Hunan Kangxin Biotechnology Co., Ltd.
C-Reactive Protein（CRP）Test Kit
（Microfluidic Fluorescent Immunoassay）

Performance evaluation comparative study data

Chengdu VACURE Biotechnology Co., Ltd.
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1 Purpose & Overview

Purpose: Evaluation and Analysis of the Performance of Fluorescence Immunoassay for the Determination of C-Reactive Protein (CRP) in 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 Beckman Coulter (USA) Inc.(Hereafter Beckman) detection system respectively to analyze whether the performance of Kangxin Detection System was good compared with domestic similar.

2 Reagents&Instruments

(1) Instruments: Beckman Coulter AU400/640

Reagents: C-Reactive Protein Test kit（Immunoturbidimetry）

Manufacturer: Beckman Coulter (USA) Inc.

(2) Instruments: Fluorescence Immunoassay Analyzer LYOFIA-I

Reagents: C-Reactive Protein（CRP）Test kit（Microfluidic luminescence）

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

Lot：0316101

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 with Patient Samples "Method Comparison and Bias Assessment with Patient Samples" to measure samples on two systems respectively. Statistical analysis of the detection data was carried out for a single measurement of each sample.

Kangxin's linearity: 0.4-100mg/L, the methodological comparison of the linearity of 0.4-100mg/mL and 0.4-20mg/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	Beckman		Kangxin	
(mg/L)	1.05	11.43	1.05	11.43

CHENGDU VACURE Biotech CO.,LTD

ADD: 4th Floor, Building 7, Sanyi Innovation Center (Phase III), No. 733, Section 2, Furong Avenue, Wenjiang District, Chengdu, SiChuan Province, China.

info@vacurebiotech.com   www.vacurebiotech.com   +86 28 85155537

1	1.01	11.84	1.15	10.82
2	1.08	11.78	1.13	10.78
3	1.07	11.13	1.01	10.83
4	1.05	11.02	0.95	10.81
5	1.03	11.69	1.01	9.96
6	1.05	11.37	0.99	10.19
7	1.11	11.58	1.16	11.76
8	1.01	11.61	1.15	11.01
9	1.02	11.46	1.15	10.45
10	1.09	10.94	0.99	11.87
Average Value	1.052	11.442	1.069	10.848
Standard Deviation	0.0349	0.3187	0.0852	0.6046
CV	3.32%	2.79%	7.97%	5.57%

4.2 Methodological comparison

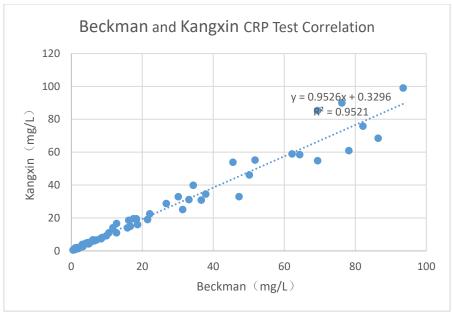| Sample/Unit (mg/L)	Beckman	Kangxin
1	0.44	< 0.4
2	0.5	0.45
3	0.97	0.65
4	1.11	1.72
5	1.46	1.53
6	1.62	1.91
7	1.84	1.26
8	2.38	2.07
9	2.06	1.53
10	3.11	3.9
11	3.28	2.56
12	3.55	3.94
13	4.23	4.71
14	4.69	4.3
15	4.77	5.01
16	4.92	4.2
17	5.16	4.68
18	6.04	6.5
19	6.11	6.64
20	6.45	6.01
21	7.06	6.57
22	8.25	7.38

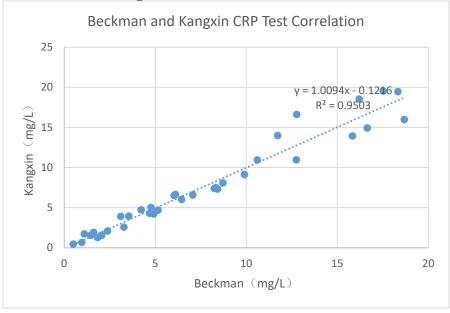|		
23	8.33	7.49
24	8.43	7.31
25	8.72	8.06
26	9.9	9.11
27	10.61	10.94
28	11.73	13.98
29	12.77	16.6
30	12.75	10.95
31	15.83	13.93
32	16.2	18.52
33	16.65	14.92
34	17.52	19.52
35	18.33	19.44
36	18.68	15.96
37	21.5	18.99
38	22.13	22.45
39	26.77	28.74
40	30.15	32.9
41	31.4	25.08
42	33.16	31.13
43	34.37	39.83
44	36.62	30.84
45	37.89	34.51
46	45.56	53.86
47	47.27	32.93
48	50.18	46.11
49	51.77	55.18
50	62.22	58.92
51	64.35	58.5
52	69.4	54.76
53	69.39	85.29
54	76.23	89.93
55	78.19	60.91
56	82.16	75.81
57	86.45	68.46
58	93.5	98.99

4.2.1 Data Analysis

Test Range: 0.4-100 mg/L: Take Beckman's detection value as X, and Kangxin's detection value as Y, to make a regression curve.

Beckman and Kangxin CRP Test Correlation

$y = 0.9526x + 0.3296$
$R^2 = 0.9521$

Test Rang: 0.4-20 mg/L: Take the Beckman's detection value as X, and Kangxin's detection value as Y, to make a regression curve.

Beckman and Kangxin CRP Test Correlation

$y = 1.0094x - 0.1216$
$R^2 = 0.9503$

5 Conclusion

In this study, the correlations within the detection range of the Kangxin detection system: 0.4-100 mg/L and 0.4-20 mg/L were: R2 = 0.9521, R2 = 0.9503, It has a good correlation with the Beckman fully automatic electrochemiluminescence detection system, and the precision meets the manufacturer's declared value.

Reporter：   Reviewer：   Date：