Hunan Kangxin Biotechnology Co., Ltd.

Ferritin（FER）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 Ferrintin (FER) 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 Roche Diagnostics GmbH (Hereafter Roche) detection system respectively to analyze whether the performance of Kangxin Detection System was good compared with domestic similar.

2 Reagents&Instruments

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

Reagents: Ferrintin test kit (Electrochemiluminescence)

Manufacturer: Roche Diagnostics GmbH

（2）Manufacturer: Fluorescence Immunoassay Analyzer LYOFIA-I

Reagents: Ferrintin（FER）Test Kit（Microfluidic luminescence）

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

Lot: 1C16501

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 the three systems respectively, each sample is measured once, and the test data are counted analyze.

Kangxin's linearity: 5-2000ng/mL, the methodological comparison of the linearity of 5-2000ng/mL and 5-500ng/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 (ng/mL)	Roche		Kangxin	
	31.80	365.50	31.80	365.50
1	31.74	372.3	33.57	344.13
2	33.5	358.39	27.1	389.73
3	31.56	369.75	27.43	359.66
4	30.96	374.31	33.36	330.15
5	34.6	355.05	33.11	337.5
6	30.26	353.97	29.67	347.51
7	33.04	379.4	30.77	380.32
8	31.92	357.37	31.97	366.11
9	33.06	353.97	34.39	371.28
10	32.64	356.83	29.38	354.29
Average Value	32.33	363.13	31.08	358.07
Standard Deviation	1.22	9.20	2.48	18.06
CV	3.78%	2.53%	7.97%	5.04%

4.2 Methodological comparison

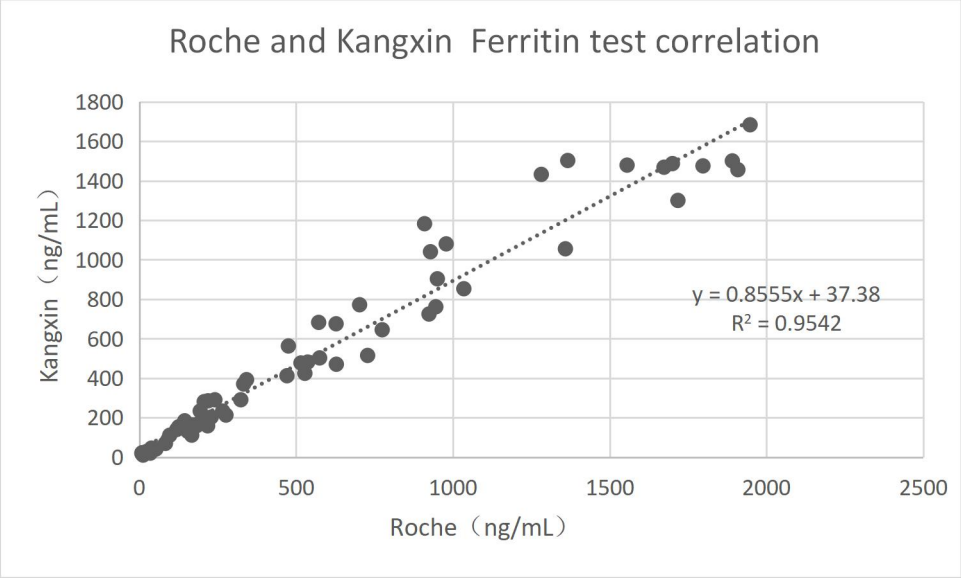
Sample/Unit（ng/mL）	Roche	Kangxin
1	5	＜5
2	5.1	5.18
3	5.33	＜5
4	5.4	5.77
5	5.5	6.49
6	5.7	＜5
7	7.8	19.54
8	8.8	21.92
9	9	15.66
10	11.9	9.94
11	11.92	12.89
12	12.71	13.31
13	22.3	27.6
14	34.7	19.82
15	38.4	45.18
16	52.9	40.95
17	83.1	69.27
18	96.8	110.51
19	119.4	139.9
20	125.76	153.6
21	144.54	183.61
22	146.9	176.01
23	154.32	130.47
24	165.88	135.32
25	166.92	111.05

