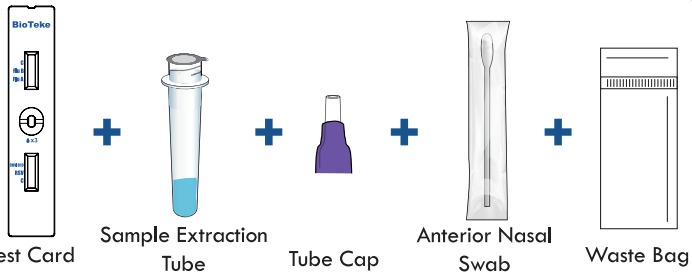
Multiple Respiratory Multipathogen Antigen Test Kit *(immunochromatographic assay)*

BioTeke
USER INSTRUCTION

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

-For anterior nasal 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

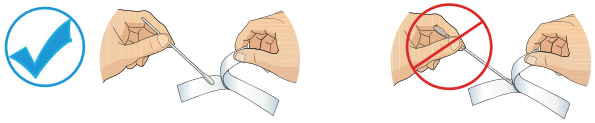
Wash your hands thoroughly for at least 20 seconds before the test.

2

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

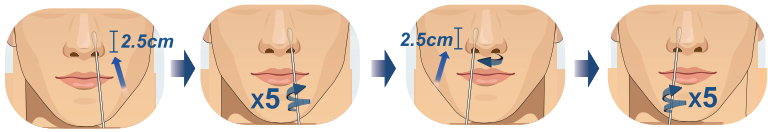
3

NOTE:Please blow your nose before collection.
Remove the swab from its wrapper and take out the swab by holding the handle. Being careful not to touch the fabric tip of the swab with your hands.



4

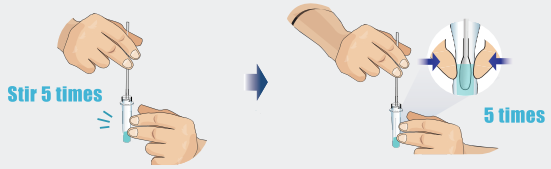
Gently insert the swab into your nostril less than one inch (about 2.5cm). Slowly rub the swab against all of the inside walls of your nostril. Make at least 5 big circles. Do not just spin the swab. Repeat this step in your other nostril using the same swab.



NOTE: With children, the maximum depth of insertion into the nostril may be less than 3/4 inch.

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 finger 5 times.

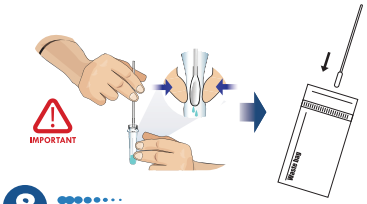


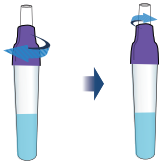
6

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 into waste bag provided.

7

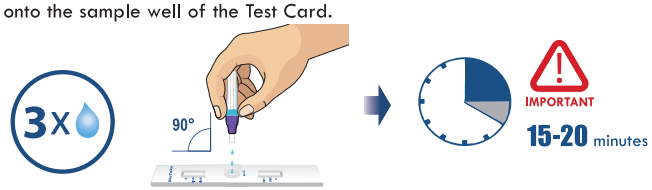
Screw the purple tube cap onto the sample tube and then unscrew the top white cap.





8

Open the pouch and take out the Test Card. Place it on a flat, dry and clean surface. Turn the tube integrated dropper capupside 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]

SARS-CoV-2 positive: Two coloured lines appear in the RSV/COVID-19 test window. A dark blue/purple line is in the (C) section and a red line is in the (COVID- 19) section.

Respiratory Syncytial virus (RSV) positive: Two coloured lines appear in the RSV/COVID-19 test window. A dark blue/purple line is in the (C) section and a blue line is in the (RSV) section.

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

Influenza B (Flu B) positive: Two coloured lines appears in the 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.

