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

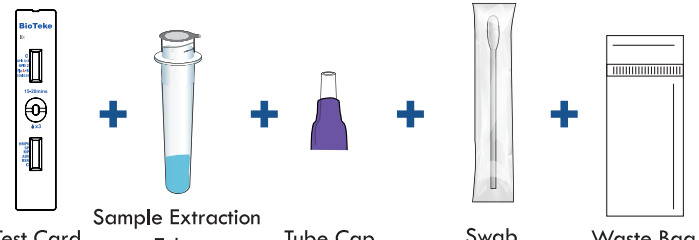
(Immunochromatographic Assay)

BioTeke 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 anterior nasal swabs or oropharyngeal swabs.
-Please read the instructions carefully before you begin testing.

CE IVD



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.

1

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

2

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

3

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.

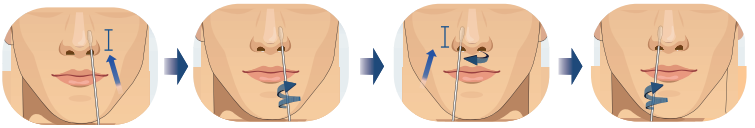
Remove the swab from its wrapper and take out the swab by holding the handle. Do not touch the fabric tip of the swab with your hands.

4

Anterior nasal swab collection:

NOTE: Please blow your nose before swabbing for specimen collection.

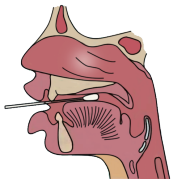
Gently insert the swab for less than one inch (about 2.5cm) into one nostril. Slowly rub the swab against all of the inside of your nose. Make at least 5 big circles. Do not just spin the swab. Repeat this step in your other nostril using the same swab.



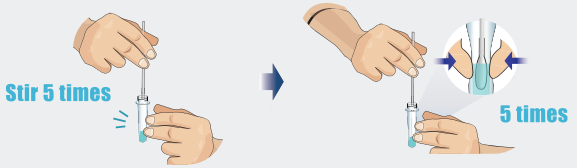
NOTE: With children, the maximum depth of insertion into the nostril maybe less than 3/4 inch, please adjust according to age.

Oropharyngeal swabs collection:

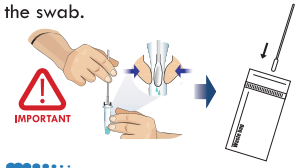
Oropharyngeal swab collection: Insert the swab in the mouth completely into the pharynx, centering on the red swelling of the pharynx wall and upper anterior tonsils. Wipe both sides of pharyngeal tonsils and pharynx posterior wall with moderate force, avoid touching the tongue, and remove the swab.



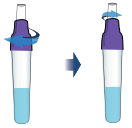
5 Insert the swab into the sample tube. Touch the bottom of the sample tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by fingers 5 times.



6 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 the swab.



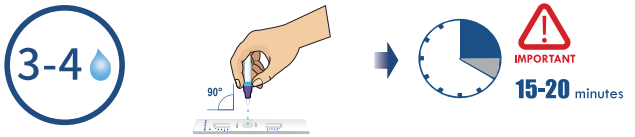
7 Screw the purple tube cap onto the sample tube and then unscrew the top white cap.



8

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.)



9 Results Interpretation

IMPORTANT

NOTE:
The test results should not be read after 30 minutes.

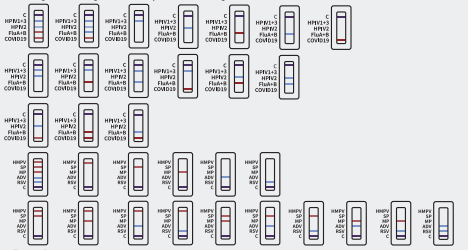
(Positive)

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 influenza B virus.

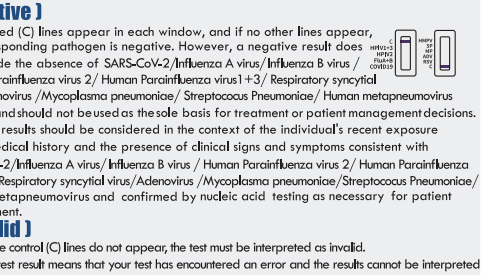
Note: A positive result means that you are likely to be infected with SARS-CoV-2/Influenza A virus/ Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae/ Streptococus Pneumoniae/ Human metapneumovirus.

Note: Test results should always be interpreted in the context of clinical observations and epidemiological data when making final diagnoses and patient management decisions.



(Negative)

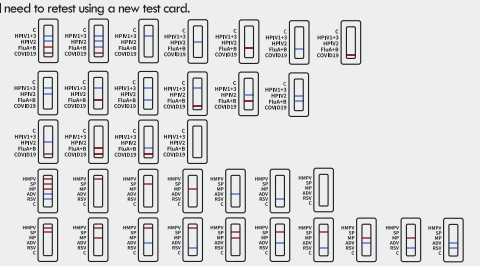
Two colored (C) lines appear in each window, and if no other lines appear, the corresponding pathogen is negative. However, a negative result does not exclude the absence of SARS-CoV-2/Influenza A virus/ Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae/ Streptococus Pneumoniae/ Human metapneumovirus infection and should not be used as the sole basis for 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/Streptococus Pneumoniae/ Human metapneumovirus and confirmed by nucleic acid testing as necessary for patient management.



(Invalid)

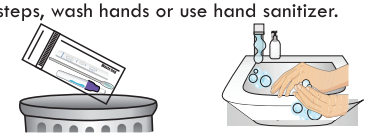
If any of the control (C) lines do not appear, the test must be interpreted as invalid.

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.



10

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.



USER INSTRUCTION

For anterior nasal swabs or oropharyngeal swabs.

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

PRODUCT NAME

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

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/ Streptococus Pneumoniae/Human metapneumovirus from human anterior nasal swabs or 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/ Streptococus Pneumoniae/Human metapneumovirus 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 /Streptococus Pneumoniae/Human metapneumovirus 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 virus1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae/Streptococus Pneumoniae/Human metapneumovirus 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 chromat o graphy process as "normal".

MATERIALS PROVIDED

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

Components	Main Ingredients	Loading quantity (Specification)	
		1 Test/Kit	20 Tests/Kit
Test card	Test strip containing specific SARS-CoV-2/Influenza A virus/ Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus1+3/ Respiratory syncytial virus/ Adenovirus /Mycoplasma pneumoniae/Streptococus Pneumoniae/Human metapneumovirus monoclonal antibody, Anti-mouse IgG polyclonal antibody	1pc	20pcs
Sample extraction tube		1pc	20pcs
Tube cap		1pc	20pcs
swab		1pc	20pcs
Waste bag		1pc	20pcs

Note:
1. Test cards are sealed together with desiccant in an aluminum foil pouch.
2. 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

1. 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 false negatives.

PERFORMANCE CHARACTERISTICS

1. 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 an d were uniform in color.

4. Analytical specificity
1) Clinical study

SARA–CoV–2

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	137	0	137
	Negative	1	1172	1173
Total		138	1172	1310

Statistic	Value	95%CI
Sensitivity	99.28%	(96.03%~99.98%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.92%	(99.58%~100.00%)

Influenza A

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	120	0	120
	Negative	2	1188	1190
Total		122	1188	1310

Statistic	Value	95%CI
Sensitivity	98.36%	(94.20%~99.80%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

Influenza B

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	122	0	122
	Negative	2	1186	1188
Total		124	1186	1310

Statistic	Value	95%CI
Sensitivity	98.39%	(94.30%~99.80%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

Human Parainfluenza virus2

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	124	0	124
	Negative	2	1184	1186
Total		126	1184	1310

Statistic	Value	95%CI
Sensitivity	98.41%	(94.38%~99.81%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

Human Parainfluenza virus1+3

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	125	0	125
	Negative	2	1183	1185
Total		127	1183	1310

Statistic	Value	95%CI
Sensitivity	98.43%	(94.43%~99.81%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

Respiratopry syncytial virus

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	131	0	131
	Negative	2	1177	1179
Total		133	1177	1310

Statistic	Value	95%CI
Sensitivity	98.50%	(94.67%~99.82%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

Adenovirus

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	127	0	127
	Negative	2	1181	1183
Total		129	1181	1310

Statistic	Value	95%CI
Sensitivity	98.45%	(94.51%~99.81%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

Mycoplasmal Pneumonia

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	119	0	119
	Negative	1	1189	1190
Total		120	1189	1310

Statistic	Value	95%CI
Sensitivity	99.17%	(95.44%~99.98%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.92%	(99.57%~100.00%)

Streptococcus Pneumoniae

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	134	0	134
	Negative	3	1174	1176
Total		136	1174	1310

Statistic	Value	95%CI
Sensitivity	98.53%	(94.79%~99.82%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

Human metapneumovirus

		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative	
SARS–CoV–2/Flu A+B/HPIV2/HPIV1+3/RSV/ADV/MP/SP/HMPV Antigen Rapid Test Kit	Positive	118	0	118
	Negative	2	1190	1192
Total		120	1190	1310

Statistic	Value	95%CI
Sensitivity	98.33%	(94.79%~99.82%)
Specificity	100.00%	(99.69%~100.00%)
Total coincidence rate	99.85%	(99.45%~99.98%)

2) Cross-reactivity
There is no cross-reactivity with the following pathogens:

No.	Virus/ Bacteria name	Strain	Concentration / CT value
1	Coronavirus HKU I	GZ/1804-138	CT: 23
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/0402/2012	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	Haemophilus influenzue	GIM 1.961.	4.8×10^7 CFU/mL
19	Chlamydia pneumoniae	ATTC VRJ-2282, TW183	4.2×10^2 TCID$_{50}$/mL
20	Streptococcus pyogenes	ATCC 19615	1.6×10^8 CFU/mL
21	Pooled human pharyngeal washes	N/A	100%
22	Bordetella pertussis	GDM 1.952	2.6×10^9 CFU/mL
23	Legionella pnuemophila	Philadelphial, Brenner	1.9×10^6 CFU/mL
24	Staphylococcusaureus aureus	CMCC(B) 26003	2.6×10^9 CFU/mL
25	Staphylococcus epidermidis	191 (Winslow and Winslow) Evans	7.7×10^5 CFU/mL
26	Candida albicans	CMCC(F) 129002	1.3×10^8 CFU/mL

Bioteke test detects all the pathogens listed below:
SARS-CoV-2/Influenza A virus/Influenza B virus / Human Parainfluenza virus 2/ Human Parainfluenza virus1+3/ Respiratory syncytial virus/Adenovirus /Mycoplasma pneumoniae/ Streptococus Pneumoniae/ Human metapneumovirus.

No.	Virus/Bacteria name	Strain	Concentration/ CT value
1	Influenza A virus 2009HIN1	L19-A1/Si chuan/SWL1/2009	4.2×10^6 TCID$_{50}$/mL
2	Influenza A virus seasonal HIN1	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 TCID$_{50}$/mL
4	Influenza A virus H5N1	A/Chicken/Liaoning/SD007/2017(H5N1)	CT: 20
5	Influenza A virus H7N9	A/Guangd/17SF003/2016(H7N9)	CT: 20
6	Influenza B virus Yamagata	GZ/174/201803	5.6×10^6 TCID$_{50}$/mL
7	Influenza B virus Victoria	GZ/133/201712	1.0×10^6 TCID$_{50}$/mL
8	Respiratory syncytial virus A	RSVA/GZ/Hecin1705-74	1.3×10^5 TCID$_{50}$/mL
9	Respiratory adenovirus type I	ADVI IGZ/Hecin1608-21	2.4×10^8 TCID$_{50}$/mL
10	Respiratory adenovirus type 2	GZ/1705-34/2017	5.6×10^5 TCID$_{50}$/mL
11	Respiratory adenovirus type 3	ADV3/GZ/0101/2011	1.0×10^6 TCID$_{50}$/mL
12	Respiratory adenovirus type 4	ADV4/GZ/Hecin1611-72/2016	5.6×10^5 TCID$_{50}$/mL
13	Respiratory adenovirus type 5	ADV/GZ/1801-54	1.0×10^7 TCID$_{50}$/mL
14	Respiratory adenovirus type 7	ADV7/GZ/1706-198	3.2×10^7 TCID$_{50}$/mL
15	Respiratory adenovirus type 55	ADV55/GZ/1612-129	3.2×10^8 TCID$_{50}$/mL
16	SARS-CoV-2	Wild Type	2.8×10^6 TCID$_{50}$/mL
17	Mycoplasma pneumoniae	ATCC 15531	1.0×10^9 Copies/mL
18	Human Parainfluenza virus 1	PIV1/Guangzhou/07011	1.3×10^7 TCID$_{50}$/mL
19	Human Parainfluenza virus 2	PIV2/GZ/Hecin171134/2017	5.6×10^7 TCID$_{50}$/mL
20	Human Parainfluenza virus3	PIV3/Guangzhou/0903/2012	3.2×10^5 TCID$_{50}$/mL
21	Human Parainfluenza virus 4a	ATCC VR-1378, M-25	4.5×10^5 TCID$_{50}$/mL
22	Human Parainfluenza virus 4b	ATCC VR-1377, CHI 9503	1.3×10^7 TCID$_{50}$/mL
23	Streptococcus pneumoniae	(Klein) Chester	1.0×10^6 CFU/mL
24	Human metapneumovirus	GZ/1803-107	1.0×10^5 TCID$_{50}$/mL

3) Hook effect: This kit doesn't have hook effect.

PRECAUTIONS

1. 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

	Date of manufacture		Keep away from sunlight		Use-by date
	Manufacturer		Keep dry	LOT	Batch code
	Do not re-use	2°C 30°C	Temperature limit		Consult instructions for use
Σ	Contains sufficient for <n> test		Do not use if package is damaged	IVD	*in vitro* diagnostic device
CE	CE mark of conformity				

EC REP MedUnion S.L.
Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain

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BioTeke Corporation (Wuxi) Co., Ltd.
No. 90 Huiming Road, Huishan, Wuxi City, Jiangsu, China, 214000
Email:info@bioteke.cn

图纸名称	呼吸道十联检抗原检测试剂盒说明书A4 英文	文件号	RD2114-17-04-001-A0	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	