

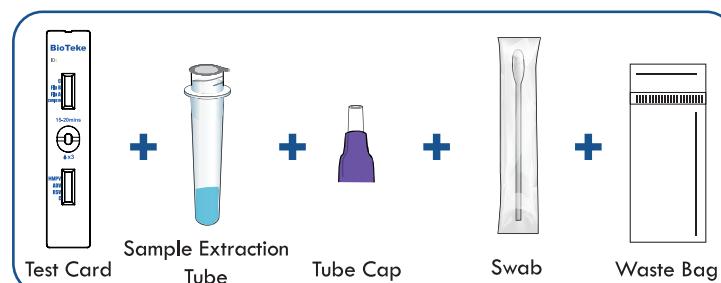
SARS-CoV-2/Flu A/Flu B/RSV/ADV/HMPV Antigen Rapid Test Kit

(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.



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.

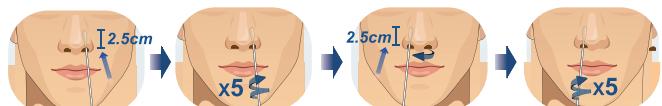


4 
Anterior nasal swab collection:

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.

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



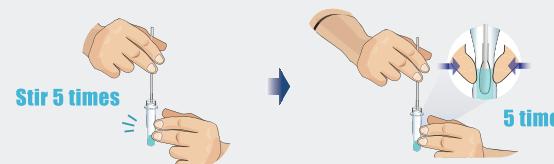
NOTE: With children, the maximum depth of insertion into the nostril maybe less than 3/4 inch, please adjust according to age.

Oropharyngeal swabs collection:

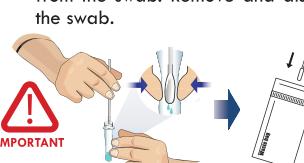
Oropharyngeal swab collection: Insert the swab in the mouth completely into the pharynx, centering on the red swelling of the pharynx wall and upper anterior tonsils. Wipe both sides of pharyngeal tonsils and pharynx posterior wall with moderate force, avoid touching the tongue, and remove the swab.



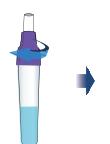
5 Insert the swab into the sample tube. Touch the bottom of the sample tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by fingers 5 times.



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



NOTE:

The test results should not be read after 30 minutes.

[Positive]

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

Influenza A (Flu A) positive: Two colored lines appears in the COVID-19/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 COVID-19/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/HMPV test window. A dark blue/purple line is in the (C) section and a blue line is in the (RSV) section.

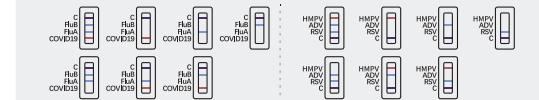
Adenovirus (ADV) positive: Two colored lines appear in the RSV/ADV/HMPV test window. A dark blue/purple line is in the (C) section and a blue line is in the (ADV) section

Human metapneumovirus (HMPV) positive: Two coloured lines appear in the (RSV/ADV/HMPV) test window. A dark blue/purple line is in the (C) section and a red line is in the (HMPV) 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/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.



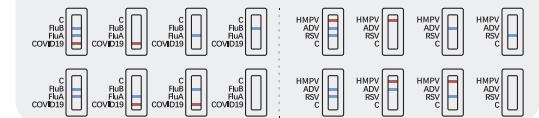
[Negative]

In the SARS-CoV-2/Influenza A virus/Influenza B virus and Respiratory syncytial virus/Adenovirus/Human metapneumovirus detection window, two dark blue/purple lines appear in the (C) section and no line appears in the detection area (COVID-19/Flu A/Flu B/RSV/ADV/HMPV). It indicates that SARS-CoV-2, Influenza A virus, Influenza B virus, Respiratory syncytial virus, Adenovirus or Human metapneumovirus 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, Adenovirus or 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, Respiratory syncytial virus, Adenovirus and Human metapneumovirus, 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.





