FAPON BIOTECH

Co-Creator of Diagnostic Ecosystem

Raw Material Catalogue for Cardiac Markers

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Introduction

Cardiovascular diseases (CVDs) refer to ischemic or hemorrhagic diseases of the heart, brain and systemic tissues caused by hyperlipidemia (HLP), increased blood viscosity, atherosclerosis and hypertension. CVDs account for one-third of deaths throughout the world and are the leading cause of death. Therefore, rapid diagnosis, reliable identification and monitoring of high-risk individuals are vital in reducing the risk of CVD-associated death and disability.

Cardiac markers are a large category of molecules. And their concentration will increase significantly when CVDs occur or at the risk of occurrence. For different pathophysiological processes of the CVD, different cardiac markets can be used in clinical applications such as auxiliary diagnosis, risk assessment, and follow-up treatment. For example, cardiac troponin (cTn) is released into blood when cardiomyocytes are damaged, and elevated serum cTn levels indicate cardiac injury. cTn immunoassay has become the key method for the diagnosis of acute myocardial infarction (AMI).

Content

NT-proBNP

Clinical Significance

N-terminal pro-brain natriuretic peptide (NT-proBNP) is the product of cardiomyocyte synthesis and cleaving by the action of protease. NT-proBNP has a longer half-life and is more stable than BNP. This makes NT-proBNP more sensitive in detecting early or mild heart failure. It is the preferred serum marker for heart failure as recommended by heart failure guidelines (ECS / ACC / AHA / HFSA / CSC). It is suited to wide clinical application in the prevention and screening of heart failure, evaluating efficacy and prognosis as well as risk stratification in patients with heart failure.

Featured Antibodies

Catalog No.	Source	Epitope	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BRJNBNPS106	Mouse	13-27aa	1B1	IgG1	Conjugate	10mMPB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BEENBNPS101	Mouse	27-31aa	1H2	IgG1	Conjugate				
BRCNBNPS101	Mouse	64-67aa	1D3	IgG1	Coating				
BRCNBNPS102	Mouse	39-46aa	1C4	IgG1	Coating				
BRJNBNPS103	Mouse	13-27aa	5A7	IgG1	Conjugate				
BRJNBNPS108	CHO	43-50aa	1B8	IgG1	Coating				
BECBNPS103	CHO	13-24aa	36A8	IgG1	Coating				
BEJBNPS102	CHO	34-39aa	33F9	IgG2b	Conjugate				

Featured Pairs

Pair No.	Catalog No.	Usage	Platform		
			CLIA	Colloidal Gold	Immunofluorescence
Pair 1	BRJNBNPS102	Conjugate	√	√	√
	BRJNBNPS108	Coating			
Pair 2	BRJNBNPS103	Conjugate	-	√	√
	BRJNBNPS108	Coating			
Pair 3	BEJBNPS102	Conjugate	√	√	√
	BECBNPS103	Coating			

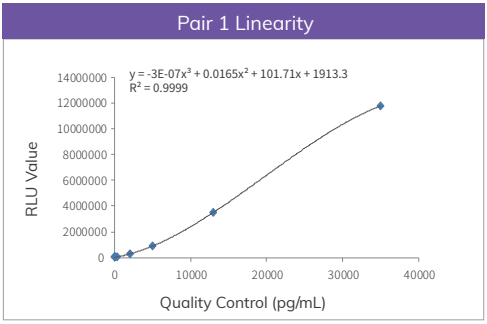
Pairing Antigen

Catalog No.	Source	Buffer	Storage Condition	Shelf Life	Purity
GRCBNPS101	*E.coli*	20mM PB+150mM NaCl	-20°C±5°C	3 Years	≥90%

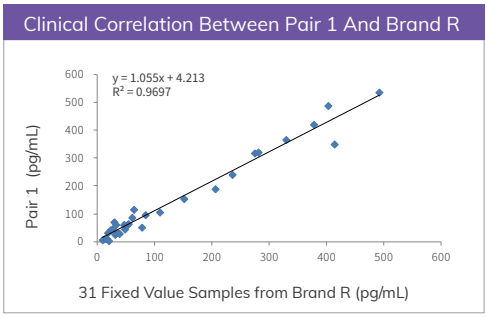
Performance

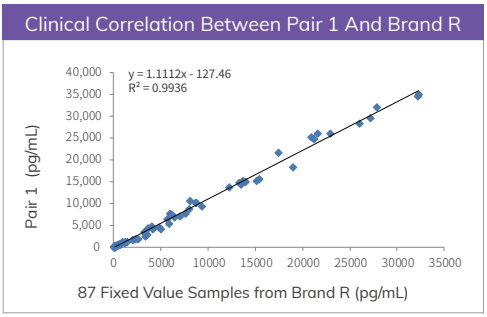
CLIA Platform

1. The linear range is 5-35000 pg/mL.



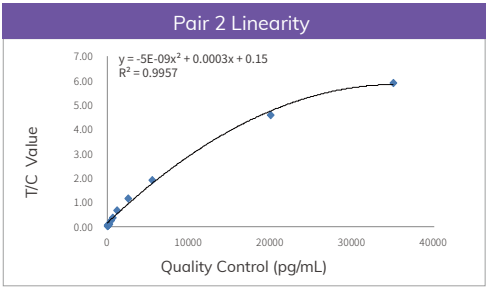
2. Use Pair 1 to test 31 low-value samples in a range of 5–500 pg/mL, the clinical correlation to Brand R is 0.96. Use Pair 1 to test 87 samples in a range of 5-35000 pg/mL, the clinical correlation to Brand R is 0.99.



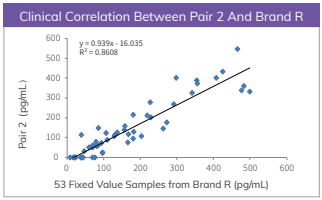


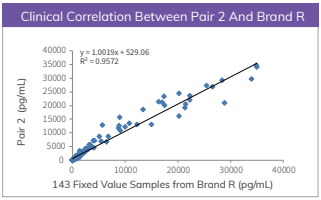
Immunofluorescence Platform

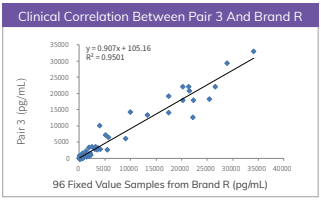
1. The linear range is 0-35000 pg/mL and the limit of detection is 50 pg/mL.



2. Use Pair 2 to test 53 low-value samples in a range of 5–500 pg/mL, the clinical correlation to Brand R is 0.86. Use Pair 2 to test 143 samples in a range of 5-35000 pg/mL, the clinical correlation to Brand R is 0.95. Use Pair 3 to test 96 samples in a range of 5-35000 pg/mL, the clinical correlation to Brand R is 0.95.







Colloidal Gold Platform

- The total coincidence rate of Pair 2 to Brand R is 96.32%
- The limit of detection of Pair 2 is 125 pg/mL
- The specificity is 97.8% by testing 203 clinical samples

cTnI

Clinical Significance

Cardiac troponin I (cTnI) is one of the most sensitive and specific markers of myocardial cell injury. It is an important indicator for judging myocardial cell injury in acute myocardial infarction, myocarditis and other diseases. Fapon Biotech has launched its innovative pairing materials for cTnI through accurate screening of antibody pairs. They are suitable for immunofluorescence and colloidal gold platforms, giving more accurate and sensitive performance and higher quality assurance.

Featured Antibody

Catalog No.	Source	Epitope	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BRJCTNIS108	CHO	41-49aa	31F1	IgG1	Conjugate	10mM PB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BRNCTNIN103	CHO	86-90aa	23A3	IgG1	Coating				
BRNCTNIN110	CHO	ITC Compound	40A10	IgG1	Coating				
BRNCTNIN108	CHO	TNC	35C8	IgG1	Coating				
BRNCTNIN106	CHO	25-40aa	36H6	IgG1	Coating				
BRNCTNIN107	CHO	23-29aa	37E7	IgG2a	Conjugate				
BRNCTNIN109	CHO	169-178aa	39F9	IgG2a	Conjugate				
BRNCTNIN110	CHO	190-196aa	40A10	IgG1	Conjugate				
BRNCTNIN113	CHO	24-40aa	23C12	IgG1	Conjugate				
BRNCTNIN105	CHO	41-49aa	24A5	IgG1	Coating				
BRNCTNIN102	CHO	83-93aa	26G2	IgG1	Coating				
BRJCTNIS110	CHO	24-40aa	31F11	IgG1	Conjugate				
BECCTNIS103	Goat	27-40aa	-	/	Coating				
BBNCTNIN102	Mouse	162-202aa	8C4	IgG2b	Conjugate				
BRJCTNIS106	Mouse	83-93aa	11C4	IgG1	Conjugate				

Featured Pairs

Pair No.	Catalog No.	Usage	Platform	
			Colloidal Gold	Immunofluorescence
Pair 1	BRNCTNIN113	Conjugate	√	√
	BRNCTNIN105	Coating		
	BRNCTNIN102	Coating		
	BRNCTNIN108	Coating/Conjugate		
Pair 2 NEW	BRNCTNIN106	Conjugate	√	√
	BRNCTNIN105	Coating		
	BRNCTNIN102	Coating		
	BRNCTNIN108	Coating		
Blocker	HIRE-M-009+HIER-R-001	Recommended concentration for sample pad, 0.3 mg/mL+0.2 mg/mL	√	√

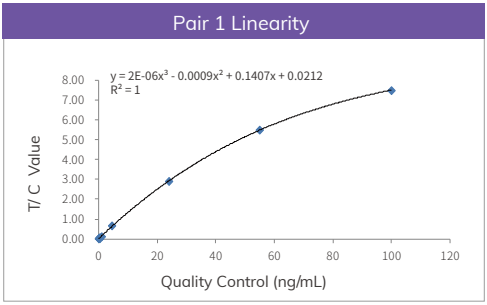
Pairing Antigen

Catalog No.	Source	Buffer	Storage Condition	Shelf Life	Purity
GRNCTNIN101	*E.coli*	25mM Tris-HCl+0.1%SDS+5mM EDTA,pH8.0	-20°C±5°C	3 Years	≥90%

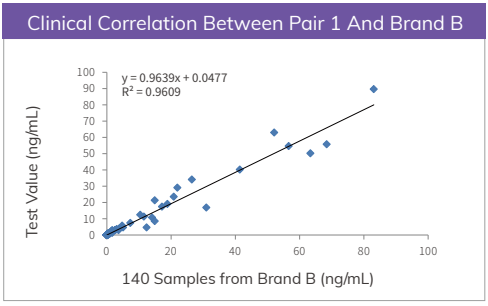
Performance

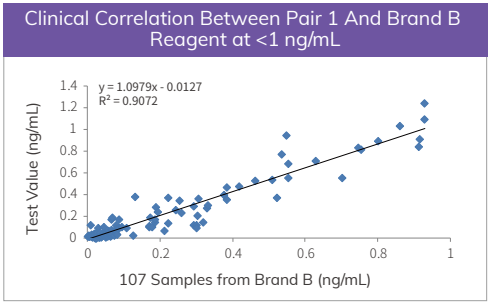
Immunofluorescence Platform

1. The linear range is 0.08-100 ng/mL and the limit of detection is 0.08 ng/mL.

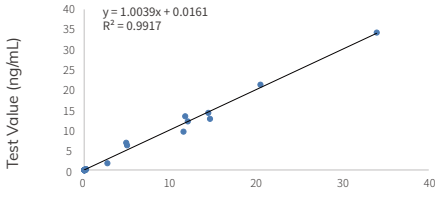


2. High clinical correlation values were shown between Fapon Biotech and top international Brand B and Brand A.

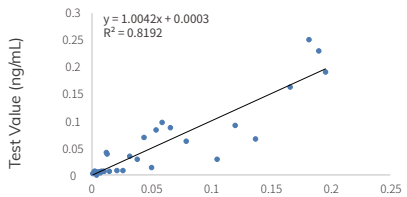




Clinical Correlation Between Pair 2 And Brand A



Clinical Correlation Between Pair 2 And Brand A Reagent at <0.2ng/mL



Colloidal Gold Platform

1. 46 positive samples of fixed values from Company B (cut off=0.04 ng/ml) were tested and 45 samples were found positive by Fapon Biotech cTnI. The positive detection rate is 97.83% and the minimum detection limit is 0.3 ng/ml.

Sample No.	Fixed Value Samples of Company B (ng/ml)	Colour Intensity of Fapon Biotech cTnI
1	0.11	B+
2	0.299	C9+
3	0.441	C8
4	0.489	C7-
5	0.478	C7-
6	0.598	C6
7	0.575	C7
8	0.575	C7
9	0.54	C8
10	0.507	C7
11	0.608	C7
12	0.788	C7
13	0.772	C7
14	3.011	C5
15	3.785	C5
16	3.922	C3
17	2.67	C4
18	1.461	C5
19	1.054	C5
20	1.646	C5
21	0.919	C7
22	0.983	C6
23	13.984	C1

Sample No.	Fixed Value Samples of Company B (ng/ml)	Colour Intensity of Fapon Biotech cTnI
24	13.481	C2
25	12.332	C2-
26	9.759	C2
27	8.797	C2
28	7.428	C3
29	6.974	C3
30	5.372	C5
31	5.71	C4
32	4.753	C3-
33	25.603	C1
34	24.272	C1
35	20.854	C1-
36	19.483	C2
37	16.048	C1
38	16.219	C1
39	15.758	C1
40	15.84	C1
41	15.028	C1
42	25.414	C1
43	27.452	C1
44	28.8	C1
45	29.849	C1
46	29.277	C1

CK-MB

Clinical Significance

Creatine kinase (CK, also known as creatine phosphokinase) belongs to a highly conserved phosphotransferase family called phosphocreatine (guanidino) kinase, which is expressed widely in different cells and tissues throughout the body. CK consists of any two subunits of M chain (muscle type) or B chain (brain type), and there are three different isoenzymes in the human body: CK-BB, CK-MM and CK-MB. CK-MB (CK-2) exists mostly in the myocardium and is therefore a cardiac marker of myocardial injury.

CK-MB is normally undetectable or very low in the blood, but it is rapidly elevated in patients with diseases of the myocardium or skeletal muscles. CK-MB is more concentrated in the myocardium than skeletal muscles (i.e., 22% in the myocardium and 1-3% in skeletal muscles). The measurement of plasma or serum CK-MB levels is an important tool for diagnosing AMI and is one of the routine tests for emergency patients. [1,2,3]

Featured Antibody

Catalog No.	Source	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BRJCKMBS101	Mouse	1D10	IgG1	Conjugate	10mMPB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BRCCKMBS101	Mouse	1C11	IgG1	Coating				

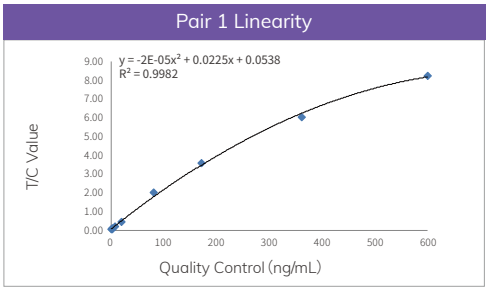
Featured Pairs

Pair No.	Catalog No.	Usage	Platform			
			CLIA	Colloidal Gold	Immunofluorescence	Clinical Biochemistry
Pair 1	BRJCKMBS101	Conjugate	√	√	√	√
	BRCCKMBS101	Coating				

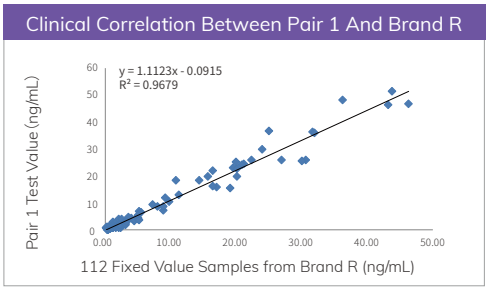
Performance

Immunofluorescence Platform

1. The linear range is 0-600 ng/mL and the limit of detection is 0.5 ng/mL.



2. High clinical correlation value was shown between Fapon Biotech featured pair and top international Brand R.



MYO

Clinical Significance

Myoglobin (MYO) is a cytoplasmic protein that binds oxygen on a heme group and it harbors a globulin group consisting of eight alpha helices connected by loops. MYO is found in the striated muscles, cardiomyocytes and smooth muscle cells, and plays the role of an oxygen store.[4] Myoglobin is a sensitive marker of muscle injury and is released into the circulation within 1-3 hours after AMI, with a gradual increase that reaches a peak at 4-7 hours, and returns to the baseline level after 24-36 hours.[5]

Featured Antibodies

Catalog No.	Source	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BRJMYOS101	Mouse	3B2	IgG1	Conjugate	10mMPB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BRCMYOS102	Mouse	2H9	IgG1	Coating				
BRCMYOS101	Mouse	3A7	IgG2a	Coating				
BRJMYOS103	CHO	22B6	IgG1	Conjugate				
BRCMYOS105	CHO	24C1	IgG1	Coating				

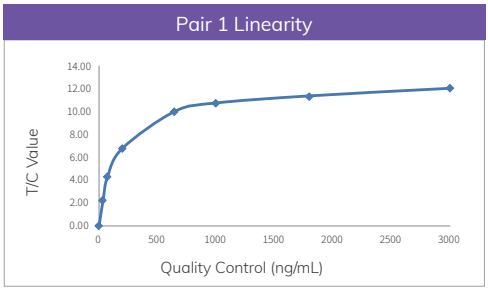
Featured Pairs

Pair No.	Catalog No.	Usage	Platform	
			Colloidal Gold	Immunofluorescence
Pair 1 NEW	BRJMYOS103	Conjugate	√	√
	BRCMYOS105	Coating		

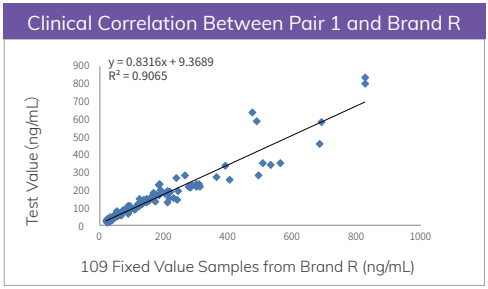
Performance

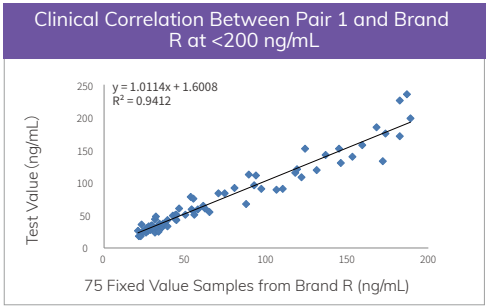
Immunofluorescence Platform

1. The linear range is 0-100 ng/mL. The limit of detection is 10 ng/mL. Hook effect is >3000 ng/mL.



2. High clinical correlation values were shown between Fapon Biotech featured pair and top international Brand R.





D-Dimer

Clinical Significance

D-Dimer is a fibrin degradation product formed after a blood clot is degraded by fibrinolysis. It can be used as a marker of secondary hyperfibrinolysis. The application of D-Dimer is valuable in the diagnosis and disease course monitoring of disseminated intravascular coagulation (DIC). D-Dimer levels are elevated in the early stage of DIC formation, and be continuously elevated by over 10 times with the development of the disease course. Therefore, D-Dimer can be used as the primary indicator for the early diagnosis and course monitoring of DIC.[6]

Featured Antibodies

Catalog No.	Source	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BBNDIMN103	Mouse	5D8	IgG1	Coating	10mMPB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BBNDIMN104	Mouse	2D7	IgG1	Conjugate				
BBNDIMN106	Mouse	8G6	--	Conjugate/Coating				
BBNDIMN108	Mouse	7A6	--	Conjugate/Coating				
BRCDIMS101	CHO	28D1	IgG1	Coating				

Featured Pairs

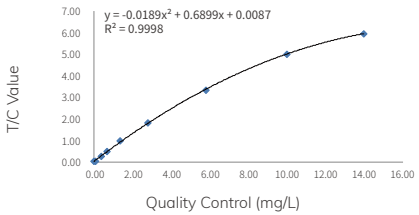
Pair No.	Catalog No.	Usage	Platform: Immunofluorescence
Pair 1 NEW	BBNDIMN106	Conjugate	√
	BRCDIMS101	Coating	
Pair 2 NEW	BBNDIMN108	Conjugate	
	BRCDIMS101	Coating	

Performance

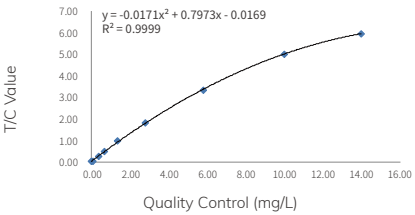
Immunofluorescence Platform

1. The linear range is 0-15 mg/L and the limit of detection is 0.06 mg/L.

Pair 1 Linearity

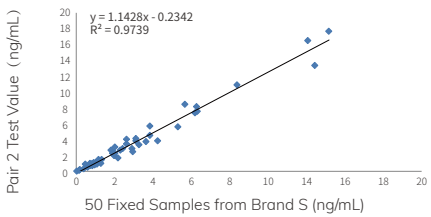


Pair 2 Linearity

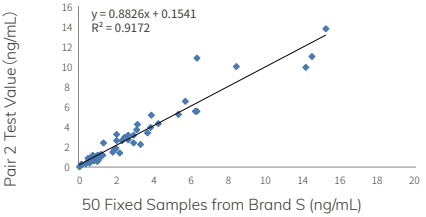


2. High clinical correlation values were shown between Fapon Biotech featured pairs and top international Brand S.

Clinical Correlation Between Pair 1 And Brand S



Clinical Correlation Between Pair 2 And Brand S



cTnT

Clinical Significance

The cTn complex is composed of three subunits, troponin T (cTnT), troponin I (cTnI) and troponin C (cTnC). The cTnT concentration of < 0.1 μg/L is normal, > 0.2 μg/L is the diagnostic critical value, and a concentration of > 0.5 μg/L can be diagnosed as AMI. Therefore cTnT is widely used as a marker of cardiomyocyte injury.

Featured Antibodies

Catalog No.	Source	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BRNCTNTS101	Mouse	5G8	IgG1	Coating	10mMPB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BRNCTNTS102	Mouse	15C9	--	Conjugate				

Featured Pairs

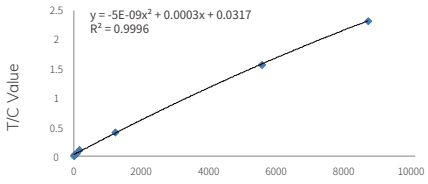
Pair No.	Catalog No.	Platform	
		CLIA	Immunofluorescence
Pair 1	BRNCTNTS101 / BRNCTNTS102	√	√

Performance

Immunofluorescence Platform

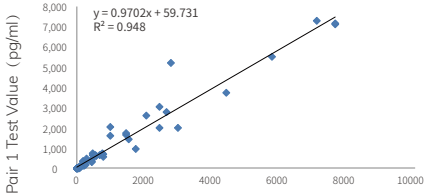
1. The linear range is 0-10000 pg/mL and the limit of detection is 100 pg/mL.

Pair 1 Linearity



2. High clinical correlation value was shown between Fapon Biotech featured pair and top international Brand R.

Clinical Correlation Between Pair 1 And Brand R



H-FABP

Clinical Significance

Heart type-fatty acid binding protein (H-FABP) is one of the most abundant proteins inside cardiomyocytes. The combination of the low molecular weight and cytoplasmic location of H-FABP makes H-FABP a highly sensitive early marker of acute coronary syndrome, which can be detected as early as 30 minutes after an ischemic attack. H-FABP reaches its peak level about 6-8 hours later, and returns to normal level within 24-30 hours.

Featured Antibodies

Catalog No.	Source	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BRJFABPS102	Mouse	8E6	IgG1	Conjugate	10mM PB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BRCFABPS102	Mouse	9A3	IgG1	Coating				
BRJFABPS101	Mouse	15C8	IgG1	Conjugate				
BRCFABPS101	Mouse	12F9	IgG1	Coating				
BRJFABPS202	CHO	24F1	IgG1	Conjugate				
BRCFABPS202	CHO	26H2	IgG1	Coating				

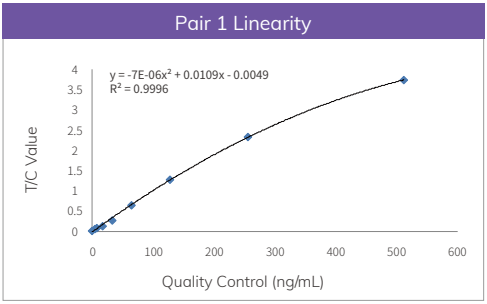
Featured Pairs

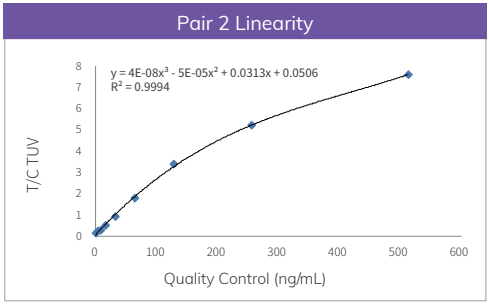
Pair No.	Catalog No.	Usage	Platform	
			Immunofluorescence	Colloidal Gold
Pair 1	BRJFABPS202	Conjugate	√	√
	BRCFABPS202	Coating		
Pair 2	BRJFABPS102	Conjugate		
	BRCFABPS102	Coating		
Pair 3	BRJFABPS101	Conjugate		
	BRCFABPS101	Coating		

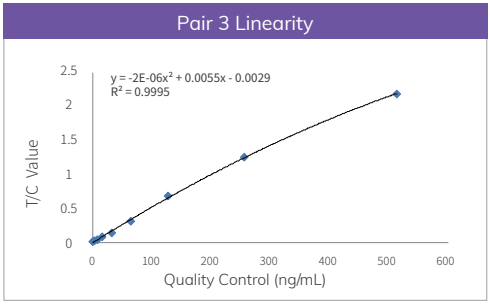
Performance

Immunofluorescence Platform

1. The linear range is 0-500 ng/mL.







Lp-PLA2

Clinical Significance

Lipoprotein-associated phospholipase A2 (Lp-PLA2), also known as platelet-activating factor acetylhydrolase (PAF-AH), which is secreted by macrophages, T cells and mast cells in the tunica intima, is a highly specific marker of vascular inflammation, and can be used as an indicator for dynamic monitoring of the degree of vascular specific inflammation and atherosclerosis inflammation.[7]

Featured Antibodies

Catalog No.	Source	Clone	Isotype	Usage	Buffer	Storage Condition	Shelf Life	Purity
BRCLPS101	Mouse	11G5	IgG1	Coating	10mM PB+150mM NaCl+0.1% P300, pH7.4	-20°C±5°C	3 Years	≥90%
BRJLPS101	Mouse	18A6	IgG1	Conjugate				
FPZ0674	Mouse	5C9	--	Coating				
BRJLPS102	Mouse	12A2	--	Conjugate				

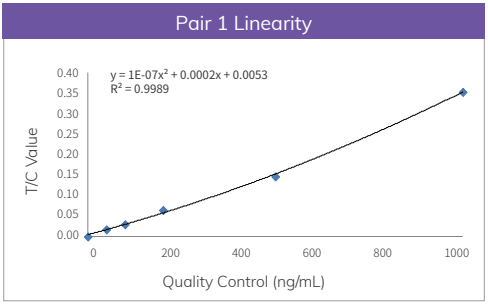
Featured Pairs

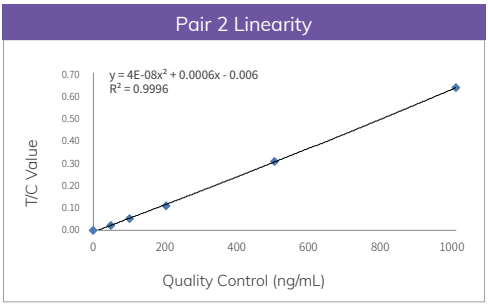
Pair No.	Catalog No.	Usage	Platform	
			Colloidal Gold	Immunofluorescence
Pair 1	BRCLPS101	Coating	√	√
	BRJLPS101	Conjugate		
Pair 2	FPZ0674	Coating		
	BRJLPS102	Conjugate		

Performance

Immunofluorescence Platform

1. The linear range is 0-1000 ng/mL.





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