

**Hunan Kangxin Biotechnology Co., Ltd.**  
**Carcinoembryonic Antigen 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 a fluorescence immunoassay analyzer for detecting carcinoembryonic antigen (CEA) in serum. Refer to EP15-A2 to calculate the intra batch precision CV. Referring to the EP9-A2 document, calculate the linear regression equations and correlation coefficients between Hunan Kangxin Biological and Roche detection systems to analyze whether the Kangxin Biological detection system performs well compared to similar domestic products.

## 2 Reagents & Instruments

(1) Instruments: Electrochemiluminescence fully automatic immune analyzer

Reagent: Carcinoembryonic antigen (CEA) assay kit

Manufacturer: Roche Diagnostics GmbH

(2) Instrument: Fluorescence immunoassay analyzer LYOFIA-I

Reagent: Carcinoembryonic Antigen Kit (Microfluidic Fluorescent Immunoassay)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

## 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.

The detection range of the Kangxin's Test kit is: 1-500 ng/mL, and the methodological comparison of the detection ranges of 1-500 ng/mL and 1-50 ng/mL of the Kangxin's Test kit

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<br>(ng/mL) | Roche  |        | Kangxin |        |
|-------------------------|--------|--------|---------|--------|
|                         | 1      | 5.18   | 50.65   | 5.55   |
| 2                       | 5.04   | 48.13  | 4.91    | 52.95  |
| 3                       | 4.97   | 49.89  | 5.06    | 45.56  |
| 4                       | 4.89   | 52.16  | 5.41    | 50.05  |
| 5                       | 5.11   | 49.62  | 5.65    | 48.41  |
| 6                       | 5.14   | 52.91  | 4.59    | 50.23  |
| 7                       | 5.15   | 51.31  | 5.11    | 52.71  |
| 8                       | 5.32   | 50.98  | 5.01    | 47.27  |
| 9                       | 5.32   | 52.48  | 4.64    | 44.60  |
| 10                      | 5.05   | 52.05  | 5.42    | 51.58  |
| Average Value           | 5.12   | 51.02  | 5.14    | 49.23  |
| Standard Deviation      | 0.1381 | 1.4861 | 0.3665  | 2.8417 |
| CV                      | 2.70%  | 2.91%  | 7.14%   | 5.77%  |

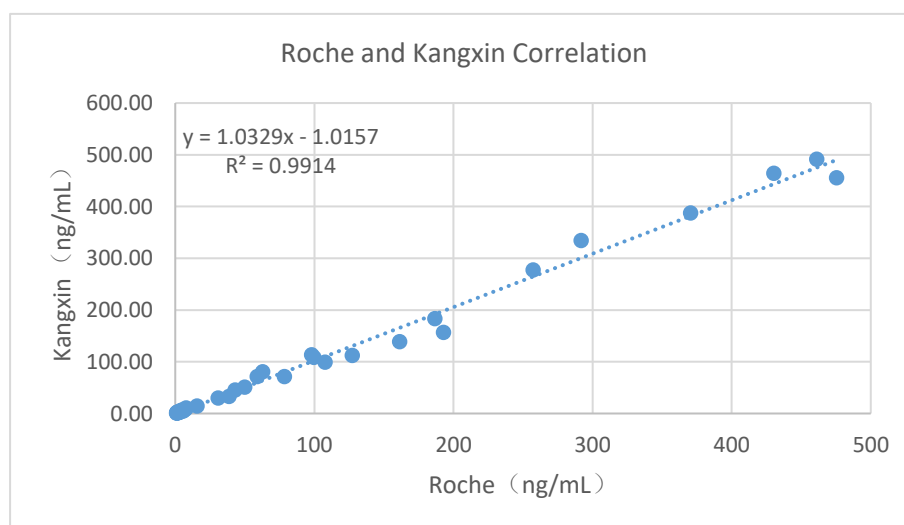
#### 4. 2 Methodological comparison

| Sample/Unit<br>(ng/mL) | Roche | Kangxin |
|------------------------|-------|---------|
| 1                      | 1.01  | 0.83    |
| 2                      | 1.09  | 1.52    |
| 3                      | 1.16  | 1.35    |
| 4                      | 1.23  | 1.27    |
| 5                      | 1.29  | 1.05    |
| 6                      | 1.34  | 0.96    |
| 7                      | 1.37  | 1.89    |
| 8                      | 1.58  | 0.96    |
| 9                      | 1.9   | 1.85    |
| 10                     | 2     | 2.57    |
| 11                     | 2.56  | 1.54    |
| 12                     | 2.82  | 1.85    |
| 13                     | 2.91  | 3.95    |
| 14                     | 3.24  | 2.18    |
| 15                     | 4.05  | 5.15    |
| 16                     | 5.06  | 6.58    |
| 17                     | 5.57  | 3.98    |
| 18                     | 5.8   | 5.80    |
| 19                     | 6.38  | 5.90    |
| 20                     | 7.51  | 8.86    |
| 21                     | 7.83  | 10.34   |
| 22                     | 15.74 | 14.45   |
| 23                     | 30.93 | 29.78   |
| 24                     | 38.55 | 32.73   |
| 25                     | 43.06 | 45.28   |
| 26                     | 49.94 | 50.43   |
| 27                     | 58.83 | 70.81   |

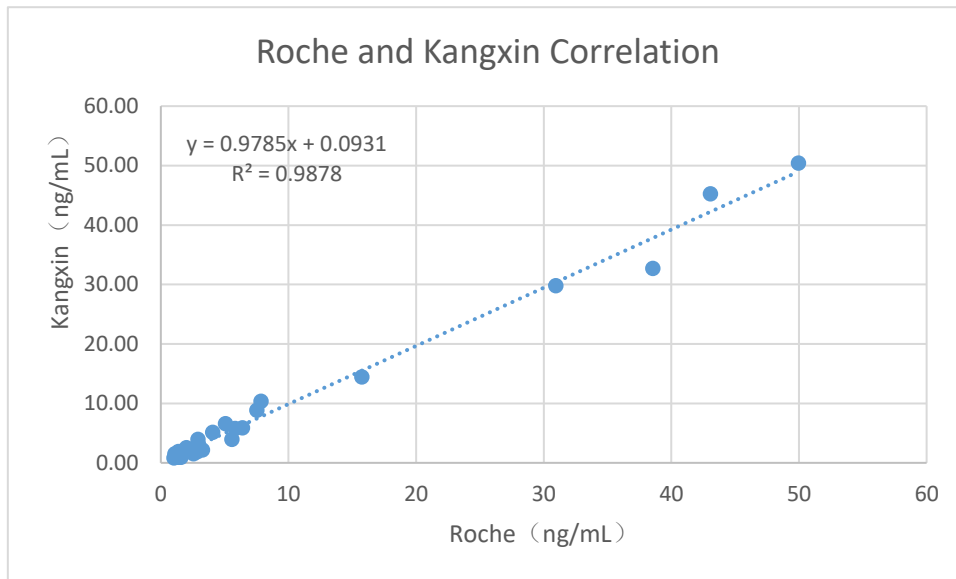
|    |        |        |
|----|--------|--------|
| 28 | 62.87  | 80.25  |
| 29 | 78.45  | 71.35  |
| 30 | 97.99  | 113.31 |
| 31 | 99.74  | 108.1  |
| 32 | 107.69 | 98.82  |
| 33 | 127.22 | 112.08 |
| 34 | 161.38 | 138.79 |
| 35 | 186.63 | 182.97 |
| 36 | 192.78 | 156.52 |
| 37 | 257.21 | 277.32 |
| 38 | 291.84 | 334.17 |
| 39 | 370.37 | 387.09 |
| 40 | 430.32 | 464.07 |
| 41 | 461.25 | 490.93 |
| 42 | 475.31 | 455.43 |

#### 4. 2. 1 Data Analysis

Detection range: 1-500 ng/mL: take Roche's detection value as X and Kangxin's measured value as Y to make a regression curve.



Detection range: 1-50 ng/mL; Take Roche's detection value as X and Kangxin's measured value as Y to make a regression curve. .



## 5 Conclusion

In this study, the correlation between the Kangxin biological detection system and the detection range of 1-500 ng/mL and 1-50 ng/mL was  $R^2=0.9914$  and  $R^2=0.9878$ , respectively, indicating good correlation with the Roche electrochemical luminescence fully automated immune analyzer detection system. The precision meets the manufacturer's declared standards.

Reporter: Ye Lijuan      Reviewer: Chen Jiao      Date: 2023.5.16