Hunan Kangxin Biotechnology Co.,Ltd.

Dengue Antigen (Dengue NS1) Test 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 fluorescent immunoassay analyzer for the determination of dengue antigen (Dengue NS1) in serum.Refer to the EP9-A2 document to calculate the negative and positive coincidence rates between Hunan Kangxin Biotechnology (Here after Kangxin)and Abbott Ireland Diagnostics Division (Hereafter Abbott) detection products, so as to analyze whether the performance of Kangxin's Detection System is good compared with similar products.

2 Reagents&Instruments

（1）Reagent：Dengue fever antigen (DENGUE NS1 Ag) kit (colloidal gold method)

Manufacturer: Abbott Ireland Diagnostics Division

（2）Instrument：Fluorescence Immunoassay Analyzer LYOFIA-I

Reagent: Dengue fever antigen (Dengue NS1) detection kit (Microfluidic Fluorescent Immunoassay)

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

Lot：4F17401

3 Test Content

3.1 Comparability research 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 on the two systems, each sample is measured once, and the test data is positive and negative. Sex matching rate statistics.

Abbott testing products can directly observe the colloidal gold reaction results, and judge whether it is a negative or positive test result; the test result interpretation of Kangxin's kit: the test result of the sample is reported as a test value within 0-100, and if the test value is ≤1, it is judged The sample is dengue antigen negative; if the test value is >1, the sample is judged to be dengue antigen positive.

4 Test Results

4.1 Methodological comparison

Sample	Abbott	Kangxin
1	Positive	1.43
2	Positive	2.19
3	Positive	1.65
4	Positive	2.03
5	Positive	1.49
6	Positive	1.21
7	Positive	2.76
8	Positive	1.86
9	Positive	1.86
10	Positive	1.91
11	Negative	0.15
12	Negative	0.51
13	Negative	0.18
14	Negative	0.79
15	Negative	0.87
16	Negative	0.12
17	Negative	0.45
18	Negative	0.03
19	Negative	0.67
20	Negative	0.62

4.1.1 Data Analysis

A total of 20 samples were tested, of which 10 were negative and 10 positive by Abbott testing products, and 10 negative Abbott samples were tested by Weikang testing products, all 10 of which were $\leqslant 1$, the results were negative, and the negative coincidence rate was 100%; All 10 cases of Abbott positive samples detected by

Weikang testing products were >1, and the results were all positive, with a positive coincidence rate of 100%; the overall negative and positive coincidence rate was 100%.

5 Conclusion

In this study, the Kangxin biological detection system has a good negative-positive coincidence rate compared with Abbott's detection products, and the overall negative-positive coincidence rate is 100%.

Reporter： Reviewer： Date：