纸		
设计/日期		审核/日期		批准/日期	