Hunan Kangxin Biotechnology Co.,Ltd.

Fecal Occult Blood (FOB) 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 the Kangxin fluorescent immunoassay analyzer for the determination of fecal occult blood (FOB) in Feces. 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 Hangzhou Abon biotechnology Co., Ltd. (Hereafter Abon) detection system respectively, to analyze whether the performance of Kangxin detection system was good compared with domestic similar products.

2 Reagents&Instruments

（1）Reagents：Fecal Occult Blood (FOB) Rapid Test kit（Colloidal gold method）

Manufacturer：Hangzhou Abon biotechnology Co., Ltd.

（2）Instrument：Fluorescence Immunoassay Analyzer LYOFIA-I

Reagent：Fecal Occult Blood (FOB) Test kit（Microfluidic luminescence）

Manufacturer: Hunan Kangxin Biotechnology Co., Ltd.

Lot：4E17501

3 Test Content

3.1 Precision assessment

Negative and positive samples were detected in the two detection systems, and the measurement was repeated 10 times. The Weikang system calculated the mean ($\overline{X}$) and standard deviation (S) of the 10 measurement results to obtain the coefficient of variation (CV). The results should not be different. Less than the value declared by the manufacturer.

Manufacturer(Kangxin) declared value：Kangxin（CV）：≤10%；

3.2 Comparison 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.

Abon detection products can directly observe the colloidal gold reaction result, and judge it as negative or positive test result; the test result interpretation of Kangxin biological kit: the test result of the sample is reported as a test value within 0-100, if the test value is ≤1, then The sample is judged to be FOB negative; if the detection value is >1, the sample is judged to be FOB positive.

4 Test Results

4.1 Precision assessment

Repeat times	Abon		Kangxin	
Sample	Negative	Postive	Negative	Postive
1	Negative	Postive	0.84	14.64
2	Negative	Postive	0.62	13.70
3	Negative	Postive	0.75	13.70
4	Negative	Postive	0.80	12.30
5	Negative	Postive	0.73	12.60
6	Negative	Postive	0.78	12.38
7	Negative	Postive	0.65	13.27
8	Negative	Postive	0.77	11.36
9	Negative	Postive	0.85	11.42
10	Negative	Postive	0.76	15.25
Average Value	/	/	0.755	13.062
Standard Deviation	/	/	0.074	1.290
CV	/	/	9.78%	9.88%

4.2 Methodological comparison

Sample	Abon	Kangxin
1	Negative	0.50

2	Negative	0.00
3	Negative	0.15
4	Negative	0.04
5	Negative	0.03
6	Negative	0.00
7	Negative	0.09
8	Negative	0.17
9	Negative	0.20
10	Negative	0.11
11	Negative	0.10
12	Negative	0.09
13	Negative	0.10
14	Negative	0.07
15	Negative	0.04
16	Negative	0.01
17	Negative	0.03
18	Negative	0.02
19	Negative	0.00
20	Negative	0.37
21	Negative	0.03
22	Negative	1.02
23	Negative	0.00
24	Negative	0.12
25	Negative	0.00
26	Positive	35.44
27	Positive	12.80
28	Positive	>100
29	Positive	>100
30	Positive	46.21
31	Positive	1.83
32	Positive	2.32
33	Positive	9.98
34	Positive	56.11
35	Positive	21.17
36	Positive	36.35
37	Positive	20.33
38	Positive	13.43
39	Positive	99.93
40	Positive	9.15

41	Positive	2.02
42	Positive	84.41
43	Positive	25.66
44	Positive	62.69
45	Positive	2.12
46	Positive	75.78
47	Positive	2.22
48	Positive	17.03
49	Positive	21.43
50	Positive	5.95
51	Positive	12.85
52	Positive	3.30

4.2.1 结果分析

A total of 52 samples were tested, of which 25 cases were negative and 27 cases were positive for Aibo testing products, 25 cases were tested for Abon negative samples by Kangxin testing products, 24 cases were ≤1, the results were negative, and 1 case was all >1 , the result was positive, and the negative coincidence rate was 96%; the results of 27 Abon positive samples tested by Kangxin testing products were all >1, and the results were all positive, with a positive coincidence rate of 100%; the overall negative and positive coincidence rate was 98%.

5 Conclusion

In this study, Kangxin biological detection system has a good negative-positive coincidence rate compared with Aibo detection products, and the overall negative-positive coincidence rate is 98%. The precision of Weikang products meets the declared standards.

Reporter：   Reviewer：   Date：