Hunan Kangxin Biotechnology Co., Ltd.

High Sensitive Cardiac Troponin I (hs-cTnI) Test Kit

(Microfluidic Fluorescent Immunoassay)

Comparison Study Data of Performance Evaluation

Chengdu VACURE Biotechnology Co., Ltd.

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1. Purpose & Overview

Purpose: Evaluation and analysis the performance of fluorescent immunoassay for the Determination of High Sensitive Cardiac Troponin I (hs-cTnI) in Serum and Plasma. The intra-assay precision CV was calculated with reference to EP15-A2. Refer to EP9-A2 to calculate the linear regression equation and correlation coefficient between Hunan Kangxin Biotechnology Co., Ltd. (Hereafter Kangxin) and Abbott Ireland Diagnostics Division (Hereafter Abbott) detection system respectively, to analyze whether the performance of Kangxin detection system is good compared with domestic similar products.

2. Reagents & Instruments

（1）Instruments：ARCHITECT i2000SR system

Reagent: High Sensitive Cardiac Troponin I (hs-cTnI) Test Kit (Chemiluminescent Microparticle Immunoassay)

Manufacturer: Abbott Ireland Diagnostics Division

（2）Instruments: Fluorescent Immunoassay Analyzer LYOFIA-I

Reagent: High Sensitive Cardiac Troponin I (hs-cTnI) Test Kit (Microfluidic Fluorescent Immunoassay)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

LOT：0816101

3. Test Content

a) Precision assessment

Test samples at two concentration levels in 2 detection systems, repeat the test 10 times. Then calculate the average value ($\overline{X}$) and standard deviation (S) based on previous testing results, which can 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%;

b) Comparison study of system results

Refer to the "Method Comparison and Bias Assessment with Patient Samples" in EP9-A2 that measure samples on three systems respectively and only can be carried out a single measurement of each sample, finally get the statistical analysis of the detection date.

The test (linearity) range is 9-50000 pg/mL for High Sensitive Cardiac Troponin I (hs-cTnI) Test Kit that manufactured by Kangxin, and they have a methodological comparison of test range for 9-50000pg/mL and 9-2000mL.

Taking the detection result of the comparison system as the X-axis and the detection result of the test system as the Y-axis, making a regression curve to obtain the regression formula and the correlation coefficient "r".

4. Test Results

a) Precision assessment

Repeat times (pg/mL)	Abbott			Kangxin		
	50	270	1180	50	270	1180
1	49.2	273.0	1183.0	47.3	252.9	1147.0
2	51.0	260.0	1174.0	57.3	246.3	1191.5
3	47.7	274.0	1158.0	47.9	278.8	1162.4
4	52.2	265.0	1167.0	46.4	274.5	1159.3
5	52.4	278.0	1183.0	56.4	280.9	1071.6
6	48.6	270.0	1242.0	47.0	296.2	1116.3
7	47.7	281.0	1232.0	44.2	256.6	1167.9
8	47.8	264.0	1154.0	52.0	285.5	994.4
9	52.4	279.0	1166.0	53.1	300.8	1106.4
10	51.7	256.0	1161.0	55.9	253.3	1074.6
Average Value	50.1	270.0	1182.0	50.8	272.6	1119.1
Standard Deviation	2.1	8.5	30.6	4.8	19.3	59.5
CV	4.12%	3.14%	2.59%	9.39%	7.07%	5.32%

b) Methodological Comparison

Sample/Unit	Abbott	Kangxin

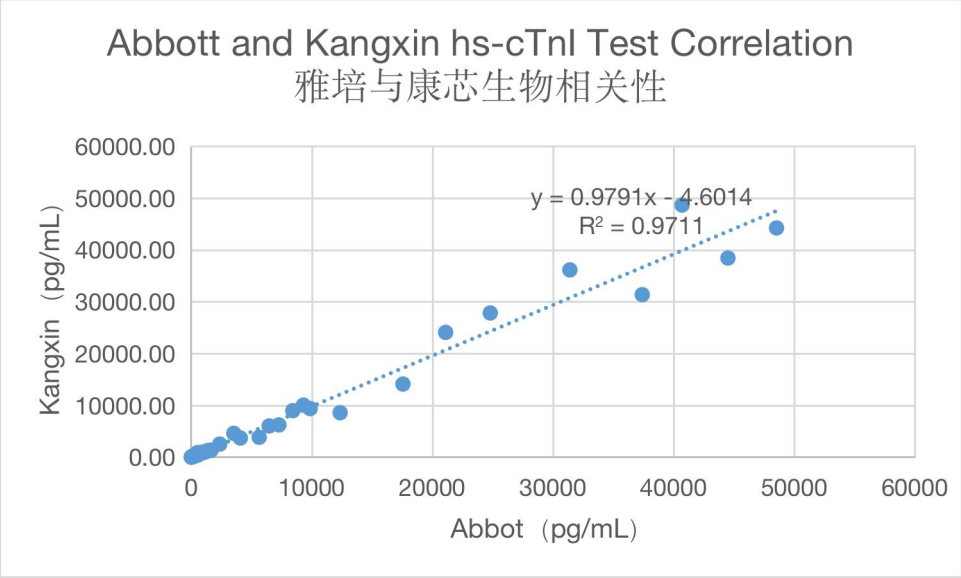
(pg/mL)		
1	12.1	5.81
2	14.5	12.91
3	18.9	7.10
4	32.4	51.23
5	57	42.11
6	76	55.37
7	99	79.91
8	110	78.64
9	120	98.52
10	150	102.73
11	170	150.94
12	190	267.34
13	210	256.15
14	250	242.10
15	270	280.15
16	340	283.13
17	360	242.17
18	430	481.25
19	470	587.64
20	520	358.94
21	530	865.81
22	610	550.68
23	630	499.65
24	720	842.43
25	750	738.90
26	840	902.60
27	870	819.84
28	930	811.41
29	980	937.16
30	1180	980.43
31	1350	1259.20
32	1650	1325.84
33	2370	2508.95
34	3540	4588.49
35	4080	3680.38
36	5640	3825.22
37	6470	6015.73
38	7280	6212.14
39	8430	8957.17
40	9310	10037.48

41	9870	9361.94
42	12350	8566.93
43	17560	14098.42
44	21100	24076.82
45	24800	27813.20
46	31400	36130.61
47	37400	31350.75
48	40700	48646.23
49	44500	38418.35
50	48530	44226.98

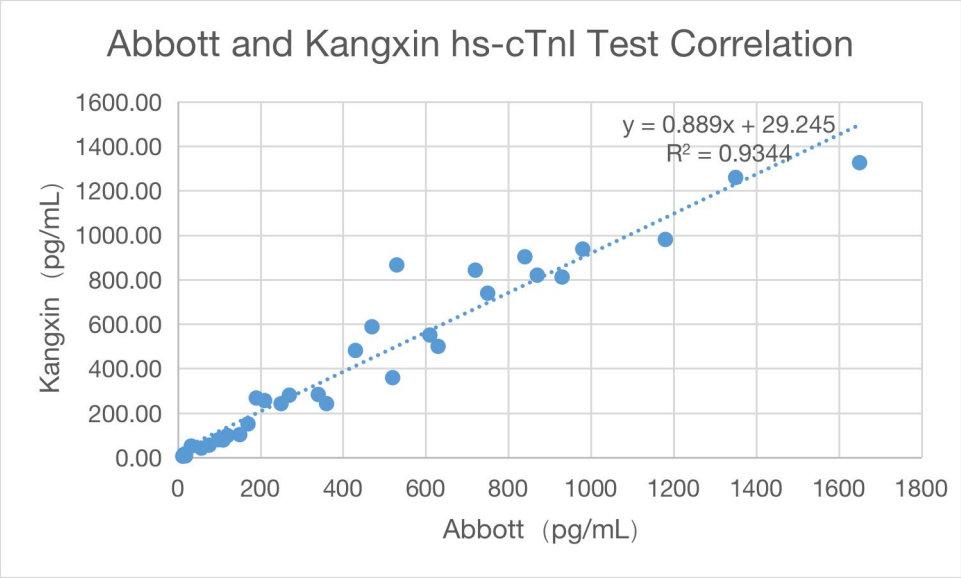
i. Data Analysis

Test System: Hunan Kangxin Biotechnology Co., Ltd.'s Microfluidic Time-resolved Fluorescent System

Test Range: 9-50000 pg/mL： Take Abbott's detection value as X-axis, and Kangxin's detection value as Y-axis to make a regression curve.



Test Rang: 9-2000pg/mL: Take the Abbott's detection value as X-axis, and Kangxin's detection value as Y-axis to make a regression curve.



5. Conclusion

In this study, the test range of Kangxin's detection system: 9-50000 pg/mL, 9-2000 pg/mL, and get the correlations are $R^2 = 0.9711$, $R^2 = 0.9344$, which has a good correlation with Abbott's ARCHITECT i2000SR system. And the precision meets the manufacturer's declared value as well as clinical use.

Reporter: Reviewer (Auditor): Date: