FAPON

A GLOBAL LEADING IVD REAGENT RAW MATERIALS AND ONE-STOP SOLUTIONS PROVIDER

Raw Materials for Influenza A/B Antigen Detection

- Detection in the NIBSC & newly released China CDC influenza panels
- Excellent reactivity and specificity
- No cross-reaction to other respiratory diseases

Fapon Biotech Inc.

There are an estimated 1 billion seasonal flu (Influenza) cases annually around the world. Influenza is an acute respiratory infection caused by influenza viruses which circulate in all parts of the world among all age groups. Influenza spreads predominantly via the droplet and is highly contagious. There are four types of influenza viruses, types A, B, C and D. Among them, Influenza A and B viruses circulate and cause seasonal epidemics of disease.

Featured Antibody Pairs

Product	Pair No.	Catalog No.	Source	Clone	Isotype	Application	Blocker	Platform
Influenza A	Pair 1	BRCINFS102	CHO	31B4	IgG1	Coating	√	Lateral Flow & Immunofluo-rescence
		BRJINFS102	CHO	30C6	IgG2a	Conjugate	√	
	Pair 2	BRJINFS102	CHO	30C6	IgG2a	Coating	√	
		BRCINFS102	CHO	31B4	IgG1	Conjugate	√	
	Pair 3	BRCINFS103	CHO	30A5	IgG2a	Coating	√	
		BRCINFS102	CHO	31B4	IgG1	Conjugate	√	
Influenza B	Pair 1	BRNINFJ203	CHO	30D4	IgG2a	Coating	√	
		BRNINFC202	CHO	30E3	IgG1	Conjugate	√	
	Pair 2	BRNINFC201	Mouse	2F3	IgM	Coating	√	
		BRNINFJ204	CHO	30E2	IgG2b	Conjugate	√	
	Pair 3	BRNINFJ203	CHO	30D4	IgG2a	Coating	√	
		BRNINFC201	Mouse	2F3	IgM	Conjugate	√	

Performance

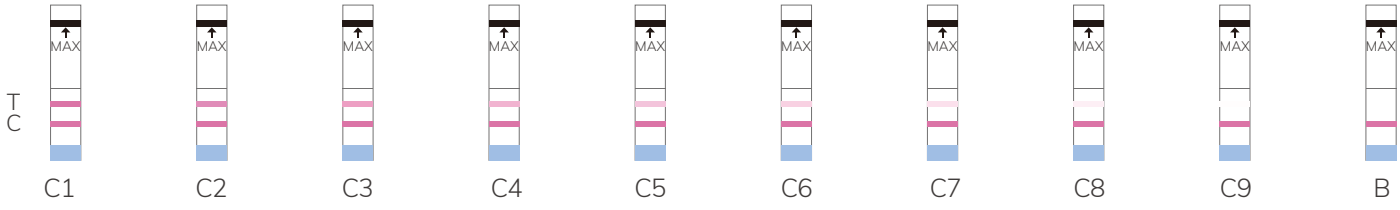
Reactivity - Influenza A Antibody Pairs

Sample Info				Reactivity		
Source	Type of Virus	Viral Strain	Dilution Ratio	Pair 1	Pair 2	Pair 3
Fapon Quality Control	Cultured-based Virus	H1N1	1:500	C2	C3+	C3+
			1:5000	C5+	C5	C5
			1:50000	C7	C8+	C8+
		H3N2	1:500	C1	C1	C1
			1:5000	C3	C3	C3
			1:50000	C5+	C5	C5
		H5N1	1:20	C2	C3+	C3+
			1:200	C6+	C6	C6
			1:2000	C8+	C9+	C9+
		H7N9	1:20	C2+	C2	C2
			1:200	C5+	C5	C5
			1:2000	C7	C8	C8

Sample Info				Reactivity		
Source	Type of Virus	Viral Strain	Dilution Ratio	Pair 1	Pair 2	Pair 3
NIBSC Standard	Inactivated Virus	Influenza Virus Infectious NYMC X-185	20	C1+	C1+	C1+
			1000	C6	C7	C7
		Influenza Virus infectious Resvir-14 (H3N2)	20	C2	C3	C3
			1000	C8	C9	C9
		Influenza Virus infectious NIB-26 (H3N2)	20	C2+	C2	C2
			1000	C7	C9+	C9+
		Influenza Antigen A/Texas /50/2012 (NYMC X-223A)	20	C6	--	--
			1000	C9+	C9+	C9+
		Influenza Virus infectious A/Beijing/32/92 (H3N2)	20	C1	C2+	C2+
			1000	C7	C8+	C8+
		Influenza Virus infectious A/Shanghai/24/90	20	C1	C2	C2
			1000	C7	C8	C8
		Influenza Virus infectious A/Sichuan/346/98 (H3N2)	20	C1	C1	C1
			1000	C8+	C8	C8
Others		2019/H3N2	20	C1	C2+	C2+
		2019/H1N1	20	C1	C2	C2
		2019/H1N1	20	C1	C1	C1
		A/Brisbane/10/2007	--	Detectable		
		A/Perth/16/2009				
		A/California/7/2004				
		A/Brisbane/59/2007				
		A/Victoria/361/2011				
		A/California/7/2009				
		A/New Caledonia/20/1999				
		A/Wisconsin/67/2005				
		A/Solomon Islands/3/2006				
	H1N1 Virus	A/Taiwan/1/86(8IN73)				
		A/Beijing/262/95(8IN73-2)				
		Influenza Virus infectious A/Guizhou/54/89 (H3N2)				
		Influenza Virus infectious A/Wuhan/359/95 (H3N2)				
	H3N2 Virus	A/Victoria/210/2009w				
		A/Kiev/301/94(8IN74-2)				
		H3N2 A/Panama/2007/ 998IN74-1				
		A/Shandong/9/93(8IN74)				
		A/Texas/50/2012				
		A/Hiroshima/52/2005				

Reactivity - Influenza B Antibody Pairs

Sample Info				Reactivity		
Source	Type of Virus	Viral Strain	Dilution Ratio	Pair 1	Pair 2	Pair 3
Fapon Quality Control	Cultured-based Virus	Influenza B Quality Control	30	C4	C4+	C4
			300	C6	C6+	C6
			3000	C8	C8+	C8
NIBSC Standard	Inactivated Virus	Influenza Virus infectious NYMC BX-7	20	C4	C4+	C4+
			1000	C9	C9	C9
		Influenza virus infectious NYMC BX-39	20	C3	C3+	C3
			1000	C8+	C8+	C8+
Others		BY-V1908875256	32	C4	C3	C4+
			640	C6	C5	C6+
		BV-V1906106179	64	C5	C5+	C5
			640	C7	C7+	C7
		BV-V1906106180	100	C7	C7	C7
			1000	C9	C9	C9
		BV-V1906106181	100	C6	C7	C7
			1000	C8	C9	C9
		BV-V1906106182	100	C5	C6+	C6
			1000	C8	C8	C8
		B/Shanghai/361/02	--	Detectable		
		B/Malaysia/2506/2004				
		B/Massachusetts/2/2012				
		B/Wisconsin/01/2010				
		B/Tokio/53/99				
		Influenza Virus infectious B/Sichuan/379/99				
		B/Qingdao/102/91				
		B/Brisbane/60/2008				
		B/Florida/04/2006				
		B/Victoria/504/00				
		Influenza Virus infectious B/Shanghai/361/2002				



Result interpretation: the higher the number, the lower the activity, B refers to undetectable

Cross-Reactivity

Tested Fapon Influenza A/B antibodies with SARS-CoV-2, Mycoplasma Pneumoniae, Parainfluenza, RSV, Adenovirus and other viral pathogens at different concentrations, results showed no detection, suggesting no cross-reaction and false-positive results.

Type of Pathogen	Pathogen	Type of Virus	Concentration	Result
SARS-CoV-2	S/ N Protein	Recombinant antigen	10 μg/mL	No cross-reaction with Influenza A/B
		Cultured-based virus	1:200 Dilution	
Mycoplasma Pneumoniae	Mycoplasma pneumonia	Inactivated virus	50 μg/mL	
Parainfluenza	Parainfluenza 2		5 μg/mL	
RSV	RSV		50 μg/mL	
Adenovirus	Adenoviridae		10 μg/mL	
Influenza B	Influenza B virus	Cultured-based virus	55 μg/mL	No cross-reaction with Influenza A
Influenza A H1N1	Influenza A virus		2 μg/mL	No cross-reaction with Influenza B
Influenza A H3N2			36 μg/mL	
Influenza A H5N1			15 μg/mL	
Influenza A H7N9			40 μg/mL	
Others	EB virus	Inactivated virus	30 μg/mL	No cross-reaction with Influenza A/B
	Mumps virus		50 μg/mL	
	Varicella-zoster virus		50 μg/mL	
	Human cytomegalovirus		1:10 Dilution	
	Measles virus		1:10 Dilution	
	Rotavirus		1:10 Dilution	

Specificity

Tested Fapon Influenza A & B Antibody Pairs and Combo (Influenza A Pair 1 + Influenza B Antibody Pair 2) respectively with 106 clinical throat swab samples, results showed 100% specificity, no false-positive results.

Batch to Batch Consistency

Evaluated three batches of Fapon Influenza Antibody Pairs on the lateral flow platform, results showed a small colour difference at 0.5C, confirming low batch difference and high product stability can be achieved in production.

Stability

Fapon Influenza Antibody Pairs showed little changes in activity and specificity levels in different temperature, storage periods, and repeated freezing/thawing at 18 times, confirming excellent product stability.

Temperature (°C)	Evaluation Period (Days)
-80	21
-20	21
-4	21
Room Temperature	7/14/21
37	7/14/21
45	7

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