USER INSTRUCTION

For anterior nasal swabs or oropharyngeal swabs.

SARS-CoV-2/Flu A/Flu B/RSV/ADV/HMPV
Antigen Rapid Test Kit (Immunochromatographic Assay)

PRODUCT NAME

SARS-CoV-2/Flu A/Flu B/RSV/ADV/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/Respiratory syncytial virus/Adenovirus/Human metapneumovirus from human anterior nasal swabs or oropharyngeal swab specimens.

SARS-CoV-2/Flu A/Flu B/RSV/ADV/HMPV Antigen Rapid 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/Human metapneumovirus 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 does not safely rule out viral respiratory infections.

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/ 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/ Respiratory syncytial virus/ Adenovirus/ 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/ Respiratory syncytial virus/ Adenovirus/ 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 chromatography 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/ Respiratory syncytial virus/ Adenovirus/ 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 serve as 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 in the context of their signs and symptoms, their medical history, other 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 clinically necessary, negative results 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. Specifically, 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.

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
 - (i) Clinical study

SARS-CoV-2		QIAstrix-Dx Respiratory SARS-CoV-2 Panel		Total
Positive	Negative	Positive	Negative	Total
SARS-CoV-2/Flu A/ Flu B/RSV/ADV/ HMPV Antigen Rapid Test Kit	Positive	82	0	82
	Negative	3	467	470
	Total	85	467	552
Statistic	Value	95%CI		
Sensitivity	96.47%	(90.03%~99.73%)		
Specificity	100.00%	(99.23%~100.00%)		
Total coincidence rate	99.46%	(98.42%~99.89%)		
Influenza A		QIAstrix-Dx Respiratory SARS-CoV-2 Panel		Total
Positive	Negative	Positive	Negative	Total
SARS-CoV-2/Flu A/ Flu B/RSV/ADV/ HMPV Antigen Rapid Test Kit	Positive	70	0	70
	Negative	3	479	482
	Total	73	479	552
Statistic	Value	95%CI		
Sensitivity	95.89%	(68.46%~99.14%)		
Specificity	100.00%	(99.21%~100.00%)		
Total coincidence rate	99.46%	(98.42%~99.89%)		
Influenza B		QIAstrix-Dx Respiratory SARS-CoV-2 Panel		Total
Positive	Negative	Positive	Negative	Total
SARS-CoV-2/Flu A/ Flu B/RSV/ADV/ HMPV Antigen Rapid Test Kit	Positive	80	0	80
	Negative	2	470	472
	Total	82	470	552
Statistic	Value	95%CI		
Sensitivity	97.56%	(91.47%~99.70%)		
Specificity	100.00%	(99.22%~100.00%)		
Total coincidence rate	99.64%	(98.70%~99.96%)		
Human metapneumovirus		QIAstrix-Dx Respiratory SARS-CoV-2 Panel		Total
Positive	Negative	Positive	Negative	Total
SARS-CoV-2/Flu A/ Flu B/RSV/ADV/ HMPV Antigen Rapid Test Kit	Positive	63	0	63
	Negative	2	487	489
	Total	65	487	552
Statistic	Value	95%CI		
Sensitivity	96.92%	(89.32%~99.63%)		
Specificity	100.00%	(99.25%~100.00%)		
Total coincidence rate	99.64%	(98.70%~99.96%)		
Adenovirus		QIAstrix-Dx Respiratory SARS-CoV-2 Panel		Total
Positive	Negative	Positive	Negative	Total
SARS-CoV-2/Flu A/ Flu B/RSV/ADV/ HMPV Antigen Rapid Test Kit	Positive	75	0	75
	Negative	3	474	477
	Total	78	474	552
Statistic	Value	95%CI		
Sensitivity	96.15%	(89.17%~99.20%)		
Specificity	100.00%	(99.22%~100.00%)		
Total coincidence rate	99.46%	(98.42%~99.89%)		
Respiratory syncytial virus		QIAstrix-Dx Respiratory SARS-CoV-2 Panel		Total
Positive	Negative	Positive	Negative	Total
SARS-CoV-2/Flu A/ Flu B/RSV/ADV/ HMPV Antigen Rapid Test Kit	Positive	63	0	63
	Negative	3	486	489
	Total	66	486	552
Statistic	Value	95%CI		
Sensitivity	95.45%	(87.29%~99.05%)		
Specificity	100.00%	(99.24%~100.00%)		
Total coincidence rate	99.46%	(98.42%~99.89%)		

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

No.	Virus/ Bacteria 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

No.	Virus/Bacteria name	Strain	Concentration/ CT value
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/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/Hecin171134/20 17	5.6×10 ⁷ TCID ₅₀ /mL
19	Human Parainfluenza virus 3	PIV3/Guangzhou/0903/2 012	3.2×10 ⁶ 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, CHI9503	1.3×10 ⁷ TCID ₅₀ /mL
22	MERS-coronavirus	EMC/2012	1.6×10 ⁵ TCID ₅₀ /mL
23	Mycoplasma pneumoniae	ATCC 15531	1.0×10 ⁶ Copies/mL
24	Haemophilus influenzae	GIM 1.961.	4.8×10 ⁷ CFU/mL
25	Chlamydia pneumoniae	ATTC VRJ-2282, TW183	4.2×10 ² TDID ₅₀ /mL
26	Streptococcus pyogenes	ATCC 19615	1.6×10 ⁸ CFU/mL
27	Pooled human pharyngeal washes	N/A	100%
28	Bordetella pertussis	GDM 1.952	2.6×10 ⁹ CFU/mL
29	Legionella pneumophila	Philadelphia, Brenner	1.9×10 ⁶ CFU/mL
30	Staphylococcus aureus	CMCC(B) 26003	2.6×10 ⁹ CFU/mL
31	Staphylococcus epidermidis	191 (Winslow and Winslow) Evans	7.7×10 ⁶ CFU/mL
32	Candida albicans	CMCC(F) 129002	1.3×10 ⁸ CFU/mL
33	Streptococcus pneumoniae	(Klein) Chester	1.0×10 ⁶ CFU/mL

No.	Virus/Bacteria name	Strain	Concentration/ CT value
1	Influenza A virus 2009H1N1	L19-A1/Sichuan/SWL1/2009	4.2×10 ⁵ TCID ₅₀ /mL
2	Influenza A virus seasonal H1N1	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/Guangdong/17SF003/2016(H7N9)	CT: 20
6	Influenza B virus Yamagata	GZ/174/201803	5.6×10 ⁵ TCID ₅₀ /mL
7	Influenza B virus Victoria	GZ/133/201712	1.0×10 ⁶ TCID ₅₀ /mL
8	Respiratory syncytial virus	RSVA/GZ/Hecin1705-74	1.3×10 ⁷ TCID ₅₀ /mL
9	Respiratory adenovirus type I	ADV1GZ/Hecin1608-21	2.4×10 ⁵ 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 ⁷ 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	ADV5/GZ/1612-129	3.2×10 ⁷ TCID ₅₀ /mL
14	Respiratory adenovirus type 7	ADV7/GZ/1706-198	3.2×10 ⁸ TCID ₅₀ /mL
15	Respiratory adenovirus type 55	ADV55/GZ/1612-129	3.2×10 ⁷ TCID ₅₀ /mL
16	SARS-CoV-2	Wuhan-Hu-1	2.8×10 ⁵ TCID ₅₀ /mL
17	Human metapneumovirus	GZ/1803-107	1.0×10 ⁷ 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-thaw 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, 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.
11. If you have any questions or suggestions on the use of this kit, please contact the manufacturer.
12. 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.
13. 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

图纸名称	说明书-英文	文件号	RD2508-040401-101-A1	材质	双胶纸
尺寸	A4	色号	见图纸		
设计/日期		审核/日期		批准/日期	