Hunan Kangxin Biotechnology Co., Ltd.

Interleukin-6（IL-6） test kit

(Microfluidic Fluorescent Immunoassay)

Comparison Study Data of Performance Evaluation

Chengdu VACURE Biotechnology Co., Ltd.

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1.Purpose & Overview

Purpose: Evaluation and analysis the performance of fluorescent immunoassay for the Determination of interleukin-6（IL-6）in serum.

The intra-assay precision CV was calculated with reference to EP15-A2.

Refer to EP9-A2 to calculate the linear regression equation and correlation coefficient between Hunan Kangxin Biotechnology (Here after Kangxin） and Roche Diagnostics GmbH (Here after Roche) detection system respectively, to analyze whether the performance of Kangxin detection system is good compared with domestic similar products.

2.Reagents & Instruments

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

Reagent:：Interleukin-6 test kit（Electrochemiluminescence）

Manufacturer：Roche Diagnostics GmbH

（2）Instrument：Fluorescent Immunoassay Analyzer LYOFIA-I

Reagent：Interleukin-6 (IL-6) test kit（Microfluidic Fluorescent Immunoassay）

Manufacturer：Hunan Kangxin Biotechnology Co., Ltd.

LOT：0516101

3 Test Content

3.1 Precision assessment

Test samples at two concentration levels in 2 detection systems, repeat the test 10 times. Then calculate the average value ($\overline{X}$) and standard deviation (S) based on previous testing results, which can 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 study of system results

Refer to the “Method Comparison and Bias Assessment with Patient Samples” in EP9-A2 that measure samples on two systems respectively and only can be carried out a single measurement of each sample, finally get the statistical analysis of the detection date.

The detection range of Kangxin Biological kit is：2-3000pg/mL， methods were compared for the detection range of 2-3000pg/mL and 2-250pg/mL, 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, making a regression curve to obtain the regression formula and the correlation coefficient “r”

4 Test Result

4.1 Precision assessment

Repeat times (pg/mL)	Roche		Kangxin	
	48.26	543.82	48.26	543.82
1	50.55	532.31	47.13	551.85
2	48.54	530.41	52.07	490.79
3	48.91	567.35	45.42	556.06
4	49.99	568.17	50.19	503.17
5	50.56	554.11	51.52	523.52
6	49.07	530.09	51.73	490.32
7	49.01	537.62	43.25	516.16
8	50.03	538.55	45.24	522.49
9	46.61	542.57	50.94	539.75
10	49.62	566.14	48.27	514.49
Average Value	49.289	546.732	48.576	520.86

Standard Deviation	1.1720	15.7567	3.1738	23.0422
CV	2.38%	2.88%	6.53%	4.42%

4.2 Methodological Comparison

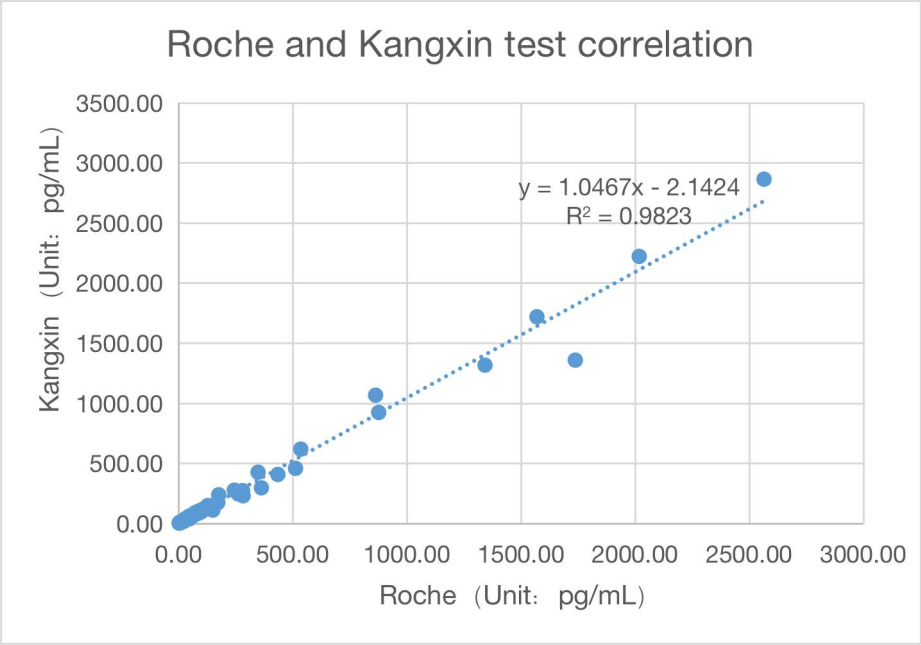
Sample/Unit (pg/mL)	Roche	Kangxin
1	1.92	< 2
2	2.05	2.74
3	2.35	4.06
4	2.93	3.94
5	3.58	3.03
6	3.94	6.26
7	4.31	6.59
8	4.58	4.58
9	5.02	5.25
10	6.35	6.21
11	6.77	5.27
12	7.51	7.42
13	8.25	8.25
14	8.84	12.65
15	9.27	8.73
16	9.41	10.27
17	10.33	10.20
18	10.92	13.41
19	15.29	19.35
20	16.40	16.40
21	17.51	19.09
22	18.53	15.15

23	22.82	17.69
24	24.01	27.90
25	25.96	30.15
26	29.76	39.45
27	31.28	33.91
28	31.57	33.35
29	38.47	42.38
30	46.50	60.94
31	46.52	38.00
32	49.17	45.44
33	53.39	61.42
34	62.74	64.44
35	65.65	67.86
36	65.65	74.54
37	72.36	88.66
38	74.07	80.98
39	79.81	87.20
40	80.56	83.35
41	84.77	100.19
42	86.55	84.70
43	93.77	103.28
44	95.07	102.00
45	96.77	94.83
46	101.75	100.50
47	103.30	116.17
48	125.00	126.75
49	127.25	148.48
50	149.61	110.63

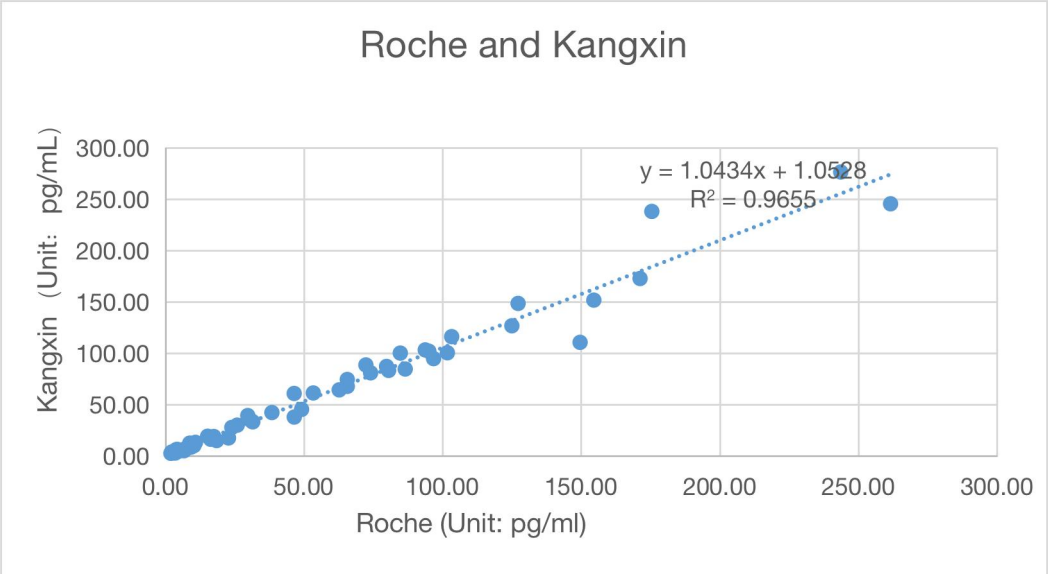
51	154.57	151.70
52	171.24	172.71
53	175.48	237.94
54	243.60	276.26
55	261.58	245.36
56	279.73	272.40
57	282.40	229.43
58	347.76	425.45
59	362.10	295.82
60	434.53	407.20
61	511.79	457.82
62	534.80	617.92
63	862.74	1066.24
64	876.29	922.69
65	1342.05	1316.12
66	1569.46	1718.72
67	1737.51	1357.74
68	2017.72	2220.95
69	2564.55	2863.19
70	3872.42	＞3000

4.2.1 Data Analysis

Test range ： 2-3000 pg/mL： Take Roche’s detection value as X-axis, and Kangxin’s detection value as Y-axis to make a regression curve.



Test Range： 2-250 pg/mL： Take Roche's detection value as X-axis, and Kangxin's detection value as Y-axis to make a regression curve.



5 Conclusion

In this study, the test range of Kangxin's detection system：2-3000pg/mL、2-250 pg/mL ,and get the correlations are： $R^2 = 0.9823$ 、 $R^2 = 0.9655$， which has a good correlation with Roche Cobas fully automatic electrochemiluminescence detection system， and the precision meets the manufacturer's declared value as well as clinical use.

Reporter: Reviewer : Date: