

**Placental Growth Factor (PLGF) and Soluble fms-like
Tyrosine Kinase-1 (sFLT-1) Combo Test Kit
(Microfluidic Fluorescent
Immunoassay)**

Performance evaluation comparative study data

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1 Purpose & Overview

Purpose: To evaluate and analyze the performance of antibody immunoassay analyzer in the determination of placental growth factor (PLGF) and soluble fms-like tyrosine repair-1 (sFLT-1) 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 Holding AG. (Hereafter Roche) detection system respectively to analyze whether the performance of Kangxin Detection System was good compared with domestic similar.

2 Reagents&Instruments

(1) Control group

Instruments: Roche cobas e Analyzer

Reagents: Placenta Growth Factor Detection Kit (Electrochemiluminescence Method)、Soluble fms-like tyrosine kinase-1 detection kit (electrochemiluminescence method)

Manufacturer: Roche Diagnostics (Shanghai) Co., Ltd. (Here after Roche)

(2) Experimental group

Instruments: LYOFIA-I Analyzer

Reagents: PLGF&sFLT-1) Test Kit (Microfluidics Fluorescent Immunoassay)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd. (Hereafter Kangxin)

Lot: 3E16C01

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. Besides, PLGF selects the concentration of $200 \pm 40\text{pg/mL}$ and

2000±400pg/mL for detection; sFLT-1 selects the concentration of 1000±200pg/mL and 10000±2000pg/mL for detection

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: PLGF is 15-10000 pg/mL, methodological comparison of the detection range; sFLT-1 is 100-85000pg/mL, methodological comparison of the detection range, the ratio of sFLT-1/PLGF was calculated for methodological comparison.

Take the test results of the comparison system as the X axis, and the test results of the test system as the Y axis, draw a regression curve, and obtain the regression formula and the correlation coefficient r.

4 Test Results

4.1 Precision assessment

Repeat times	PLGF				sFLT-1			
	Roche (pg/mL)		Kangxin (pg/mL)		Roche (pg/mL)		Kangxin (pg/mL)	
1	201	1767	219.43	1765.76	925	9011	908.44	8832.34
2	200	1752	187.45	1757.42	869	8987	825.18	8582.14
3	215	1699	229.78	1703.43	943	9360	1050.47	9864.47
4	198	1660	185.34	1609.42	936	9034	967.98	9737.57
5	184	1654	184.72	1639.12	955	9002	953.13	8882.69
6	202	1621	218.13	1504.78	970	9215	1020.78	9217.71
7	207	1650	212.11	1521.13	954	9220	995.42	9879.64
8	214	1755	229.86	1790.94	922	9635	921.41	10298.76

9	211	1750	211.42	1752.44	981	9188	987.97	9220.31
10	201	1702	197.75	1699.73	953	9117	832.23	8469.47
Average Value	203.30	1701.00	207.60	1674.42	940.80	9176.90	946.30	9298.51
Standard Deviation	9.12	52.88	17.62	102.27	31.23	201.38	75.13	619.56
CV	4.48%	3.11%	8.49%	6.11%	3.32%	2.19%	7.94%	6.66%

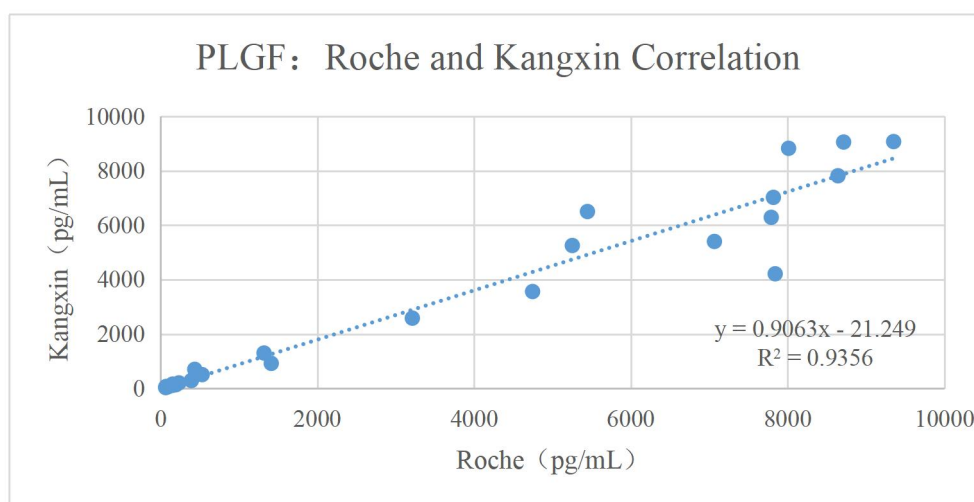
4.2 Methodological comparison

Sample	PLGF		sFLT-1		Ratio of sFLT-1/PLGF	
	Roche (pg/mL)	Kangxin (pg/mL)	Roche (pg/mL)	Kangxin (pg/mL)	Roche	Kangxin
1	66	30.11	305	102.79	4.62	3.41
2	92	58.74	452	312.45	4.91	5.32
3	152	114.12	735	505.44	4.84	4.43
4	393	291.78	1055	610.42	2.68	2.09
5	530	506.69	1801	2004.62	3.40	3.96
6	1412	920.84	2082	961.67	1.47	1.04
7	4746	3561.46	3611	2045.21	0.76	0.57
8	5253	5253.74	4500	3163.01	0.86	0.60
9	7066	5401.75	6965	7013.14	0.99	1.30
10	7818	7022.41	8548	6567.84	1.09	0.94
11	8714	9055.76	10119	6563.09	1.16	0.72
12	9352	9073.41	12255	5786.44	1.31	0.64
13	8642	7816.46	13594	13464.19	1.57	1.72
14	8012	8825.67	15097	14546.64	1.88	1.65
15	7841	4213.49	18469	15611.79	2.36	3.71
16	7791	6288.44	19464	19144.98	2.50	3.04
17	5446	6501.74	22991	19744.34	4.22	3.04

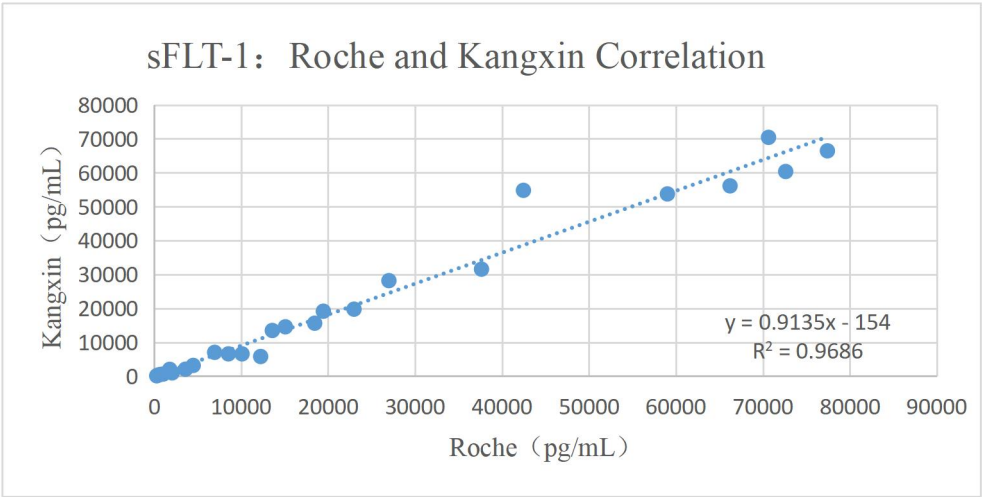
18	3212	2583.41	27001	28164.95	8.41	10.90
19	1320	1301.35	37646	31546.43	28.52	24.24
20	436	701.64	42466	54796.64	97.40	78.10
21	234	203.76	59019	53734.64	252.22	263.72
22	195	135.88	66220	56114.54	339.59	412.97
23	153	158.41	70643	70423.87	461.72	444.57
24	72	72.78	72616	60351.65	1008.56	829.23
25	65	45.97	77413	66443.53	1190.97	1445.37

4. 2. 1 Data Analysis

- a. Linearity of PLGF test: 15-10000 pg/mL, taking the comparative detection value as X and the actual measurement value of Kangxin Bio as Y, draw a regression curve.



- b. Linearity of sFLT-1 test: 100-85000 pg/mL, taking the comparative detection value as X and the actual measurement value of Kangxin Bio as Y, draw a regression curve.



5 Conclusion

In this study, the detection range of Kangxin’s detection system LYOFIA system: PLGF in the range of 15-10000 pg/mL, the correlation is: $R^2 = 0.9356$, and the correlation of sFLT-1 in the range of 100-85000 pg/mL is: $R^2 = 0.9686$, which has a good correlation with the Roche’s electrochemiluminescence detection system. The precision meets the standard declared by the manufacturer.

Reporter: :

Reviewer:

Date: