# Hunan Kangxin Biotechnology Co., Ltd.
# NT-proBNP Test kit
# （Microfluidic Fluorescence Immunoluminescence Assay）
# Performance evaluation comparative study data

**Chengdu VACURE Biotechnology Co., Ltd.**

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## 1 Purpose & Overview

Purpose: To evaluate and analyze the performance of fluorescence immunoassay for the determination of Amino-Terminal pro-brain natriuretic peptide (NT-proBNP) in human serum. The intra-assay precision CV was calculated with reference to EP15-A2. Refer to the EP9-A2 file to calculate the linear regression equation and correlation coefficient between Hunan Kangxin Biotechnology Co., Ltd. (hereafter Kangxin) and Roche diagnostics GmbH (hereafter Roche),.In order to analyze whether the performance of Kangxin is good compared with domestic similar products.

## 2 Reagents&Instruments

（1）Instruments：Electrochemiluminescence automatic immunoassay analyzer　cobas e 411

Reagents：Brain Natriuretic Titanium Precursor Detection Kit

（Electrochemiluminescence）

Manufacturer：Roche Diagnostics GmbH

（2）Instruments：Fluorescence Immunoassay Analyzer LYOFIA-I

Reagents：N-terminal brain natriuretic peptide precursor（NT-proBNP）Test Kit（Microfluidic Fluorescence Immunoluminescence Assay）

Manufacturer：Hunan Kangxin Biotechnology Co., Ltd.

Lot：0216401

## 3 Test content

### 3. 1 Precision assessment

Test samples at two concentration levels in 2 detection systems, repeat the test 10 times, calculate the average of 10 test results（$\overline{X}$）and standard deviation（S）, get the coefficient of variation（CV）, the results should not be less than the value declared by the manufacturer.

Manufacturer(Kangxin) declared value：Kangxin（CV）：≤10%；

### 3. 2 Comparison of system results

Refer to the method in EP9-A2 Method Comparison and Bias Assessment Using Patient Samples "Method Comparison and Bias Assessment Using Patient Samples" to measure samples on two systems respectively, each sample was measured once, and statistical analysis was performed on the detection data.

Kangxin's linearity is：30-35000pg/mL, the methodological comparison of the linearity of 30-35000pg/mL and 30-1000pg/mL of the Kangxin's linearity was carried out respectively.

Taking the detection result of the comparison system as the X axis and the detection result of the test system as the Y axis, make a regression curve to obtain the regression formula and the correlation coefficient r.

## 4 Test Results

4. 1 Precision assessment

| Repeat times (**pg/mL**) | Roche | | Kangxin | |
|---|---|---|---|---|
| | 341 | 1003 | 341 | 1003 |
| 1 | 345 | 1013 | 332 | 1008 |
| 2 | 349 | 987 | 342 | 991 |
| 3 | 346 | 997 | 347 | 983 |
| 4 | 347 | 1012 | 335 | 1007 |
| 5 | 345 | 985 | 340 | 1022 |
| 6 | 345 | 1001 | 325 | 1027 |
| 7 | 340 | 1017 | 302 | 1043 |
| 8 | 331 | 1015 | 299 | 1065 |
| 9 | 333 | 1006 | 293 | 1078 |
| 10 | 327 | 1001 | 304 | 1087 |
| Average Value | 340.8 | 1003.4 | 321.9 | 1031.1 |
| Standard Deviation | 7.69993 | 11.31567 | 20.33306 | 36.13386 |
| CV | 2.3% | 1.1% | 6.3% | 3.5% |

4. 2 Methodological comparison

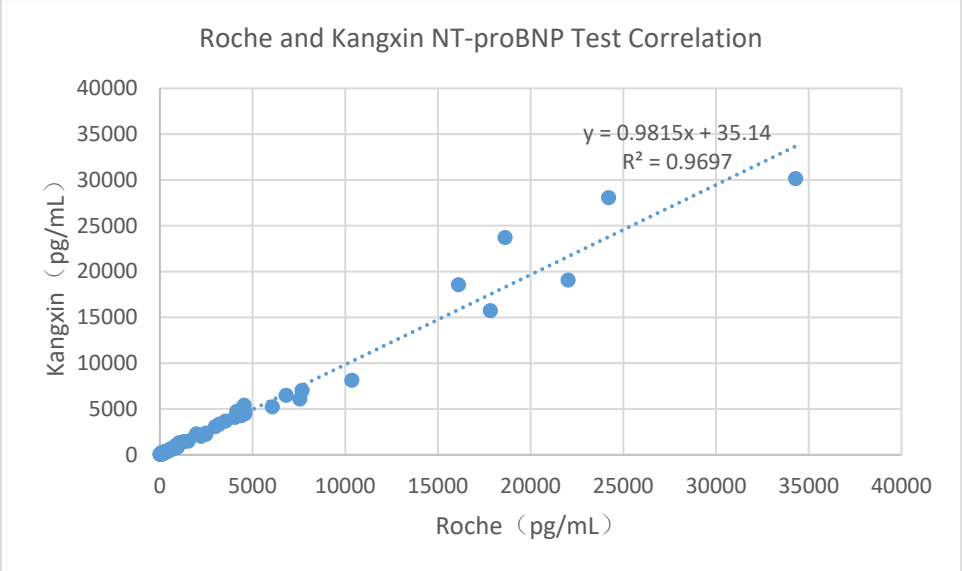
| Sample/Unit (pg/mL) | Roche | Kangxin |
|---|---|---|
| 1 | 26 | < 30 |
| 2 | 29 | 43 |
| 3 | 38 | 46 |
| 4 | 40 | 67 |
| 5 | 41 | < 30 |
| 6 | 56 | 65 |
| 7 | 59 | 160 |
| 8 | 74 | 69 |
| 9 | 80 | 106 |
| 10 | 85 | 83 |
| 11 | 85 | 57 |
| 12 | 89 | 67 |
| 13 | 129 | 117 |
| 14 | 134 | 251 |
| 15 | 137 | 61 |
| 16 | 138 | 105 |
| 17 | 144 | 138 |

| | | |
|---|---|---|
| 18 | 147 | 151 |
| 19 | 158 | 175 |
| 20 | 166 | 199 |
| 21 | 175 | 142 |
| 22 | 175 | 132 |
| 23 | 175 | 158 |
| 24 | 197 | 152 |
| 25 | 204 | 208 |
| 26 | 227 | 137 |
| 27 | 227 | 203 |
| 28 | 269 | 298 |
| 29 | 309 | 346 |
| 30 | 313 | 359 |
| 31 | 434 | 353 |
| 32 | 577 | 623 |
| 33 | 606 | 595 |
| 34 | 612 | 539 |
| 35 | 662 | 606 |
| 36 | 798 | 681 |
| 37 | 863 | 968 |
| 38 | 896 | 893 |
| 39 | 901 | 985 |
| 40 | 954 | 809 |
| 41 | 1056 | 1302 |
| 42 | 1284 | 1412 |
| 43 | 1541 | 1480 |
| 44 | 1988 | 2273 |
| 45 | 2141 | 2130 |
| 46 | 2238 | 2008 |
| 47 | 2496 | 2231 |
| 48 | 2503 | 2364 |
| 49 | 3014 | 3079 |
| 50 | 3219 | 3342 |
| 51 | 3553 | 3669 |
| 52 | 4053 | 4075 |
| 53 | 4161 | 4739 |
| 54 | 4379 | 4254 |
| 55 | 4413 | 4299 |
| 56 | 4451 | 4720 |

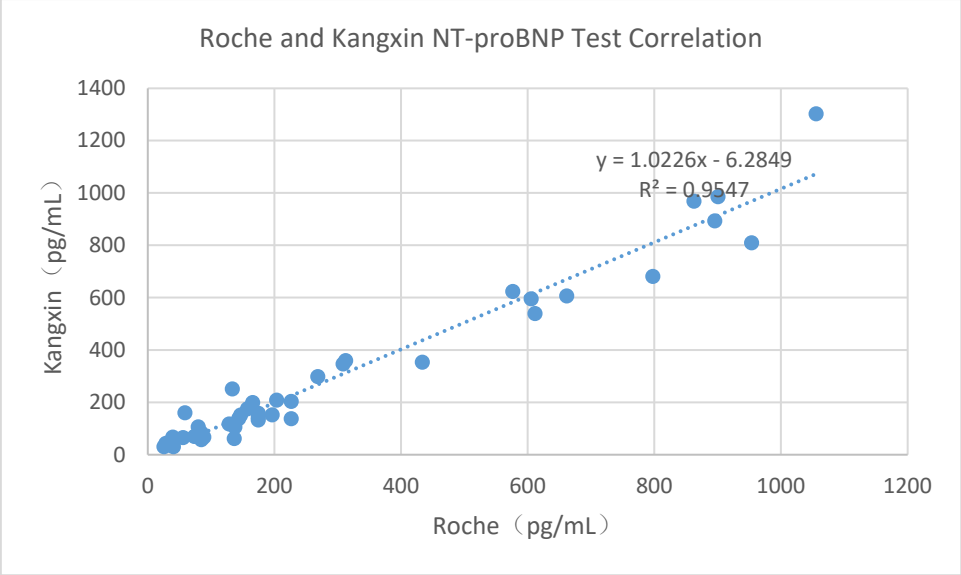
| | | |
|---|---|---|
| 57 | 4561 | 5400 |
| 58 | 4600 | 4475 |
| 59 | 4601 | 4680 |
| 60 | 6081 | 5217 |
| 61 | 6816 | 6483 |
| 62 | 7560 | 6073 |
| 63 | 7682 | 7016 |
| 64 | 10367 | 8128 |
| 65 | 16121 | 18549 |
| 66 | 17837 | 15728 |
| 67 | 18631 | 23706 |
| 68 | 22038 | 19066 |
| 69 | 24222 | 28051 |
| 70 | 34301 | 30143 |

4. 2. 1 Data Analysis

Test Range: 30-35000 pg/mL: Take Roche's detection value as X, and Kangxin's detection value as Y, to make a regression curve.




Test Range: 30-1000 pg/mL: Take the Roche detection value as X, and Kangxin's detection value as Y, to make a regression curve.




## 5 Conclusion

In this study, in the detection range of 30-35000 pg/mL and 30-1000 pg/mL, the correlations of Kangxin detection system are R2 = 0.9697, R2 = 0.9547 respectively, It has a good correlation with the Roche Cobas automatic electrochemiluminescence detection system. Precision meets manufacturer's declared standards, compared with the domestic similar amino-terminal brain natriuretic peptide precursor detection kit, it meets the clinical requirements.

Reporter: Reviewer: Date:

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