

Hunan Kangxin Biotechnology Co., Ltd.
Procalcitonin (PCT) Test Kit
(Microfluidic Fluorescent Immunoassay)

Performance evaluation comparative study data

Chengdu VACURE Biotechnology Co., Ltd.

June 2022

1 Purpose & Overview

Purpose: Evaluation and analysis the performance of fluorescence immunoassay for the Determination of Procalcitonin (PCT) 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 products.

2 Reagents&Instruments

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

Reagents: Procalcitonin Test Kit (electrochemiluminescence)

Manufacturer: Roche Diagnostics GmbH

(2) Manufacturer: Fluorescence Immunoassay Analyzer LYOFIA-I

Reagents: Procalcitonin (PCT) Test Kit (Microfluidic luminescence)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

Lot: 0116301

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 ($\bar{X}$) 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) : $\leq 10\%$;

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: 0.02-100ng/mL, the methodological comparison of the linearity ranges of 0.02-100ng/mL and 0.1-10ng/mL of the Kangxin detection kit 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	
	0.53	2.15	0.53	2.15
1	0.529	2.19	0.527	2.165
2	0.525	2.167	0.53	2.127
3	0.526	2.175	0.537	2.073
4	0.516	2.143	0.557	2.032
5	0.51	2.165	0.521	1.983
6	0.516	2.141	0.494	1.951
7	0.534	2.12	0.478	1.933
8	0.532	2.161	0.459	1.931
9	0.551	2.141	0.46	1.983
10	0.544	2.099	0.451	1.987
Average Value	0.5283	2.1502	0.5014	2.0165
Standard Deviation	0.01275	0.02702	0.03782	0.08123
CV	2.4%	1.3%	7.5%	4.0%

4.2 Methodological comparison

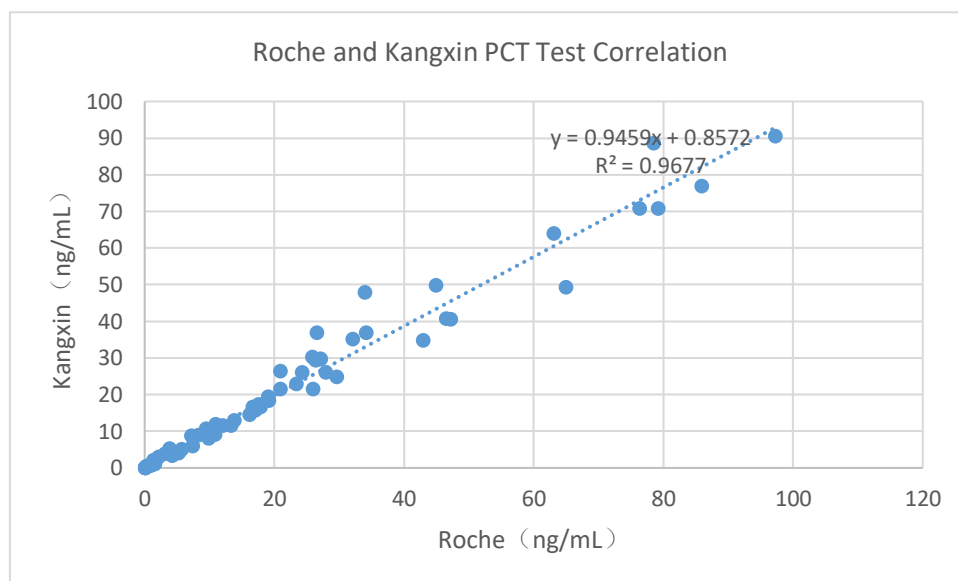
Sample/Unit	Roche	Kangxin
-------------	-------	---------

(ng/mL)		
1	0.02	0.036
2	0.021	0.023
3	0.023	0.029
4	0.024	<0.02
5	0.027	0.13
6	0.035	0.067
7	0.078	0.092
8	0.088	0.054
9	0.09	0.06
10	0.119	0.156
11	0.119	0.188
12	0.127	0.108
13	0.223	0.342
14	0.347	0.473
15	0.384	0.293
16	0.529	0.568
17	0.831	0.922
18	0.968	0.72
19	0.995	0.668
20	1.391	1.096
21	1.529	1.071
22	2.155	2.321
23	3.144	3.454
24	3.858	5.197
25	4.271	3.667
26	5.168	4.129
27	5.726	5.09
28	7.227	7.994
29	7.345	6.04
30	8.294	8.972
31	9.428	10.201
32	9.846	8.315
33	10.885	9.061
34	10.95	10.986
35	12.039	11.526
36	13.284	11.519
37	13.809	12.943
38	16.175	14.495

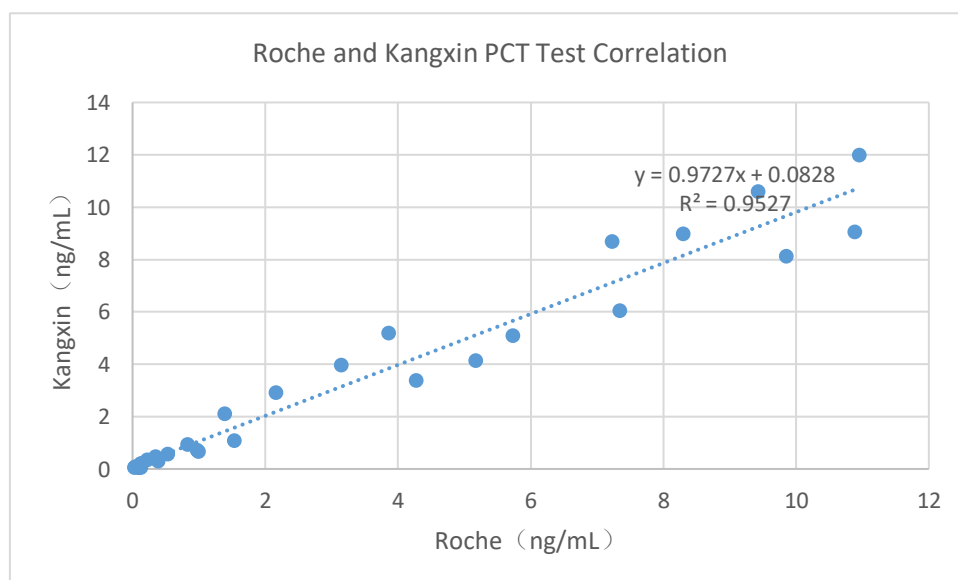
39	16.626	16.712
40	17.092	15.763
41	17.594	17.274
42	17.89	16.557
43	19.059	19.431
44	19.164	18.416
45	20.912	21.491
46	20.939	26.484
47	23.412	22.868
48	24.265	26.079
49	25.812	30.269
50	25.986	21.595
51	26.39	29.314
52	26.524	36.941
53	27.013	29.766
54	27.153	29.744
55	27.96	26.014
56	29.565	24.834
57	32.047	35.217
58	33.969	47.888
59	34.155	36.957
60	42.94	34.826
61	44.938	49.738
62	46.48	40.813
63	47.224	40.632
64	63.038	63.94
65	64.925	49.278
66	76.352	70.73
67	78.46	88.55
68	79.212	70.849
69	85.877	76.927
70	97.215	90.56

4. 2. 1 Data Analysis

Test Range: 0.02-100 ng/mL: Take Roche's detection value as X, and Kangxin's detection value as Y, to make a regression curve.



TestRange: 0.1-10 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, in the detection range of Kangxin detection system: 0.02-100ng/mL,

0.1-50 ng/mL, the correlations are: $R^2 = 0.9677$, $R^2 = 0.9527$, which has a good correlation with the Roche Cobas automatic electrochemiluminescence detection system . The precision meets the manufacturer's declared value.

Reporter:

Reviewer:

Date: