Hunan Kangxin Biotechnology Co., Ltd.

Folic acid (Folate) detection kit

（Microfluidic Fluorescent Immunoassay）

Performance evaluation comparative study data

Chengdu VACURE Biotechnology Co., Ltd.

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1 Purpose & Overview

Purpose: To evaluate and analyze the performance of a fluorescent immunoassay analyzer for the determination of folic acid (Folate) in whole blood. Refer to EP15-A2 to calculate the intra-assay precision CV. 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) to analyze whether the performance of Kangxin is good compared with similar domestic products.

2 Reagents&Instruments

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

Reagent: Folate (Electrochemiluminescence)

Manufacturer: Roche Diagnostics GmbH

（2）Instrument: Fluorescence Immunoassay Analyzer LYOFIA-I

Reagent: Folate Detection Kit (Microfluidic Fluorescence Immunoassay)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

LOT: 1E16B01

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.

The detection range of the Kangxin's kit is: 1-50ng/mL, and the methodological comparison is carried out for the detection range of the Kangxin's detection kit 1-50ng/mL and 3.89-26.8ng/mL.

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	
1	15.01	4.98	16.35	4.67
2	14.2	4.77	14.29	5.11
3	15.76	5.06	16.27	5.10
4	14.86	5.16	15.18	4.70
5	15.79	4.97	16.15	4.80
6	15.23	4.75	15.61	5.16
7	14.77	5.01	15.43	5.17
8	15.29	5.00	15.25	4.76
9	14.47	4.71	16.26	5.00
10	15.04	4.75	14.61	5.17
Average Value	15.042	4.916	15.54	4.964
Standard Deviation	0.51	0.16	0.73	0.21
CV	3.37%	3.20%	4.67%	4.19%

4.2 Methodological comparison

Sample/Unit (ng/mL)	Roche	Kangxin
1	1.76	3.81
2	1.82	1.08
3	1.88	1.26
4	2.08	3.12
5	2.66	2.76
6	2.78	1.52
7	2.96	3.36
8	3.12	1.28
9	3.67	2.57
10	3.69	1.11
11	5.64	4.61
12	5.69	5.66
13	5.9	6.10
14	5.94	4.91
15	6.13	4.9
16	6.89	4.69
17	6.93	5.46
18	7.02	4.14
19	7.08	5.5
20	8.88	5.43
21	8.92	4.69
22	9.19	6.28
23	9.51	8.19
24	10.05	8.06
25	11.2	7.06

26	12.15	15.2
27	12.91	7.11
28	13.44	7.39
29	13.67	7.69
30	13.84	8.26
31	14.55	19.48
32	16.12	16.29
33	17.96	18.2
34	19.66	19.12
35	20.13	18.51
36	20.91	15.47
37	21.64	19.27
38	21.74	19.74
39	22.31	20.61
40	22.83	21.60
41	23.53	21.66
42	23.95	15.75
43	24.24	15.84
44	24.29	17.33
45	25.2	20.60
46	25.27	25.74
47	27.52	28.46
48	27.74	28.18
49	28.35	27.1
50	29.77	30.87
51	31.27	30.61
52	31.64	27.87
53	32.47	32.2

54	33.85	29.30
55	34.17	37.77
56	35.21	48.55
57	35.59	46.37
58	36.56	28.41
59	37.32	30.75
60	39.61	28.1

4.2.1 Data Analysis

Detection range: 1-50ng/mL: Take Roche's detection value as X and Kangxin's measured value as Y to make a regression curve.
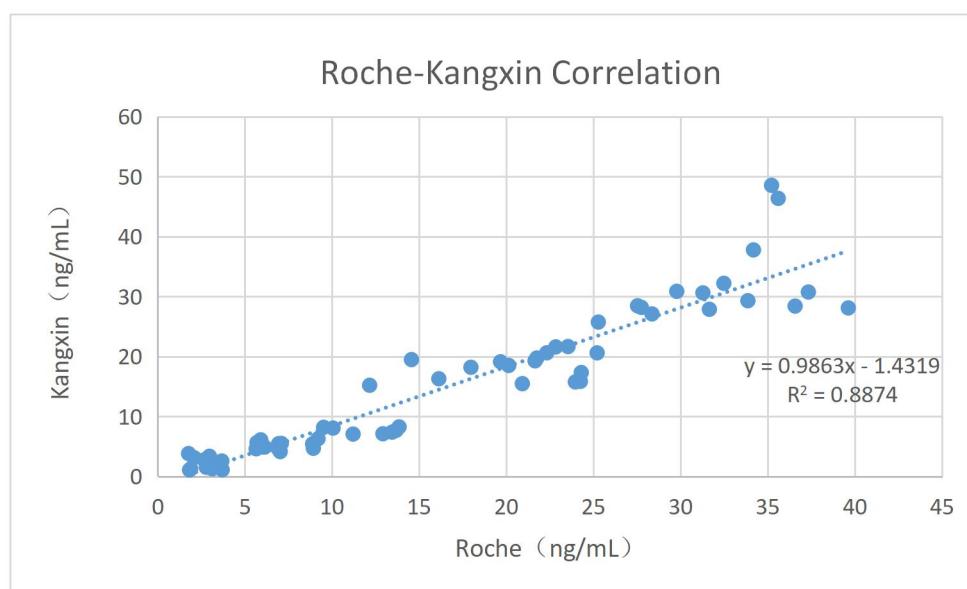
Detection range: 3.89-26.8 ng/mL: the regression curve is made by taking Roche's detection value as X and Kangxin Bio's measured value as Y.
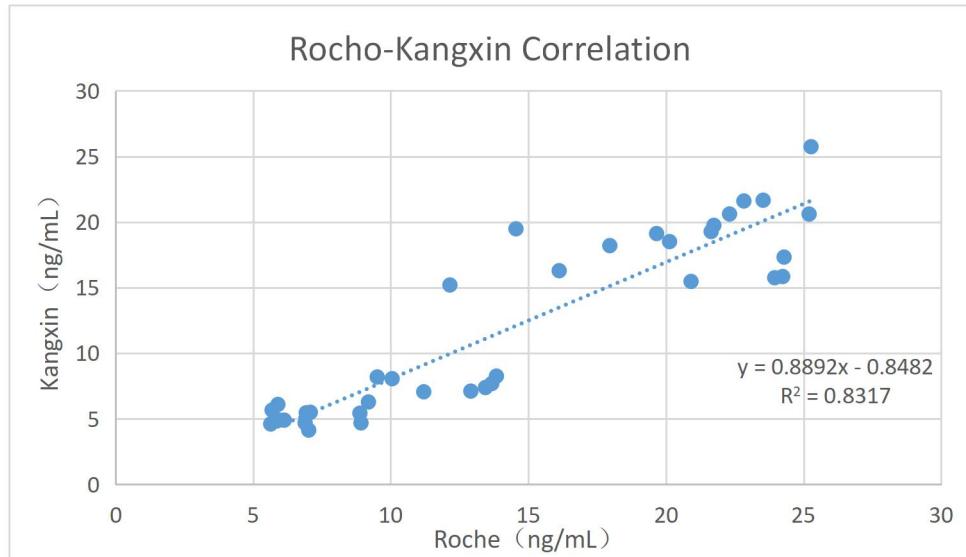
5 Conclusion

In this study, the correlations of the Kangxin biological detection system in the detection range: 1-50ng/mL and 3.89-26.8 ng/mL were: R^2 = 0.8874, R^2 = 0.8317, and the related products of Kangxin and Roche have a good correlation. The precision meets the standard declared by the manufacturer.

Reporter：   Reviewer：   Date：