# Hunan Kangxin Biotechnology Co., Ltd.

# Thyroid Stimulating Hormone (TSH) 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 Thyroid Stimulating Hormone (TSH) in Serum. 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 Siemens Healthcare Diagnostics Products GmbH (Hereafter Siemens) detection system respectively, to analyze whether the performance of Kangxin detection system is good compared with domestic similar products.

## 2. Reagents & Instruments

(1) Instrument: Fully automatic chemiluminescence immunoassay analyzer (IMI 1600)

Reagent: Thyroid Stimulating Hormone (THS) Test Kit ( Direct Chemiluminescence )

Manufacturer: Siemens Healthcare Diagnostics Products GmbH

(2) Instrument: Fluorescent Immunoassay Analyzer LYOFIA-I

Reagent: Thyroid Stimulating Hormone (THS) Test Kit (Microfluidic Fluorescent Immunoassay)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

LOT: 1816601

## 3. Test Content

3.1 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%;

3.2 Comparison study of system results

Refer to the “Method Comparison and Bias Assessment with Patient Samples” in EP9-A2 that measure samples on two 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 0.1-150mIU/L for Thyroid Stimulating Hormone (TSH) Test Kit that manufactured by Kangxin, and they have a methodological comparison of test range for 0.1-150mIU/L and 0.3 - 20mIU/L.

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 Result

4.1 Precision assessment

| Repeat times (mIU/L) | Siemens | | Kangxin | |
|---|---|---|---|---|
| | 28.7 | 3.42 | 28.7 | 3.42 |
| 1 | 28.1 | 3.57 | 27.1 | 3.17 |
| 2 | 29.9 | 3.73 | 27.5 | 3.01 |
| 3 | 28.7 | 3.71 | 28.4 | 3.29 |
| 4 | 27.4 | 3.48 | 29.1 | 3.52 |
| 5 | 28.3 | 3.7 | 29.2 | 3.17 |
| 6 | 27.8 | 3.86 | 31.7 | 2.99 |
| 7 | 28.5 | 3.64 | 32.9 | 3.37 |
| 8 | 29.6 | 3.63 | 31.3 | 3.63 |
| 9 | 30 | 3.6 | 30.7 | 3.77 |
| 10 | 31.7 | 3.37 | 28.6 | 3.97 |
| Average Value | 28.5 | 3.63 | 29.2 | 3.39 |
| Standard Deviation | 1.23 | 0.13 | 1.81 | 0.31 |
| CV | 4.31% | 3.58% | 6.21% | 9.18% |

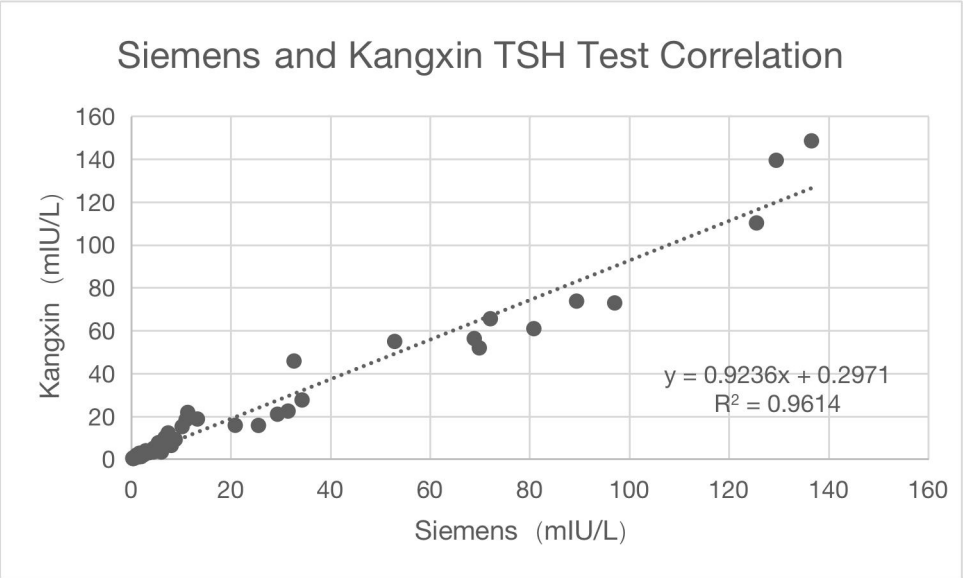
4.2 Methodological Comparison

| Sample/Unit (mIU/L) | Siemens | Kangxin |
|---|---|---|
| 1 | 0.179 | ＜0.1 |
| 2 | 0.085 | ＜0.1 |
| 3 | 0.109 | 0.17 |
| 4 | 0.125 | ＜0.1 |
| 5 | 0.131 | 0.29 |
| 6 | 0.183 | 0.11 |
| 7 | 0.218 | 0.11 |
| 8 | 0.278 | 0.18 |
| 9 | 0.334 | ＜0.1 |
| 10 | 0.357 | 0.45 |
| 11 | 0.397 | 0.31 |
| 12 | 0.487 | 0.32 |
| 13 | 0.539 | 0.73 |
| 14 | 0.558 | 0.5 |
| 15 | 0.665 | 0.49 |
| 16 | 0.925 | 0.82 |
| 17 | 1.086 | 1.42 |
| 18 | 1.122 | 1.9 |
| 19 | 1.471 | 1.11 |
| 20 | 1.528 | 1.47 |
| 21 | 1.594 | 1.24 |
| 22 | 1.686 | 2.76 |
| 23 | 1.69 | 1.27 |
| 24 | 1.958 | 2.45 |
| 25 | 1.968 | 2.68 |
| 26 | 2.039 | 1.22 |
| 27 | 2.288 | 1.89 |
| 28 | 2.491 | 2.05 |
| 29 | 2.548 | 2.98 |
| 30 | 2.618 | 2.19 |
| 31 | 2.947 | 3.87 |
| 32 | 2.988 | 3.85 |

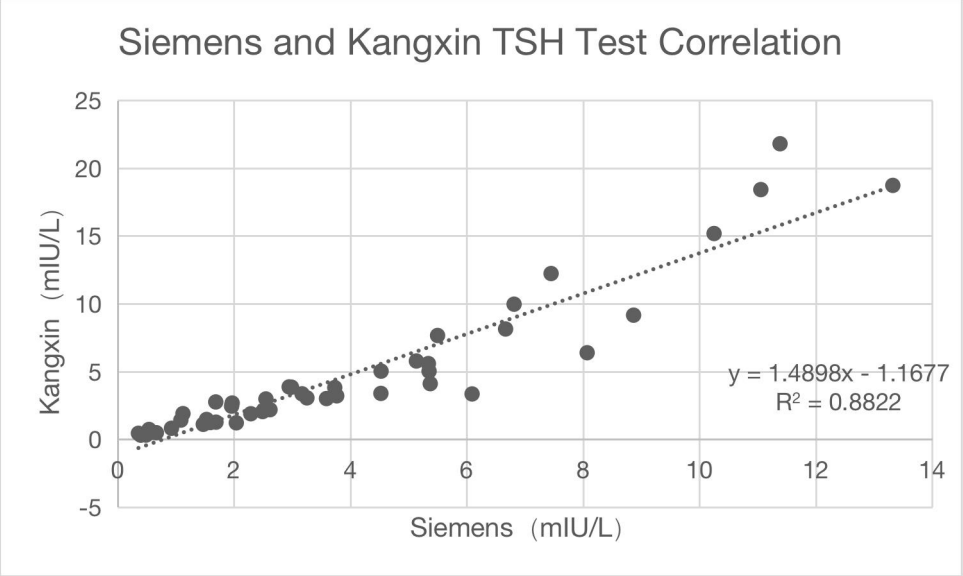
| | | |
|---|---|---|
| 33 | 3.169 | 3.36 |
| 34 | 3.253 | 3.06 |
| 35 | 3.589 | 3.01 |
| 36 | 3.731 | 3.82 |
| 37 | 3.765 | 3.21 |
| 38 | 4.524 | 3.39 |
| 39 | 4.527 | 5.03 |
| 40 | 5.134 | 5.78 |
| 41 | 5.34 | 5.59 |
| 42 | 5.352 | 5.03 |
| 43 | 5.372 | 4.11 |
| 44 | 5.498 | 7.66 |
| 45 | 6.091 | 3.35 |
| 46 | 6.667 | 8.14 |
| 47 | 6.813 | 9.97 |
| 48 | 7.449 | 12.23 |
| 49 | 8.069 | 6.39 |
| 50 | 8.867 | 9.16 |
| 51 | 10.25 | 15.18 |
| 52 | 11.054 | 18.42 |
| 53 | 11.384 | 21.8 |
| 54 | 13.322 | 18.73 |
| 55 | 20.919 | 15.79 |
| 56 | 25.577 | 15.74 |
| 57 | 29.399 | 20.96 |
| 58 | 31.52 | 22.42 |
| 59 | 32.712 | 45.78 |
| 60 | 34.325 | 27.61 |
| 61 | 52.912 | 54.92 |
| 62 | 68.886 | 56.27 |
| 63 | 69.901 | 51.91 |
| 64 | 72.118 | 65.52 |
| 65 | 80.846 | 60.88 |
| 66 | 89.422 | 73.73 |
| 67 | 97.067 | 72.88 |
| 68 | 125.534 | 110.2 |
| 69 | 129.492 | 139.43 |
| 70 | 136.569 | 148.5 |

4.2.1 Data Analysis

Test Range: 0.1-150 mIU/L： Take Siemens's detection value as X-axis, and Kangxin's detection value as Y-axis to make a regression curve.




Test Rang: 0.3-20 mIU/L: Take the Siemens'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: 0.1-150mIU/L, 0.3-20 mIU/L, and get the correlations are $R^2 = 0.9614$、$R^2 = 0.8822$, which has a good correlation with Siemens's fully automatic chemiluminescence immunoassay analyzer (IMI 1600). And the precision meets the manufacturer's declared value.

Reporter: Reviewer (Auditor): Date: