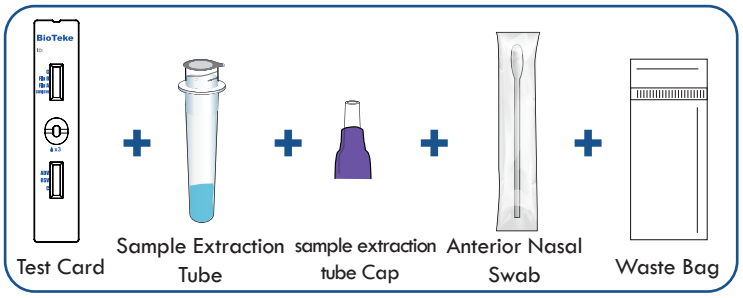
Multiple Respiratory Multipathogen Antigen Test Kit *(Immunochromatographic Assay)*

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.
-Please read the instructions carefully before you begin testing.

CE 3018 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

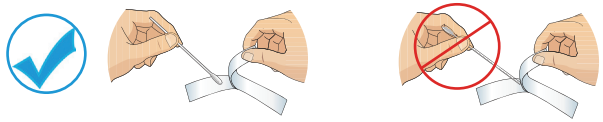
Wash your hands thoroughly for at least 20 seconds before the test.

2

Put the sample extraction tube into the kit box holderand gently peel off the aluminum foil seal.

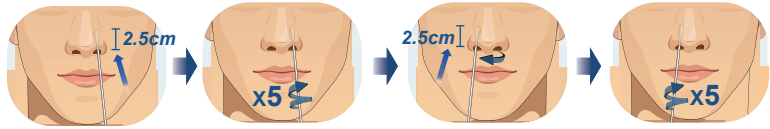
3

NOTE:If the swab package is open, it is not sterile and DO NOT use it!
NOTE: Please blow your nose before swabbing for specimen collection.
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

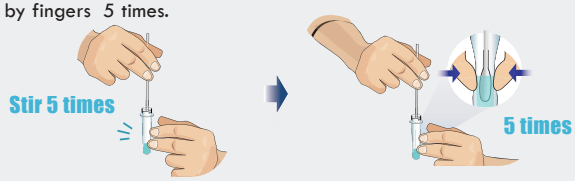
Gently insert the swab for less than one inch (about 2.5cm) into one nostril. Slowly rub the swab against all of the inside of your nose. Make at least 5 big circles. Do not just spin the swab. Repeat this step in your other nostril using the same swab.



NOTE: With children, the maximum depth of insertion into the nostril maybe less than 3/4 inch (about 1.9cm), please adjust according to age.

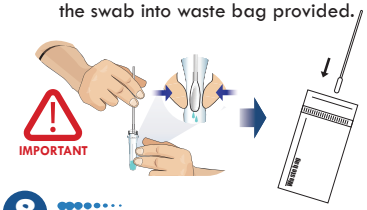
5

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



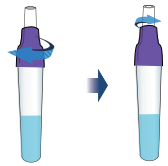
6

Remove the swab by rotating against the sample extraction tube while squeezing the sides of the sample extraction tube to release the liquid from the swab. Remove and discard the swab into waste bag provided.



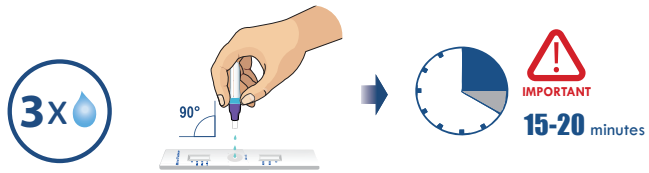
7

Screw the purple tube cap onto the sample extraction 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 sample extraction tube integrated dropper cap upside down and slowly squeeze 3 drops onto the sample well of the Test Card.



9 Results Interpretation

IMPORTANT

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

(Positive)

COVID-19 positive: Two colored lines appear in the COVID19/Flu A/Flu B test window. A dark blue/purple line is in the (C) section and a red line is in the (COVID19) section.

Influenza A (Flu A) positive: Two colored lines appears in the COVID19 /Flu A/Flu B test window. A dark blue/purple line is in the (C) section and a blue line is in the (Flu A) Section

Influenza B (Flu B) positive: Two colored lines appears in the COVID19 /Flu A/Flu B test window. A dark blue/purple line is in the (C) section and a blue line is in the (Flu B) Section.

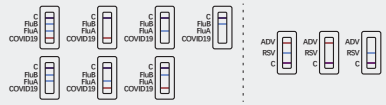
Respiratory Syncytial virus (RSV) positive: Two colored lines appear in the RSV/ADV test window. A dark blue/purple line is in the (C) section and a red line is in the (RSV) section.

Adenovirus (ADV) positive: Two colored lines appear in the RSV/ADV test window. A dark blue/purple line is in the (C) section and a blue line is in the (ADV) section

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

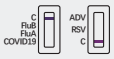
Note: A positive result means that you are likely to be infected with SARS-CoV-2 / influenza A virus / influenza B virus/Respiratory syncytial virus/Adenovirus.

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)

In the COVID19 /Flu A/Flu B/RSV/ADV detection window, two dark blue/purple lines appear in the (C) section and no line appears in the detection area (COVID19 /Flu A/Flu B/RSV/ADV). It indicates that SARS-CoV-2, Influenza A virus, Influenza B virus, Respiratory syncytial virus or Adenovirus were not detected in the sample.



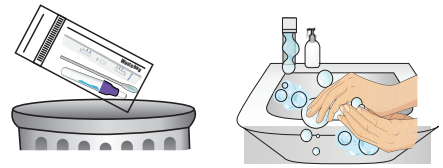
However, a negative result does not safely exclude the absence of SARS-CoV-2, Influenza A virus, Influenza B virus, Respiratory syncytial virus or Adenovirus infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be considered in the 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, Respiratory syncytial virus and Adenovirus, and confirmed by PCR test if 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.



BioTeke

USER INSTRUCTION

For anterior nasal swabs

Multiple Respiratory Multipathogen Antigen Test Kit
(Immunochromatographic Assay)

PRODUCT NAME

Multiple Respiratory Multipathogen Antigen Test Kit(Immunochromatographic Assay)

PACKAGE SPECIFICATION

1 Test/Kit; 2 Tests/Kit; 5 Tests/Kit; 20 Tests/Kit; 50 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/Respiratory syncytialvirus/Adenovirus) fromnuman anterior nasal swab specimens. Multiple Respiratory Multipathogen Antigen Test Kit is an immunochromatographic double-antibody sandwich assay intended for the qualitative detection and differentiation of SARS-CoV-2/Influenza A virus/Influenza B virus/Respiratory syncytial virus/Adenovirus from individuals who are suspected of respiratory tract disease infection.

This kit is suitable for the auxiliary diagnosis of respiratory diseases. Results may serve as clinical reference only and cannot be used alone as the sole basis for diagnosing or excluding respiratory infections . The clinical diagnosis and treatment of patients should always be considered in combination with their symptoms/signs, their medical history, other laboratory tests and treatment responses. Positive test result may need to be further confirmed, and negative result do not safely rule out viral respiratory infections.
Children under 18 years should be supported by an adult.

TEST PRINCIPLE

The kit is immunochromatographic and uses double-antibody sandwich method to detect SARS-CoV-2 /Influenza A virus /Influenza B virus / Respiratory syncytial virus/ Adenovirus 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 /Respiratory syncytial virus /Adenovirus 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/Respiratory syncytial virus/Adenovirus 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 chromatography process as "normal".

MATERIALS PROVIDED

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

Components	Main Ingredients	Loading quantity (Specification)				
		1 Test/Kit	2 Tests/Kit	5 Tests/Kit	20 Tests/Kit	50 Tests/Kit
Test card	Test strip containing specific SARS-CoV-2 /Influenza A virus /Influenza B virus / Respiratory syncytial virus / Adenovirus monoclonal antibody, Anti-mouse IgG polyclonal antibody	1pc	2pcs	5pcs	20pcs	50pcs
Sample extraction tube (0.5mL/pc)		1pc	2pcs	5pcs	20pcs	50pcs
Tube cap		1pc	2pcs	5pcs	20pcs	50pcs
Anterior nasal swab		1pc	2pcs	5pcs	20pcs	50pcs
Waste bag		1pc	2pcs	5pcs	20pcs	50pcs

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.

APPLICABLE DEVICES

N/A

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. (Ref: Rodan et al. "Application of multiplex fluorescent PCR technology in the diagnosis of acute respiratory tract infections in children." Journal of Clinical Pulmonology 2022, Vol. 27, No. 1, pp. 32-35, ISTIC (2022):Changsha Basic Research Program.)
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 show that the negative detection rate is 100% for negative samples , positive detection rate is 100% for both weak positive samples and moderate positive samples. It shows that the repeatability of this kit is good.

4. Limit Of Detection (LOD)
1) The Limit of Detection SARS-CoV-2 is 2.0×10^2 $TCID_{50}$/mL.
2) The Limit of Detection Influenza A virus is $1.0\times10^2TCID_{50}$/mL.
3) The Limit of Detection Influenza B virus is $2.0\times10^2TCID_{50}$/mL.
4) The Limit of Detection Respiratory syncytial virus is $2.0\times10^2TCID_{50}$/mL.
5) The Limit of Detection Adenovirus is $2.0\times10^2TCID_{50}$/mL.

5.Clinical study

SARS-CoV-2

		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromato-graphic assay)	Positive	125	0	125
	Negative	12	566	578
	Total	137	566	703

Statistic	Value	95%CI
Diagnostic sensitivity	91.24%	85.20%to95.39%
Diagnostic specificity	100.00%	99.35%to100.00%
Accuracy	98.29%	97.04%to99.11%

Influenza A virus

		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromato-graphic assay)	Positive	25	1	26
	Negative	6	671	677
	Total	31	672	703

Statistic	Value	95%CI
Diagnostic sensitivity	80.65%	62.53%to92.55%
Diagnostic specificity	99.85%	99.17%to100.00%
Accuracy	99.00%	97.96%to99.60%

Influenza B virus

		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromato-graphic assay)	Positive	33	0	33
	Negative	6	664	670
	Total	39	664	703

Statistic	Value	95%CI
Diagnostic sensitivity	84.62%	69.47%to94.14%
Diagnostic specificity	100.00%	99.45%to100.00%
Accuracy	99.15%	98.15%to99.69%

Respiratory syncytial virus

		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromato-graphic assay)	Positive	25	3	28
	Negative	5	670	675
	Total	30	673	703

Statistic	Value	95%CI
Diagnostic sensitivity	83.33%	65.28%to94.36%
Diagnostic specificity	99.55%	98.70%to99.91%
Accuracy	98.86%	97.77%to99.51%

Adenovirus

		RT-PCR		Total
		Positive	Negative	
Multiple Respiratory Multipathogen Antigen Test Kit (immunochromato-graphic assay)	Positive	33	0	33
	Negative	6	664	670
	Total	39	664	703

Statistic	Value	95%CI
Diagnostic sensitivity	84.62%	69.47%to94.14%
Diagnostic specificity	100.00%	99.45%to100.00%
Accuracy	99.15%	98.15%to99.69%

6.Cross-reactivity and Microbial Interference
There is no cross-reactivity and microbial interference with following pathogens:

No.	Virus/ Bacteria name	Strain	Concentration / CT value
1	Coronavirus HKU1	GUI804-138	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/mL
15	Mumps virus	Jones	1.0×10^7 $TCID_{50}$/mL
16	Varicella zoster virus	VR-1367	CT: 13
17	Human Parainfluenza virus 1	PIV1/Guangzhou/07011	1.3×10^7 $TCID_{50}$/mL
18	Human Parainfluenza virus 2	PIV2/GZ/Hecin171134/2017	5.6×10^7 $TCID_{50}$/mL
19	Human Parainfluenza virus3	PIV3/Guangzhou/0903/2012	3.2×10^5 $TCID_{50}$/mL
20	Human Parainfluenza virus 4a	ATCC VR-1378, M-25	4.5×10^5 $TCID_{50}$/mL
21	Human Parainfluenza virus 4b	ATCC VR-1377, CHI 9503	1.3×10^7 $TCID_{50}$/mL
22	MERS-coronavirus	EMC/2012	1.6×10^5 $TCID_{50}$/mL
23	Human metapneumovirus	GZ/1803-107	1.0×10^5 $TCID_{50}$/mL
24	Mycoplasma pneumoniae	ATCC 15531	1.0×10^9 Copies/mL
25	Chlamydia pneumoniae	ATCC VRJ-2282, TW183	4.2×10^2 $TCID_{50}$/mL
26	Haemophilus influenzae	GIM 1.961.	4.8×10^7 CFU/mL
27	Streptococcus pneumoniae	(Klein) Chester	1.0×10^6 CFU/mL
28	Streptococcus pyogenes	ATCC 19615	1.6×10^8 CFU/mL
29	Pooled human nasal washes	N/A	100%
30	Bordetella pertussis	GDM 1.952	2.6×10^9 CFU/mL
31	Legionella pnuemophila	Philadelphial, Brenner	1.9×10^6 CFU/mL
32	Staphylococcusaureus aureus	CMCC(B) 26003	2.6×10^9 CFU/mL
33	Staphylococcus epidermidis	191 (Winslow and Winslow) Evans	7.7×10^5 CFU/mL
34	Candida albicans	CMCC(F) 129002	1.3×10^8 CFU/mL

Bioteke test detects all the pathogens listed below:SARS-CoV-2,Influenza A/B,RSV,ADV etc.

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 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 $TCID_{50}$/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/Hecin170574	1.3×10^5 $TCID_{50}$/mL
9	Respiratory adenovirus type I	ADVI IGZ/Hecin160821	2.4×10^6 $TCID_{50}$/mL
10	Respiratory adenovirus type 2	GUI 705-34/2017	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/Hecin161172/2016	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	3.2×10^7 $TCID_{50}$/mL
16	SARS-CoV-2	Wild type	2.8×10^6 $TCID_{50}$/mL

7. Interfering substance: The following interfering substances will also not interfere with the results of the kit:

No.	Potential Interfering Substances	Active Ingredient	Test concentration	No.	Potential Interfering Substances	Active Ingredient	Test concentration
1	Antiviral drug	α-interferon	0.71mg/mL	23	Nasal corticosteroids	Triamcinolone acetonide	0.22mg/mL
2		Zanamivir	10mg/mL				
3		Ribavirin	6.42mg/L	24		Budesonide	0.128mg/mL
4		Oseltamivir	2.14mg/L	25		Mometasone	0.2mg/mL
5		Peramivir	4.29mg/L	26		Fluticasone	0.2mg/mL
6		Lopinavir	0.57mg/mL	27	Allergic symptom relief drug	Histamine Hydrochloride	0.18mg/L
7		Ritonavir	0.57mg/mL				
8		Arbidol	0.43mg/mL				
9	Antibiotic	Levofloxacin	0.54mg/mL	28	Throat tablets, oral anesthetics and analgesics	Menthol	1.7mg/mL
10		Azithromycin	0.36mg/mL				
11		Ceftriaxone	750mg/L				
12		Meropenem	1.07mg/mL	29		Ethyl 4-aminobenzoate	1.5mg/mL
13	Systemic antibacterial drugs	Tobramycin	4.38mg/L				
14	Mucin	Mucin protein, Type I-S	1%	30	Zicam Cold Remedy Nasal Gel	Sulphur	15%
15	Human blood		5%				
16	Nasal spray	Epinephrine (phenylephrine)	0.4mg/mL	31	Antibiotics, nasal ointment	Mupirocin	10mg/mL
17		Oxymetazoline	0.3mg/mL	32	Naso Gel (NeilMed)	Saline	5.0% V/V
18		Sodium chloride (with preservatives)	36mg/mL				
19		Cromolyn sodium	15.0% V/V	33	Alkalol	Galphimia glauca, Luffa operculata, Sabadilla	1:10 dilution
20	Nasal corticosteroids	Beclomethasone	0.2mg/mL				
21		Dexamethasone	0.2mg/mL	34	Sore Throat Phenol Spray	Phenol	15.0% V/V
22		Flunisolide	0.1mg/mL				

8. Hook effect: the test kit does not have high dose hook effect at the concentration of up to $1.75x10^5TCID_{50}$/mL.

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 false-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.
15.Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State.

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
IVD *in vitro* diagnostic device
Contains sufficient for <n> test
Do not use if package is damaged
CE mark of conformity

CHANGE HISTORY

Edition	Revision date	Reason for change
B1	Aug.05, 2020	First Releases
B2	Dec.01, 2022	Partial change
B3	Jul.02, 2023	Partial change
B4	Apr.30, 2024	Partial change
B5	Aug.08, 2024	Partial change
B6	Sept.27,2024	Partial change

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

BioTeke Corporation (Wuxi) Co., Ltd.
No. 90 Huiming Road, Huishan, Wuxi City,Jiangsu 214000 China
Email: info@bioteke.cn
Phone: (0510) 8332 3992

● Revision date:Sept.27, 2024
Edition: B6