Multiple positive: Two coloured (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 COVID-19/ Respiratory syncytial virus /influenza A / influenza B. Test results should always be considered in the context of clinical observations and epidemiological data when making final diagnoses and patient management decisions.

[Negative]

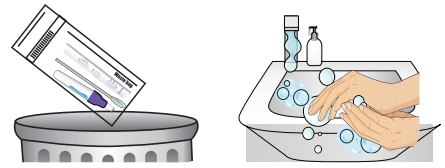
In the Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus detection window, two dark blue/purple lines appear in the (C) section and no line appears in the detection area (flu B /flu A /COVID-19 /RSV). It indicates that Influenza A virus, Influenza B virus, SARS-CoV-2 or Respiratory syncytial virus was not detected in the sample. However, a negative result does not exclude the absence of Influenza A virus, Influenza B virus, SARS-CoV-2, Respiratory syncytial virus 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 Influenza A virus, Influenza B virus, SARS-CoV-2 and Respiratory syncytial virus, and confirmed by PCR test as necessary for patient management.

[Invalid]

If any of the control (C) lines do not appear, the test is considered 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 steps, wash hands or use hand sanitizer.



BioTeke®

USER INSTRUCTION

For anterior nasal swabs

Multiple Respiratory Multipathogen Antigen Test Kit

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 multiple respiratory multipathogen antigen (Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus) from human anterior nasal swabs specimens. Multiple Respiratory Multipathogen Antigen Test Kit is an immunochromatographic double-antibody sandwich assay intended for the qualitative detection and differentiation of Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus from individuals who are suspected of respiratory tract disease infection.
This kit is suitable for the auxiliary diagnosis of respiratory diseases, the results are for clinical reference only and cannot be used as the sole basis for diagnosis and exclusion decision. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment responses. Positive test result needs to be further confirmed, negative result does not preclude respiratory diseases viruses infection.

TEST PRINCIPLE

The kit is immunochromatographic and uses double-antibody sandwich method to detect Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus antigen. During detection, the treated specimens are loaded into the sample wells of the test card. When the concentration of Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus antigen in specimen is higher than the minimum detection limit, the viral antigen will form complexes with labeled antibodies first. Under chromatography, the complexes move forward along the nitrocellulose membrane till captured by pre-coated monoclonal antibody of Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus in detection zone on nitrocellulose film to form a red or blue reaction line on the detection zone, at this point the 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, at this point the result is negative. Regardless of whether the sample contains viral antigens or not, a dark blue reaction line will appear in the quality control zone (C), the dark blue reaction line that appears in the quality control zone (C) is the criterion for determining if the chromatography process is 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 Influenza A virus/Influenza B virus /SARS-CoV-2/Respiratory syncytial virus monoclonal antibody, Anti-mouse IgG polyclonal antibody	1pc	2pcs	5pcs	20pcs	50pcs
Sample extraction tube		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 aluminum foil pouch.
2. Do not mix use different batches of test cards and sample tube.

STORAGE CONDITIONS AND SHELF LIFE

The test card and sample extraction tube should be stored at 2°C~30°C, valid for 18 months. Test cards should be used as soon as possible within 1 hour after opening the foil pouch. The bottle of sample extraction tube should be capped immediately after use and stored at 2°C~30°C, please use it within the validity period.
Date of manufacture and expiration: See package label for details.

SPECIMEN REQUIREMENTS

Direct swab specimen should be tested immediately after collection.

LIMITATIONS OF THE TEST

1. The test results of this kit are only for the reference of clinicians and should not be used as the sole basis for clinical diagnosis and treatment. Clinical management of patients should be considered in the context of their symptoms/signs, medical history, other laboratory tests and response to treatment.
2. Sample collection and sample processing have a greater impact on the detection of pathogens, and 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 method is generally lower than that of nucleic acid-based test. Therefore, the test provider should pay more attention to the negative results and make a comprehensive judgment based on other test results. It is suggested that the negative results in suspected patients should be checked by nucleic acid test or virus culture identification.
4. When the result of test kit is positive, it is recommended to combine the results of other methods (such as PCR and CT imaging) for further confirmation, and consult with local public health prevention institutions for treatment.
5. Analysis of the likelihood of false-negative results.
(i) Improper sample collection, transport and processing, and low viral titers in the sample may lead to false negative results.
(ii) The optimal sample type and the optimal sampling time after infection (peak viral titer) have not been validated, therefore, 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 and were uniform in color.

4. Analytical specificity
1) Cross-reactivity
There is no cross-reactivity with the following pathogens:

No.	Virus/ Bacteria/Parasite name	Strain	Concentration/ CT value
1	Coronavirus HKU1	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	5.6×10^4 $TCID_{50}$/mL
5	* Influenza A virus 2009H1N1	L19-A1/Si chuan/SWL1/2009	4.2×10^6 $TCID_{50}$/mL
6	* Influenza A virus seasonal H1N1	L6-A1/ Liaoning huanggu /1183/2007	5.6×10^5 $TCID_{50}$/mL
7	*Influenza A virus H3N2	L8-A3/ Brisbane /10/2007	1.0×10^6 $TCID_{50}$/mL
8	*Influenza A virus H5N1	A/Chicken/Liaoning/SD007/2017(H5N1)	CT: 20
9	*Influenza A virus H7N9	A/Guangd/17SF003/2016(H7N9)	CT: 20
10	* Influenza B virus Yamagata	GZ/174/201803	5.6×10^6 $TCID_{50}$/mL
11	* Influenza B virus Victoria	GZ/133/201712	1.0×10^6 $TCID_{50}$/mL
12	* Respiratory syncytial virus A	RSVA/GZ/Hecin1705-74	1.3×10^5 $TCID_{50}$/mL
13	Rhinovirus (group A)	A30/GZ/1710-89	4.2×10^6 $TCID_{50}$/mL
14	Rhinovirus (group B)	70/FO2-2547	1.0×10^6 $TCID_{50}$/mL
15	Respiratory adenovirus type 1	ADV1/GZ/Hecin1608-21	2.4×10^8 $TCID_{50}$/mL
16	Respiratory adenovirus type 2	GZ/1705-34/2017	5.6×10^6 $TCID_{50}$/mL
17	Respiratory adenovirus type 3	ADV3/GZ/0101/2011	1.0×10^6 $TCID_{50}$/mL
18	Respiratory adenovirus type 4	ADV4/GZ/Hecin1611-72/2016	5.6×10^5 $TCID_{50}$/mL
19	Respiratory adenovirus type 5	ADV/GZ/1801-54	1.0×10^7 $TCID_{50}$/mL
20	Respiratory adenovirus type 7	ADV7/GZ/1706-198	3.2×10^7 $TCID_{50}$/mL
21	Respiratory adenovirus type 55	ADV55/GZ/1612-129	3.2×10^8 $TCID_{50}$/mL
22	Enterovirus (CA16)	CA16/Guangzhou/0302/2011	1.8×10^7 $TCID_{50}$/mL
23	Enterovirus (Echo)	ATCC VR-39，HILL	1.0×10^6 $TCID_{50}$/mL
24	Enterovirus (EV71)	EV71/Guangzhou/0402/2012	5.6×10^6 $TCID_{50}$/mL
25	Epstein-barr virus capsid antigen	B95-8	CT: 17
26	Measles virus	Edmonston	1.0×10^7 $TCID_{50}$/mL
27	Human cytomegalovirus	RC256	3.2×10^3 $TCID_{50}$/mL
28	Rotavirus	VR-2018	CT: 20
29	Norovirus	ATCC VR-3234SD	3.6×10^5copies/μL
30	Mumps virus	Jones	1.0×10^7 $TCID_{50}$/mL
31	Varicella zoster virus	VR-1367	CT: 13
32	Human Parainfluenza virus 1	PIV1/Guangzhou/0701/2011	1.3×10^7 $TCID_{50}$/mL
33	Human Parainfluenza virus 2	PIV2/GZ/Hecin1711-34/2017	5.6×10^7 $TCID_{50}$/mL
34	Human Parainfluenza virus 3	PIV3/Guangzhou/0903/2012	3.2×10^5 $TCID_{50}$/mL
35	Human Parainfluenza virus 4a	ATCC VR-1378, M-25	4.5×10^5 $TCID_{50}$/mL
36	Human Parainfluenza virus 4b	ATCC VR-1377, CH19503	1.3×10^7 $TCID_{50}$/mL
37	MERS-coronavirus	EMC/2012	1.6×10^5 $TCID_{50}$/mL
38	Human metapneumovirus (hMPV)	GZ/1803-107	1.0×10^5 $TCID_{50}$/mL
39	Mycoplasma pneumoniae	ATCC 15531.	1.0×10^9 copies/mL
40	Chlamydia pneumoniae	ATCC VRJ-2282, TW-183	4.2×10^2 $TCID_{50}$/mL
41	Haemophilus influenzae	GIM 1.961.	4.8×10^7 CFU/mL
42	Streptococcus pneumoniae	(Klein) Chester	1.0×10^6 CFU/mL
43	Streptococcus pyogenes	ATCC 19615	1.6×10^8 CFU/mL
44	Pooled human nasal washes	N/A	100%
45	Bordetella pertussis	GDM 1.952	2.6×10^9 CFU/mL
46	Legionella pnuemophila	Philadelphia, Brenner et al.	1.9×10^6 CFU/mL
47	Staphylococcus aureus	CMCC(B) 26003	2.1×10^9 CFU/mL
48	Staphylococcus epidermidis	1191 (Winslow and Winslow) Evans	7.7×10^5 CFU/mL
49	Candida albicans	CMCC(F) 129002	1.3×10^8 CFU/mL
50	* SARS-CoV-2	Reference	2.8×10^6 $TCID_{50}$/mL

*No.5-11 Excludes cross-tests for influenza A and B viruses;
No.12 Excludes cross-tests for respiratory syncytial viruses;
No.50. Excludes cross-tests for SARS-CoV-2;

2) 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	29		Ethyl 4-aminobenzoate	1.5mg/mL
12		Meropenem	1.07mg/mL				
13	Systemic antibacterial drugs	Tobramycin	4.38mg/L	30	Zicam Cold Remedy Nasal Gel	Sulphur	15%
14	Mucin	Mucin protein, Type I-S	1%				
15	Human blood		5%	31	Antibiotics, nasal ointment	Mupirocin	10mg/mL
16	Nasal spray	Epinephrine (phenylephrine)	0.4mg/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				

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 and testing should be taken appropriate protective measures. Therefore, wear protective measures such as wearing gloves and masks should be done, and dispose of all wastes as potentially biohazardous items. (Used cotton swabs, test cards, extraction tubes, etc., should be decontaminated before disposal and tested for autoclaving.)
3. Use the swab and sample extraction tube provided with this reagent for sampling, and do not mix use different batches of test cards and sample extraction tube.
4. Use fresh specimens for testing, do not use repeated freeze-thaw samples.
5. Operate at room temperature. Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
6. Do not use reagent kits with obvious damage or test cards with damaged or expired packaging.
7. The aluminum foil pouch contains desiccant and must not be taken orally.
8. Improper sample collection or processing may result in false-negative results.
9. Ensure proper sample loading volume, results of too much or too little sample loading volume may not be credible.
10. If the initial screen is a positive sample, contact your local public health agency.
11. As with the diagnostic reagents used, the final diagnosis should be made by a physician after combining the various test parameters and clinical symptoms.
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.

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 CE mark of conformity

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