Hunan Kangxin Biotechnology Co., Ltd.

D-Dimer 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 D-Dimer in Plasma. The intra-assay precision CV was calculated with reference to EP15-A2. Referring to the EP9-A2 file, the linear regression equation and correlation coefficient between Hunan Kangxin Biotechnology Co., Ltd. (Hereafter Kangxin) and Siemens Healthcare Diagnostics Products GmbH(Hereafter Siemens) detection system were calculated respectively to analyze whether the performance of Kangxin detection system was good compared with domestic similar products.

2 Reagents&Instruments

（1）Instruments: Automatic coagulation analyzer

Reagents: D-Dimer Test Kit （Immunoturbidimetry）

Manufacturer: Siemens Healthcare Diagnostics Products GmbH

（2）Instruments: Fluorescence Immunoassay Analyzer LYOFIA-I

Reagents: D-Dimer Test Kit（Microfluidic luminescence）

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

Lot：0716201

3 Test Content

3. 1 Test Content

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: 0.1-4.4mg/L FEU, the methodological comparison of the detection ranges of 0.1-4.4mg/L FEU and 0.1-2mg/L FEU of Kangxin 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 (mg/L FEU)	Siemens		Kangxin	
	0.51	2.27	0.51	2.27
1	0.52	2.28	0.46	1.95
2	0.53	2.34	0.49	1.98
3	0.49	2.18	0.48	1.97
4	0.49	2.21	0.55	2.03
5	0.53	2.35	0.47	2.20
6	0.49	2.16	0.53	2.12
7	0.50	2.16	0.56	2.05
8	0.50	2.23	0.47	2.18
9	0.49	2.34	0.51	2.19
10	0.50	2.29	0.53	2.24
Average Value	0.504	2.254	0.505	2.091
Standard Deviation	0.0165	0.0757	0.0360	0.1080
CV	3.27%	3.36%	7.12%	5.16%

4.2 Methodological comparison

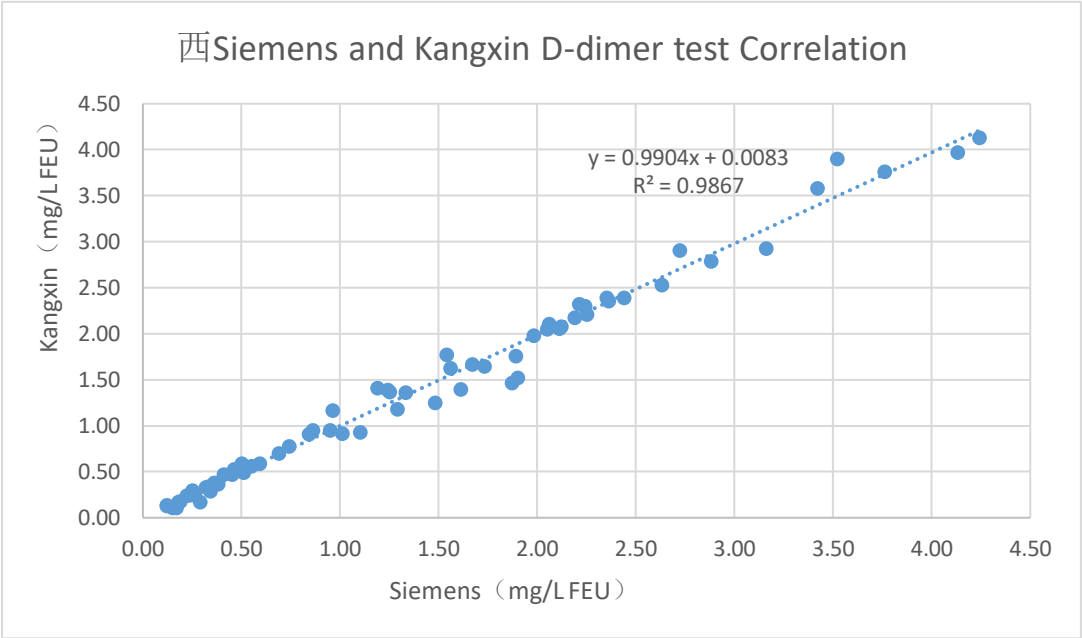
Sample/Unit （mg/L FEU）	Siemens	Kangxin
1	0.12	0.14
2	0.12	0.13
3	0.15	0.11
4	0.17	0.11
5	0.18	0.17
6	0.19	0.18
7	0.22	0.24
8	0.24	0.25
9	0.25	0.30
10	0.26	0.27
11	0.26	0.26
12	0.29	0.17
13	0.32	0.33
14	0.33	0.34
15	0.34	0.29
16	0.34	0.34
17	0.36	0.38
18	0.38	0.37
19	0.41	0.47
20	0.45	0.47
21	0.46	0.53
22	0.50	0.59
23	0.51	0.49
24	0.52	0.55
25	0.55	0.56

26	0.59	0.59
27	0.69	0.70
28	0.74	0.78
29	0.84	0.91
30	0.86	0.95
31	0.95	0.95
32	0.96	1.17
33	1.01	0.92
34	1.10	0.93
35	1.19	1.41
36	1.24	1.39
37	1.25	1.37
38	1.29	1.18
39	1.33	1.36
40	1.48	1.25
41	1.54	1.77
42	1.56	1.63
43	1.61	1.40
44	1.67	1.67
45	1.73	1.65
46	1.87	1.47
47	1.89	1.76
48	1.90	1.52
49	1.98	1.98
50	2.05	2.05
51	2.06	2.11
52	2.11	2.06
53	2.12	2.08

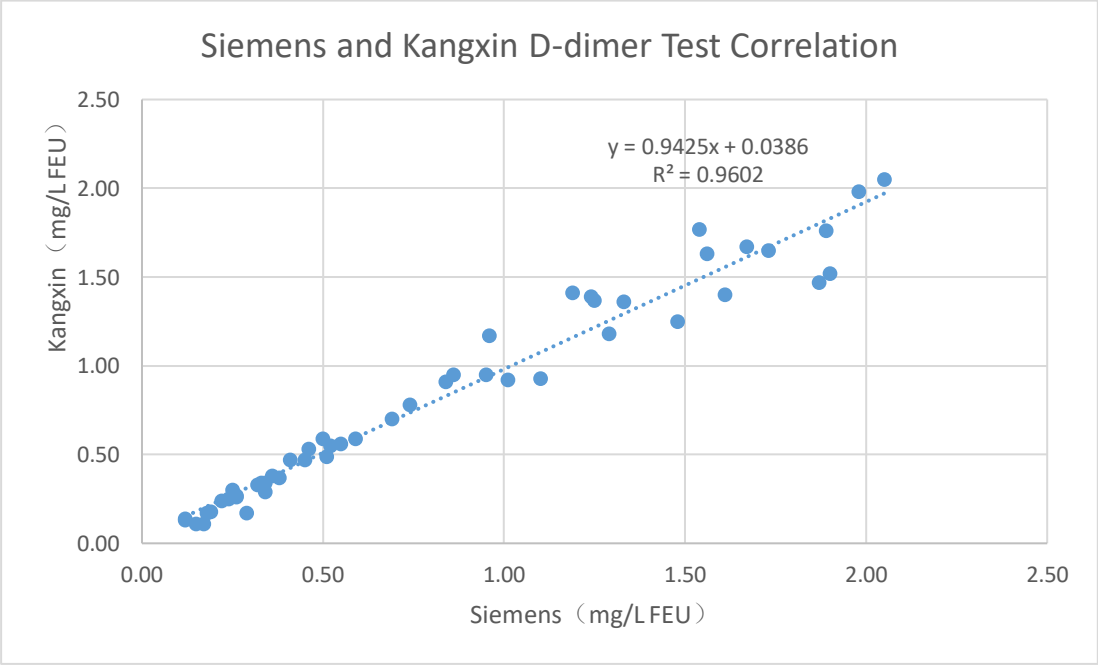
54	2.19	2.18
55	2.21	2.32
56	2.24	2.30
57	2.25	2.21
58	2.35	2.39
59	2.36	2.36
60	2.44	2.39
61	2.63	2.53
62	2.72	2.91
63	2.88	2.79
64	3.16	2.93
65	3.42	3.58
66	3.52	3.90
67	3.76	3.76
68	4.13	3.97
69	4.24	4.13
70	4.33	＞4.4

4. 2. 1 Data Analysis

Test Range：0.1-4.4 mg/L FEU：Take Siemens's detection value as X, and Kangxin's detection value as Y to make a regression curve.



Test Rang: 0.1-2 mg/L FEU: Take the Siemens's detection value as X, and Kangxin's detection value as Y, to make a regression curve.



5 Counclusion

In this study, Kangxin's detection system in the detection of D-Dimer test range: 0.1-4.4mg/L FEU, 0.1-2 mg/L FEU correlations are: $R^2 = 0.9867$, $R^2 = 0.9602$, It has a good correlation with the automatic coagulation analyzer, and the precision meets the requirements of the manufacturer's declaration and is suitable for clinical use.

Reporter： Reviewer： Date：