Hunan Kangxin Biotechnology Co., Ltd.

Total Triiodothyronine (TT4) 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 Total Triiodothyronine 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 Siemens Medical Diagnostics (Shanghai) Co., Ltd.(Here after Siemens) detection system respectively, to analyze whether the performance of Kangxin detection system is good compared with similar products.

2 Reagents & Instruments

（1）Insterument：ADVIA® Centaur system

Reagent: Triiodothyronine Assay Kit（Direct determination of CL analysis）

Manufacturer: Siemens Medical Diagnostics (Shanghai) Co., Ltd.

（2）Instrument：Fluorescent Immunoassay Analyzer LYOFIA-I

Reagent: Total Triiodothyronine (TT3) Kit （Microfluidic Fluorescent Immunoassay）

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

LOT：1616701

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 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, 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：0.4-6ng/mL， methods were compared for the detection range of 0.4-6ng/mL、0.6-4ng/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(ng/mL)	Siemens		Kangxin	
	2.54	1.08	2.54	1.08
1	2.51	1.01	2.36	1.16
2	2.42	1.11	2.52	1.02
3	2.38	1.07	2.6	1.02
4	2.43	0.99	2.54	1.08
5	2.38	0.94	2.35	1.01
6	2.43	0.95	2.56	1.11
7	2.52	1.01	2.37	0.94
8	2.41	0.97	2.54	1.11
9	2.28	0.99	2.65	0.94
10	2.47	0.96	2.25	1.06
Average Value	2.42	1.00	2.47	1.045
Standard Deviation	0.07	0.05	0.12	0.073

CV	2.73%	5.10%	5.02%	6.96%

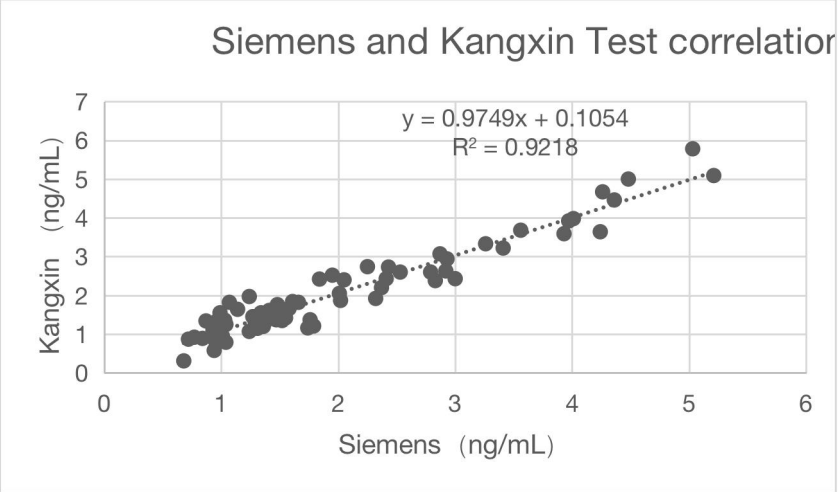
4.2Methodological Comparison

Sample/Unit (ng/mL)	Siemens	Kangxin
1	0.68	0.61
2	0.72	0.77
3	0.77	0.72
4	0.84	0.89
5	0.87	0.94
6	0.93	1.01
7	0.94	0.88
8	0.95	0.83
9	0.96	0.83
10	0.99	1.05
11	1.01	0.95
12	1.03	1.16
13	1.04	1.00
14	1.04	0.99
15	1.07	1.02
16	1.14	1.04
17	1.24	1.07
18	1.24	1.37
19	1.27	1.45
20	1.29	1.32
21	1.30	1.43
22	1.31	1.25
23	1.34	1.15
24	1.36	1.20
25	1.37	1.35
26	1.41	1.61
27	1.42	1.40
28	1.47	1.69
29	1.47	1.47
30	1.48	1.46
31	1.52	1.35

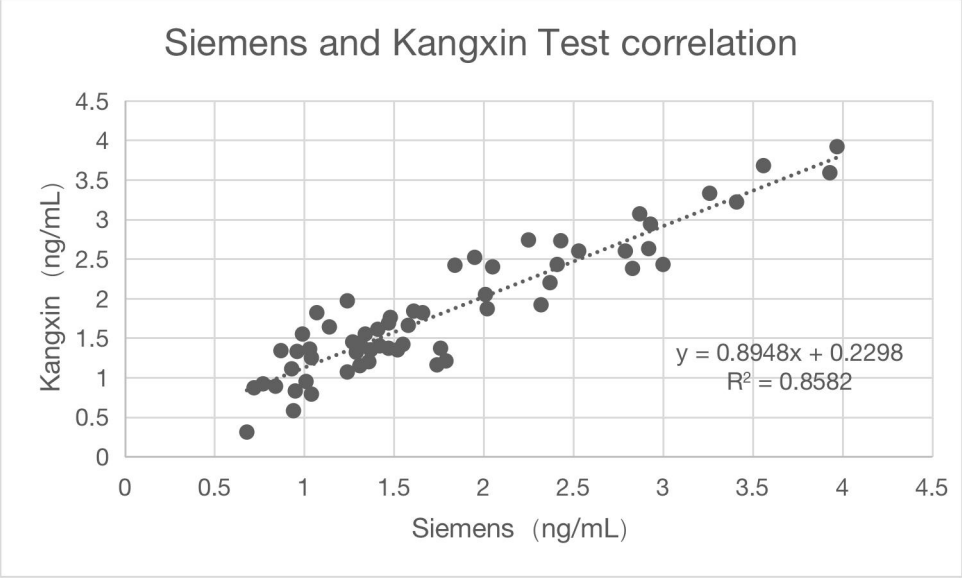
32	1.55	1.42
33	1.58	1.66
34	1.61	1.84
35	1.66	1.82
36	1.74	1.76
37	1.76	1.77
38	1.79	1.71
39	1.84	2.02
40	1.95	2.02
41	2.01	2.05
42	2.02	1.87
43	2.05	2.40
44	2.25	2.70
45	2.32	1.92
46	2.37	2.20
47	2.41	2.43
48	2.43	2.73
49	2.53	2.60
50	2.79	2.60
51	2.83	2.38
52	2.87	3.07
53	2.92	2.63
54	2.93	2.94
55	3.00	2.43
56	3.26	3.33
57	3.41	3.22
58	3.56	3.68
59	3.93	3.59
60	3.97	3.92
61	4.01	3.98
62	4.24	3.64
63	4.26	4.67
64	4.36	4.46
65	4.48	5.00
66	5.03	5.78
67	5.21	5.09
68	5.86	> 6
69	6.32	> 6
70	7.62	> 6

4.2.1 Data Analysis

Test range 0.4-6 ng/mL：Take Siemens's detection value as X-axis, and Kangxin's detection value as Y-axis to make a regression curve.



Test Range：：0.6-4 ng/mL：Take Siemens'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： 0.4-6ng/mL、0.6-4ng/mL and get the correlations are：$R^2 = 0.9218$、$R^2 = 0.8582$, which has a good

correlation with Siemens automatic electrochemiluminescence detection system(ADVIA® Centaur system) , and the precision meets the manufacturer's declared value as well as clinical use.

Reporter: Reviewer : Date: