

BioTeke

BioTeke Corporation (Wuxi) Co., Ltd.

MULTIPLE RESPIRATORY MULTIPATHOGEN ANTIGEN TEST KIT

(immunochromatographic assay)

- ✓ SARS-CoV-2
- ✓ Influenza A virus
- ✓ Influenza B virus
- ✓ RSV

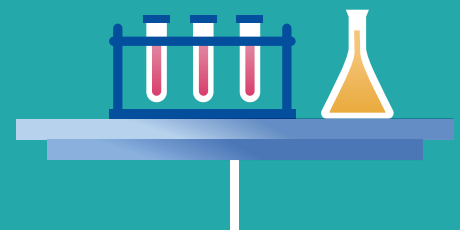


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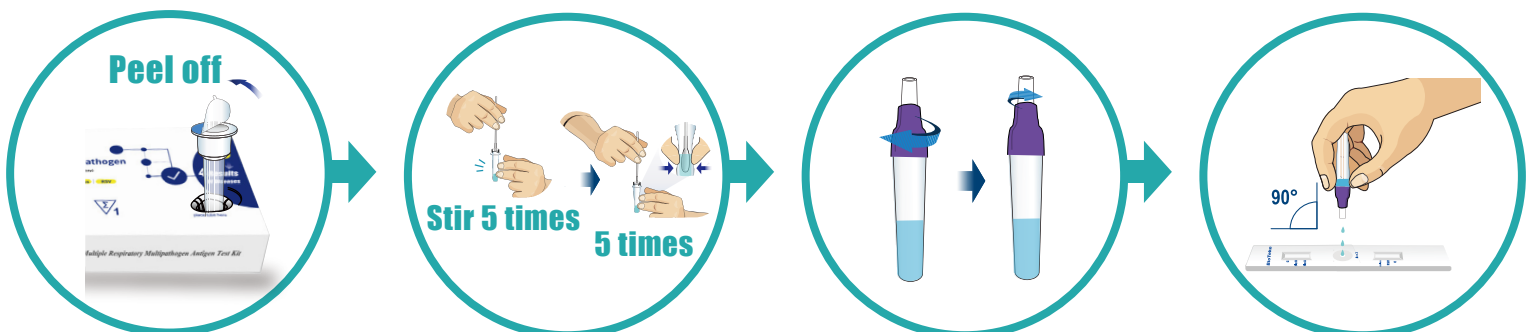
INTENDED USE

● 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.



OPERATING INSTRUCTIONS



RESULTS INTERPRETATION

[Positive]

SARS-CoV-2 positive: Two coloured lines appears in the 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.



ADVANTAGE



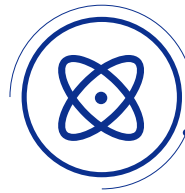
Superior performance and high accuracy.



The multi-color system is more conducive to the interpretation of inspector and can help reduce the chance of misjudgment.



Two-way chromatography, one sampling, multiple detections. Operators' detection steps will be simpler.



Automation degree is high, and the production efficiency is several times higher than that of other enterprises. lower cost.



The product form is flexible. Multiple inspections can be combined according to customers' requirements.



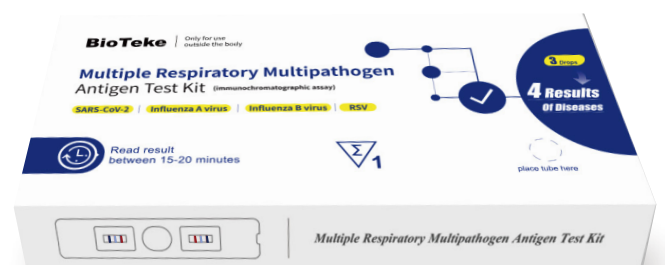
The kit can selectively detect four items, namely: SARS-CoV-2, Influenza A (FluA), Influenza B (Flu B), RSV.



- ✓ SARS-CoV-2
- ✓ Influenza A virus
- ✓ Influenza B virus
- ✓ RSV

Packing specification:

1test/box, size: 16.2x6.6x1.5cm
 600box/carton, size: 66*40*42cm ;
 20test/box, size: 24x16.6x6.5cm
 40box/carton, size: 68*49*35cm



RESULT ANALYSIS

SARS-CoV-2

		Multiple Respiratory Pathogens nucleic acid detection kit (Fluorescence PCR method)		Total
		Positive	Negative	
Multiple Respiratory multipathogen antigen test kit (immunochromatographicassay)	Positive	106	0	106
	Negative	4	456	460
Total		110	456	566

Statistic	Value	95% CI
Sensitivity	96.36%	(90.95%~99.00%)
Specificity	100.00%	(99.19%~100.00%)
Total coincidence rate	99.29%	(98.20%~99.81%)

Influenza A

		Multiple Respiratory Pathogens nucleic acid detection kit (Fluorescence PCR method)		Total
		Positive	Negative	
Multiple Respiratory multipathogen antigen test kit (immunochromatographicassay)	Positive	113	0	113
	Negative	6	447	453
Total		119	447	566

Statistic	Value	95% CI
Sensitivity	94.96%	(89.35%~98.13%)
Specificity	100.00%	(99.18%~100.00%)
Total coincidence rate	98.94%	(97.71%~99.61%)

Influenza B

		Multiple Respiratory Pathogens nucleic acid detection kit (Fluorescence PCR method)		Total
		Positive	Negative	
Multiple Respiratory multipathogen antigen test kit (immunochromatographicassay)	Positive	103	0	103
	Negative	5	447	452
Total		108	447	555

Statistic	Value	95% CI
Sensitivity	95.37%	(89.53%~98.48%)
Specificity	100.00%	(99.18%~100.00%)
Total coincidence rate	99.10%	(97.91%~99.71%)

RSV

		Multiple Respiratory Pathogens nucleic acid detection kit (Fluorescence PCR method)		Total
		Positive	Negative	
Multiple Respiratory multipathogen antigen test kit (immunochromatographicassay)	Positive	106	0	106
	Negative	7	454	461
Total		113	454	567

Statistic	Value	95% CI
Sensitivity	93.81%	(87.65%~97.47%)
Specificity	100.00%	(99.19%~100.00%)
Total coincidence rate	98.77%	(97.47%~99.50%)

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Corporation

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For more information,
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0086-510-68501244

Or visit the official website
of BioTeke:

www.bioteke.cn