

**Hunan Kangxin Biotechnology Co., Ltd.**

**Insulin-like Growth Factor I 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 the fluorescence immunoassay analyzer in determining insulin-like growth factor I (IGF-I) in plasma. Refer to EP15-A2 to calculate the intra-batch precision CV. Refer to the EP9-A2 document to calculate the linear regression equation and correlation coefficient between Hunan Kangxin Biotechnology and Siemens detection systems to analyze whether the performance of the Kangxin Biotechnology detection system is good compared with similar domestic products.

## 2 Reagents&Instruments

- (1) Instrument: Fully automatic chemiluminescence immunoassay analyzer Atellica IM

Reagents: Insulin-like growth factor I (IGF-I) assay kit (chemiluminescence method)

Manufacturer: Siemens Healthcare Diagnostics Inc.

- (2) Reagents: Insulin-like Growth Factor I Kit (Microfluidic Fluorescent Immunoassay)

Instrument: Fluorescence immunoassay analyzer LYOFIA-I

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

Lot: 3B17401

## 3 Test Content

### 3.1 Precision assessment

Detect samples in two concentration level intervals in both detection systems. Repeat the measurement 10 times. Calculate the average ( $\bar{X}$ ) and standard deviation (S) of the 10 measurement results to obtain the coefficient of variation (CV). The results should be consistent. Less than the manufacturer's declared value.

Manufacturer's declared value: Kangxin Biotechnology (CV):  $\leq 10\%$ ;

### 3.2 Study on the comparability of system results

Refer to the methods in EP9-A2 Method Comparison and Bias Assessment Using Patient Samples "Method Comparison and Bias Assessment Using Patient Samples" to measure the samples separately on the two systems. Each sample is measured in a single time, and the test data are statistically analyzed. analyze.

The detection range of Kangxin Bio's kit is: 20-1000 ng/mL. Methodological comparisons were made between the 20-1000 ng/mL and 20-350 ng/mL detection ranges of Kangxin Bio's detection kits.

Taking the comparison system detection results as the X-axis and the test system detection results as the Y-axis, draw a regression curve to obtain the regression formula and

correlation coefficient r.

## 4 Test Results

### 4.1 Precision assessment

repeat times (ng/mL)	Siemens		Kangxin	
1	100	332	95.95	319.40
2	97	318	109.23	330.67
3	104	350	112.93	345.62
4	102	317	96.10	297.70
5	97	346	113.96	302.52
6	103	310	98.62	330.94
7	93	324	102.14	293.72
8	101	343	95.32	309.67
9	93	350	114.16	346.05
10	97	318	104.61	297.14
average value	98.70	330.80	104.30	317.34
standard deviation	3.92	15.33	7.77	20.06
CV	3.97%	4.63%	7.45%	6.32%

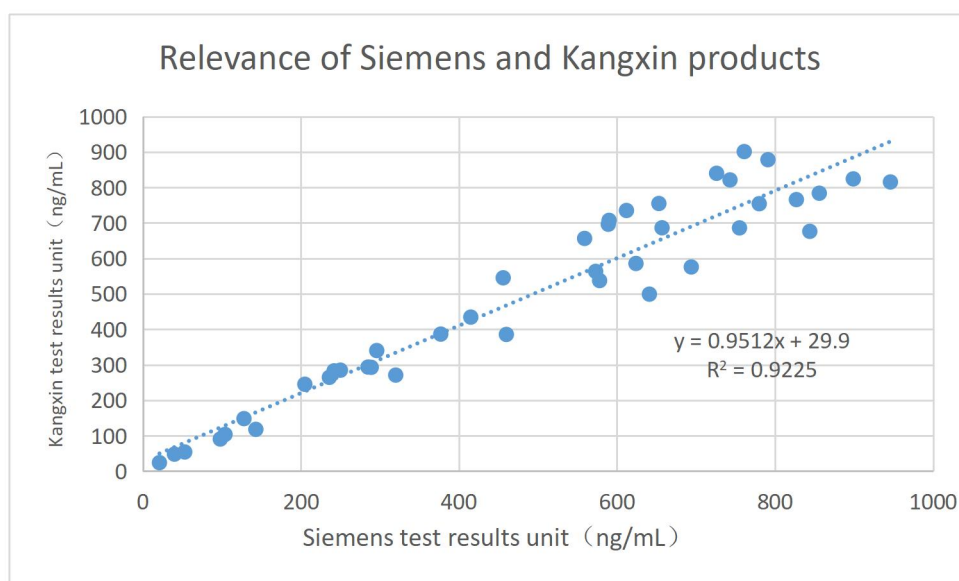
### 4.2 Methodological comparison

sample/unit (ng/mL)	Siemens	Kangxin
1	21	24.09
2	40	48.11
3	53	54.21
4	98	90.71
5	104	103.7
6	128	148.28
7	143	118
8	205	245.2
9	236	264.71
10	242	283.01
11	250	284.9
12	285	293.63
13	289	292.87
14	296	340.19
15	320	271.01
16	377	386.59
17	415	434.51
18	456	545.33

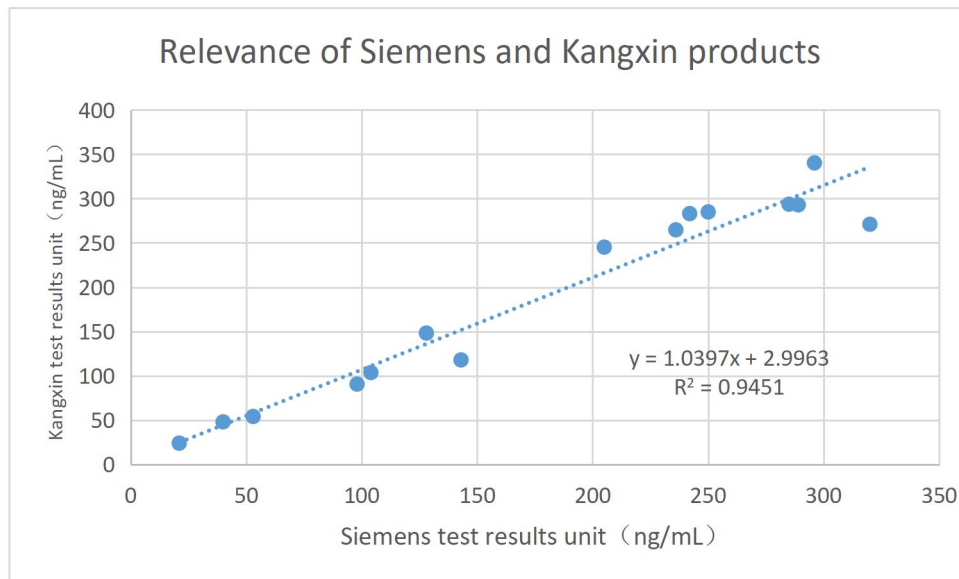
19	460	385.62
20	559	656.38
21	573	563.45
22	578	537.52
23	589	696.38
24	590	707.3
25	612	735.17
26	641	499.22
27	624	585.75
28	653	754.87
29	657	686.33
30	694	575.84
31	726	840.03
32	743	821.34
33	755	686.05
34	761	901.27
35	780	754.26
36	791	878.4
37	827	765.86
38	844	676.35
39	856	783.85
40	899	824.29
41	946	815.56

#### 4.3 Data analysis

Detection range: 20-1000 ng/mL: Taking the Siemens detection value as X, The actual measured value of Kangxin Biology is Y, and a regression curve is drawn.



Detection range: 20-350 ng/mL: Taking the Siemens detection value as X, The actual measured value of Kangxin Biology is Y, and a regression curve is drawn.



## 5 Conclusion

In this study, the correlations between the Kangxin biological detection system in the detection range: 20-1000 ng/mL and 20-350 ng/mL were:  $R^2 = 0.9225$ ,  $R^2 = 0.9451$ , respectively, and the Atellica IM fully automatic chemiluminescence immunoassay The analyzer detection system has good correlation. Precision meets manufacturer's declared standards.

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