26	170.84	162.82
27	183.48	159.86
28	188.56	168.28
29	193.95	233.23
30	196.92	171.51
31	206.72	280.68
32	217.7	158.29
33	219	284.92
34	229.04	202.45
35	240.78	290.08
36	265.68	232.76
37	276.18	212.59
38	323.5	290.25
39	332.52	370.19
40	341.84	392.14
41	470.76	412.04
42	475.27	562.77
43	515.26	476.65
44	527.82	424.28
45	536.7	481.13
46	571.77	682.28
47	574.92	502.34
48	627.36	675.15
49	628.17	470.18
50	702.36	771.69
51	727.95	514.8
52	774.36	644.92
53	909.51	1182.28

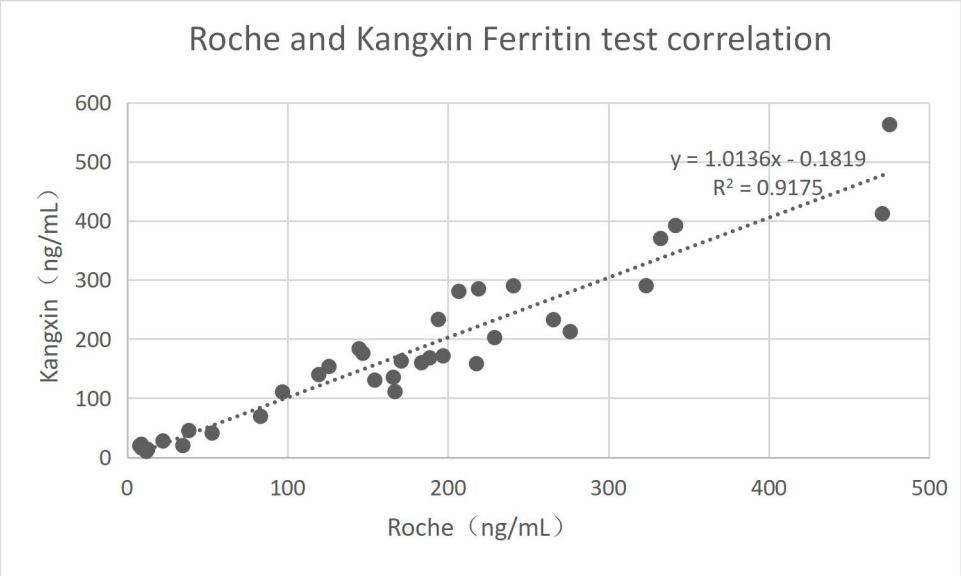
54	923.65	724.61
55	928.34	1040.23
56	945.46	761.26
57	950.36	903.07
58	978.6	1080.07
59	1034.78	852.84
60	1281.88	1432.17
61	1358.76	1055.1
62	1366.2	1502.59
63	1555.44	1479.09
64	1673.28	1468.53
65	1700.06	1486.91
66	1717.6	1300.27
67	1797.52	1475.31
68	1891.14	1500.52
69	1908.8	1456.07
70	1947.75	1683.62

4.2.1 Data Analysis

Test Range: 5-2000 ng/mL: Take Roche's detection value as X, and Kangxin's detection value as Y, to make a regression curve.



Test Rang: 5-500 ng/mL: Take the Roche's detection value as X, and Kangxin's detection value as Y, to make a regression curve.



5 Conclusion

In this study, the correlations within the detection range of the Kangxin detection system: 5-2000ng/mL and 5-500 ng/mL were: R2 =0.9542, R2 = 0.9175, It has a good correlation with the Roche cobas fully automatic electrochemiluminescence detection system, and the precision meets the manufacturer's declared value.

Reporter：　　Reviewer：　　Date：