

Hunan Kangxin Biotechnology Co.,Ltd.
Anti-Mullerian Hormone (AMH) Test Kit
(Microfluidic Fluorescent
Immunoassay)

Performance evaluation comparative study data

Chengdu VACURE Biotechnology Co., Ltd.

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1 Purpose & Overview

Purpose: Evaluation and analysis of the performance of a fluorescent immunoassay analyzer for the determination of anti-Müllerian Hormone (AMH) in serum. 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) detection system respectively, so as to analyze whether the performance of Kangxin Detection System is good compared with similar products.

2 Reagents & Instruments

(1) Instruments: Electrochemiluminescence automatic immunoassay analyzer Roche cobas θ 411

Reagent: Anti-Müllerian Hormone (AMH) Test kit (electrochemiluminescence)

Manufacturer: Roche Diagnostics GmbH

(2) Instrument: Fluorescence Immunoassay Analyzer LYOFIA-I

Reagent: Anti-Müllerian Hormone (AMH) Test kit (Microfluidic luminescence)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd

Lot: 2914601

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: 0.1-25ng/mL, compared methodologically to the detection ranges of 0.1-11ng/mL and 0.1-23ng/mL of Kangxin's detection kits 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	
	2.11	10.33	2.11	10.33
1	2.02	9.64	2.24	10.18
2	2.15	10.11	1.95	9.72
3	1.98	10.55	2.09	9.74
4	2.03	10.22	2.07	10.11
5	1.99	9.97	2.11	10.96
6	2.12	9.72	2.15	11.02
7	2.05	10.64	2.08	9.75
8	1.97	9.77	2.06	10.61
9	2.00	9.97	2.21	9.88
10	2.20	10.27	2.07	10.57
Average Value	2.051	10.086	2.103	10.254
Standard Deviation	0.079	0.339	0.082	0.503
CV	3.85%	3.36%	3.90%	4.91%

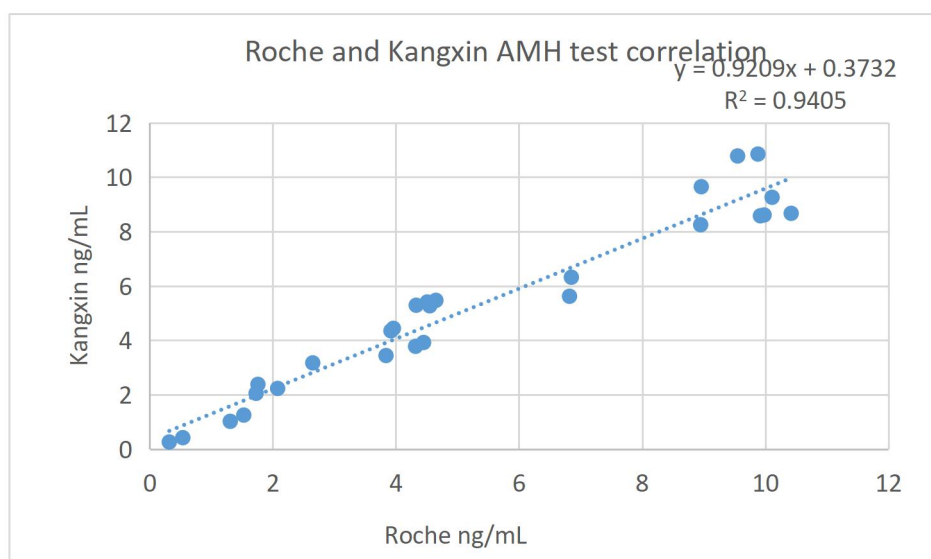
4. 2 Methodological comparison

Sample/Unit (ng/mL)	Roche	Kangxin
1	0.05	<0.1
2	0.11	<0.1
3	0.32	0.26
4	0.54	0.42
5	1.31	1.02
6	1.53	1.25
7	1.73	2.05
8	1.76	2.38
9	2.08	2.23
10	2.65	3.17
11	3.84	3.44
12	3.92	4.35
13	3.96	4.44
14	4.32	3.78
15	4.33	5.29
16	4.45	3.92
17	4.51	5.41
18	4.55	5.27
19	4.65	5.47
20	6.82	5.62
21	6.85	6.32
22	8.95	8.25
23	8.96	9.65
24	9.55	10.78
25	9.88	10.85
26	9.92	8.58
27	9.98	8.61
28	10.11	9.26
29	10.42	8.67
30	11.66	12.88
31	11.89	11.26
32	11.94	9.81
33	13.05	11.34
34	13.26	16.27
35	14.19	16.41

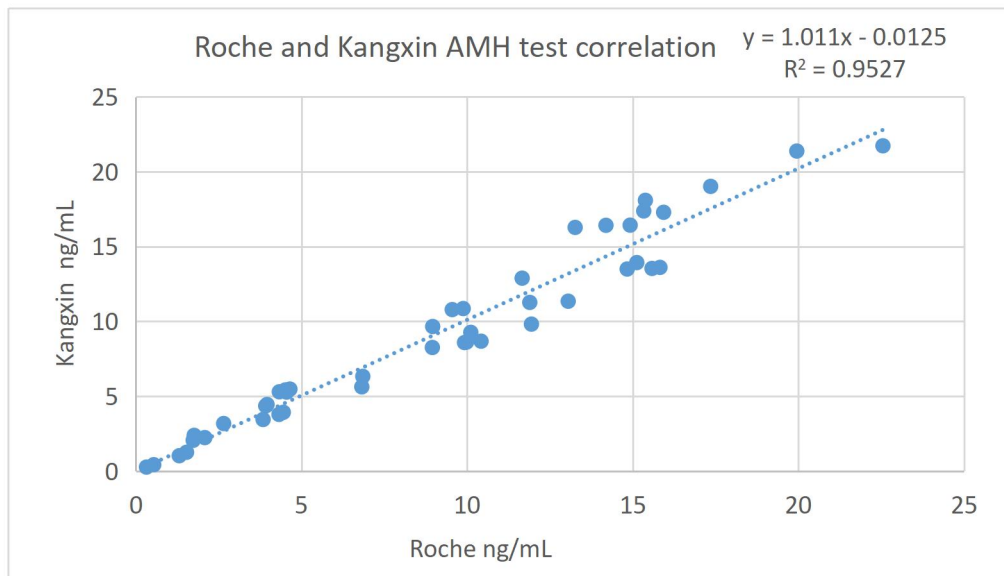
36	14.83	13.49
37	14.92	16.42
38	15.12	13.92
39	15.33	17.37
40	15.38	18.08
41	15.58	13.53
42	15.82	13.60
43	15.93	17.28
44	17.35	19.01
45	19.95	21.37
46	22.55	21.72
47	>23	24.64
48	>23	>25

4. 2. 1 Data Analysis

Test Range: 0.1-11 ng/mL: Take Roche's detection value as X, and Kangxin's detection value as Y, to make a regression curve.



Test Range: 0.1-23 ng/mL: Take the Roche's detection value as X, and Kangxin's detection value as Y, to make a regression curve.



5 Conclude

In this study, the correlations of the Kangxin biological detection system in the detection range: 0.1-11ng/mL and 0.1-23 ng/mL were: $R^2 = 0.9405$, $R^2 = 0.9527$, which is comparable to Roche's automatic electrochemiluminescence detection system good correlation. The precision meets the standard declared by the manufacturer.

Reporter:

Reviewer:

Date: