## BioTeke

BioTeke Corporation(wuxi) Co.,Ltd

# Rapid, reliable results for respiratory season



# Only 3 drops ,detect 6 diseases, increase workflow efficiency.

When it comes to SARS-CoV-2,Flu A, Flu B, Respiratory Syncytial Virus (RSV), Adenovirus (ADV) and Mycoplasma Pneumoniae testing, results from Bioteke SARS-CoV-2/Flu A /Flu B /RSV/ADV /MP antigen test kit allows physicians to make a rapid diagnosis with confidence, which is essential for reducing secondary testing, decreasing unnecessary antibiotic use, and guiding appropriate antiviral therapy.

- Easy-to-read results in 15 minutes
- Multi-color displays results
- Two-way chromatography ,only need 3 drops
- Accurate, reliable results
- · Long shelf life to adapt to seasonal fluctuations
- Variety of collection and transport options
- Convenient room temperature storage



Performance	Sensitivity	96.97%		
	Specificity	100%		
	Accuracy	98.05%		

## **Result Analysis**

SARS-CoV-2			QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative		
RSV/ ADV/ MP Antigen Rapid Test Kit		Positive	147	0	147
		Negative	6	977	983
Total		153	977	1130	
Statistic	Value		95%Cl		
Sensitivity	96.08%		(91.55%-98.55%)		
Specificity	100%		(99.62%-100%)		
Total coincidence rate	99.47%		(98.85%-99.80%)		

Influenza A			QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
			Positive	Negative	
SARS-CoV-2/ FluA/ FluB/ RSV/ ADV/ MP Antigen Rapid Test Kit		Positive	123	0	123
		Negative	2	1005	1007
Total			125	1005	1130
Statistic	Value		95%Cl		
Sensitivity	98.40%		(94.34%-99.81%)		
Specificity	100%		(99.63%-100%)		
Total coincidence rate	99.82%		(99.36%-99.98%)		

Influenza B		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total	
		Positive	Negative		
SARS-CoV-2/ FluA/ FluB/ RSV/ ADV/ MP Antigen Rapid Test Kit Negative		Positive	121	0	121
		Negative	4	1005	1009
Total		125	1005	1130	
Statistic	Value		95%Cl		
Sensitivity	96.80%		(92.01%-99.12%)		
Specificity	100%		(99.63%-100%)		
Total coincidence rate	99.65%		(99.10%-99.90%)		

M.Pneumonia		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total	
		Positive	Negative		
SARS-CoV-2/ FluA/ FluB/ RSV/ ADV/ MP Antigen Rapid Test Kit Negative		100	0	100	
		Negative	3	1027	1030
Total		103	1027	1130	
Statistic	Value		95%Cl		
Sensitivity	97.09%		(91.72%-99.40%)		
Specificity	100%		(99.64%-100%)		
Total coincidence rate	99.73%		(99.23%-99.95%)		

Adenovirus			QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total
		Positive	Negative		
SARS-CoV-2/ FluA/ FluB/ RSV/ ADV/ MP Antigen Rapid Test Kit Negative		Positive	115	0	115
		Negative	5	1010	1015
Total		120	1010	1130	
Statistic	Value		95%Cl		
Sensitivity	95.83%		(90.54%-98.63%)		
Specificity	100%		(99.64%-100%)		
Total coincidence rate	99.56%		(98.97%-99.86%)		

Respiratory syncytial virus		QIAstat-Dx Respiratory SARS-CoV-2 Panel		Total	
		Positive	Negative		
SARS-CoV-2/ FluA/ FluB/ RSV/ ADV/ MP Antigen Rapid Test Kit		Positive	97	0	97
		Negative	2	1031	1033
Total		99	1031	1130	
Statistic	Value		95%Cl		
Sensitivity	97.98%		(92.89%-99.75%)		
Specificity	100%		(99.64%-100%)		
Total coincidence rate	99.82%		(99.36%-99.98%)		

### **Operation Instructions**



## **Results Interpretation**

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

#### (Positive)

SARS-CoV-2 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.

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

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

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



#### (Negative)

In the SARS-CoV-2/Influenza A virus/Influenza B virus and Respiratory syncytial virus/Adenovirus detection/Mycoplasma pneumoniae 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/MP). It indicates that SARS-CoV-2, Influenza A virus, Influenza B virus, Respiratory syncytial virus, Adenovirus or Mycoplasma pneumoniae 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 Mycoplasma pneumoniae 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 Mycoplasma pneumoniae, 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.



Find out more at www.bioteke.cn Or you can call BioTeke national service hotline

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