

NT-proBNP (Heart Failure Marker)

- $R^2 = 0.997$, wide linear range on CLIA platform
- 3.8 pg/m low detection limit and wide linear range on immunofluorescent platform
- 100% positive detection rate on colloidal gold platform



The N-terminal pro-B-type natriuretic peptide (NT-proBNP) is synthesized by cardiomyocytes and is one of the cleavage products produced under the action of proteases. NT-proBNP has a longer half-life and better stability than BNP, hence NT-proBNP is more sensitive in the diagnosis of early or mild heart failure.

NT-proBNP is the preferred serum marker for heart failure [3-5] recommended by heart failure international guidelines (ECS/ACC/AHA/HFSA/CSC). NT-proBNP is also commonly used in a wide range of clinical applications such as preventive screening, efficacy testing, prognosis assessment, and risk stratification of heart failure patients.



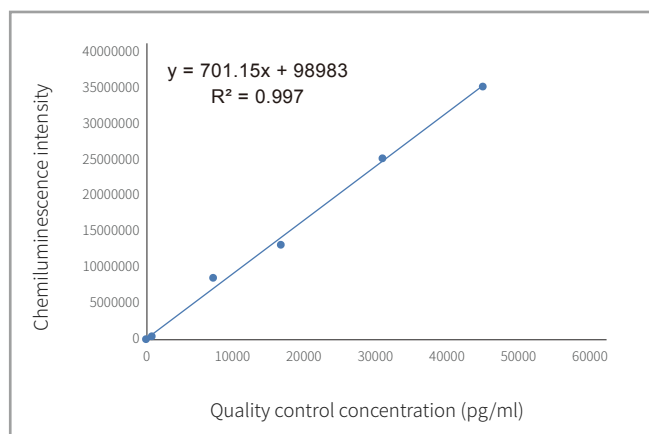
CLIA Platform

1. Pairing Recommendation

Catalog No.	Host	Recommended Usage
BRJNBNS102	Mouse	Labelling
BRJNBNS108	Recombinant Antibody	Coating

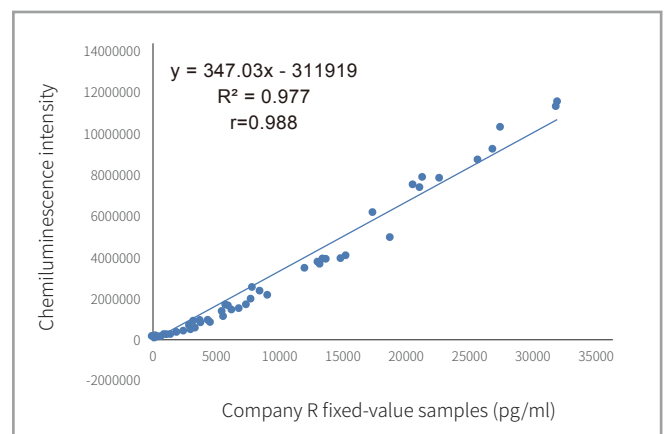
2.Linear Range & Detection Limit

Applied Fapon quality control for measurement, the pairing linear range was 0-50000 pg/ml, no hook effect was observed at 50000 pg/ml and the lowest detection limit was 5.8pg/ml.



3.Clinical Correlation

87 fixed-value samples of Company R were tested using Fapon pairing material, the correlation between Fapon pairing material and Company R samples was $R^2 = 0.977$ ($r = 0.988$), both confirmed excellent clinical correlation.





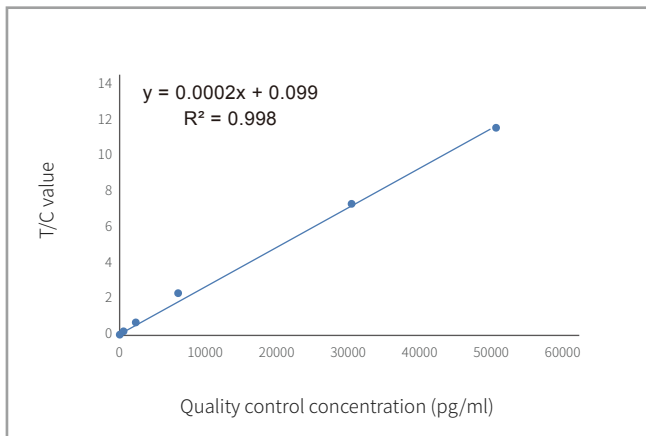
Immunofluorescence Platform

1. Pairing Recommendation

Catalog No.	Host	Recommended Usage
BRJNBNS102 or BRJNBNS103	Mouse	Labelling
BRJNBNS108	Recombinant Antibody	Coating

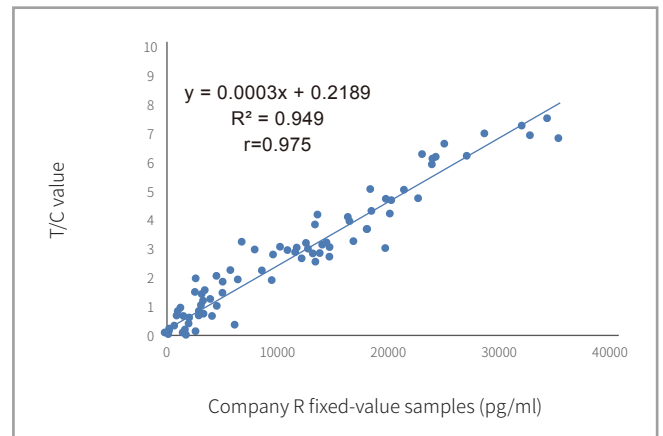
2. Linear Range & Detection Limit

Applied Fapon quality control for measurement, the pairing linear range was 0-50000 pg/ml, no hook effect was observed at 50000 pg/ml and the lowest detection limit was 3.8pg/ml.



3. Clinical Correlation

109 fixed-value samples of Company R were tested using Fapon pairing material. With a cut off value at 300 pg/ml, the overall correlation between Fapon pairing material and Company R samples was $R^2 = 0.949$ ($r = 0.975$), both confirmed excellent clinical correlation.



Colloidal Gold Platform

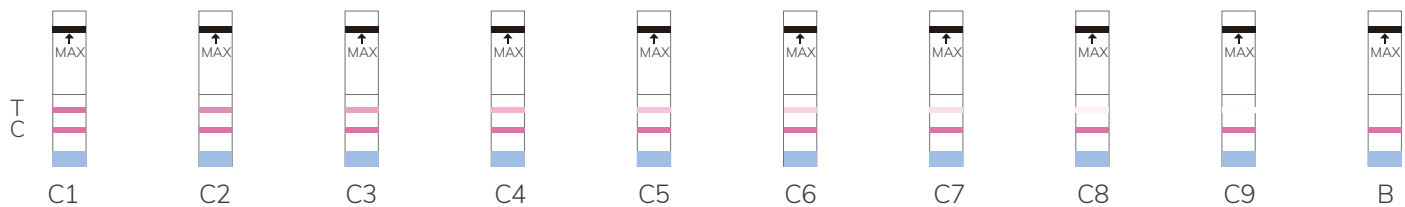
1. Pairing Recommendation

Catalog No.	Host	Recommended Usage
BRJNBNS103	Mouse	Labelling
BRJNBNS108	Recombinant Antibody	Coating

2. Positive Detection Rate & Detection Limit

50 fixed value samples of Company R were tested using Fapon pairing material and were all found positive. The detection rate was 100% and the lowest detection limit was 200pg/ml.

Sample No.	Fixed Value Sample of Company R	Color Intensity	Sample No.	Fixed Value Sample of Company R	Color Intensity
1#	186.4	C9	25#	6946	C3
2#	990.4	C8	26#	5246	C1
3#	571.3	C8	27#	6352	C1
4#	1176	C8+	28#	5392	C1
5#	2308	C8	29#	4693	C1
6#	8200	C3-	30#	2067	C8
7#	14548	C2	31#	4365	C2
8#	686.1	C4+	32#	2955	C3-
9#	13133	C1	33#	3212	C3-
10#	28387	C1	34#	9596	C6-
11#	6846	C1	35#	1748	C7
12#	212.1	C9	36#	803.3	C6-
13#	28387	C1	37#	1057	C6
14#	2761	C1	38#	961.2	C6-
15#	541.6	C4-	39#	5412	C3
16#	213.5	C6	40#	2955	C3-
17#	5925	C1	41#	7741	C3-
18#	13892	C1	42#	4365	C3
19#	10877	C1	43#	11796	C2
20#	20768	C1+	44#	5124	C4
21#	12978	C6	45#	5910	C3+
22#	7741	C3+	46#	3416	C5-
23#	5421	C3	47#	2648	C5
24#	7383	C1+	48#	1141	C8



*Colour Intensity: the greater the number, the lower the activity.

3. Specificity

500 negative samples were detected and a specificity of 97.8% was achieved.

Batch to Batch Consistency

Evaluated three batches of Fapon NT-proBNP on the CLIA, Immunofluorescence Chromatography and Colloidal Gold platforms respectively, the results confirmed small batch differences and thus high product stability can be achieved in production.

Stability

Fapon material pair showed little changes in activity and specificity levels in different temperature, storage periods, and condition of repeated freezing/thawing, confirming excellent product stability.

Temperature (C°)	Freeze-thaw Cycles (Times)	Storage Period (Days)
-80	--	21
-20	18	21
-4	--	21
Room Temperature	--	7/14/21
37	--	7/14/21
45	--	7



FAPON

Fapon Biotech Inc.

📍 No.5 Hualian Road, Taiwan High-tech industrial park,
Songshan Lake, Dongguan, Guangdong, China

☎ 86-769-22898886

✉ market@fapon.com

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LinkedIn: faponbiotech