Hunan Kangxin Biotechnology Co., Ltd.
B-type Natriuretic Protein Kit
(Microfluidic Fluorescent Immunoassay)

Performance Evaluation Study Materials

Chengdu VACURE Biotechnology Co., Ltd.
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1 Purpose and overview

According to the requirements of the State Food and Drug Administration's announcement on the release of the catalog of in vitro diagnostic reagents exempt from clinical trials (2021 No. 70), B-type Natriuretic Protein Kit(Microfluidic Fluorescent Immunoassay) developed by our company In vitro diagnostic reagents for clinical trials. The company intends to evaluate the clinical performance of in vitro diagnostic reagents through the evaluation of clinical samples covering the intended use and interference factors.

2 Reagents and instruments

（1） instrument：Atellica solution

Reagent：B-type Natriuretic Protein Kit（direct chemiluminescence）

manufacturer：Siemens Healthcare Diagnostic lnc

（2）instrument：Fluorescence Immunoassay Analyzer

Reagent：B-type Natriuretic Protein Kit(Microfluidic Fluorescent Immunoassay)

manufacturer：Hunan Kangxin Biotechnology Co., Ltd.

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 are counted analyze.

Take the test results of the comparison system as the X axis, and the test results of the test system as the Y axis, draw a regression curve, and obtain the regression formula and the correlation coefficient r.

4 Test results

4. 1 Methodological comparison

sample/unit	Comparison reagent: Siemens	Evaluation Reagent: Hunan Kangxin
1	397.62	409.69
2	55.12	57.58
3	2712.59	2699.74
4	1020.02	1008.08
5	145.84	142.31
6	489.49	466.85
7	1006.81	976.78
8	11.86	11.89
9	109.29	111.11
10	245.36	256.7
11	22.76	22.48

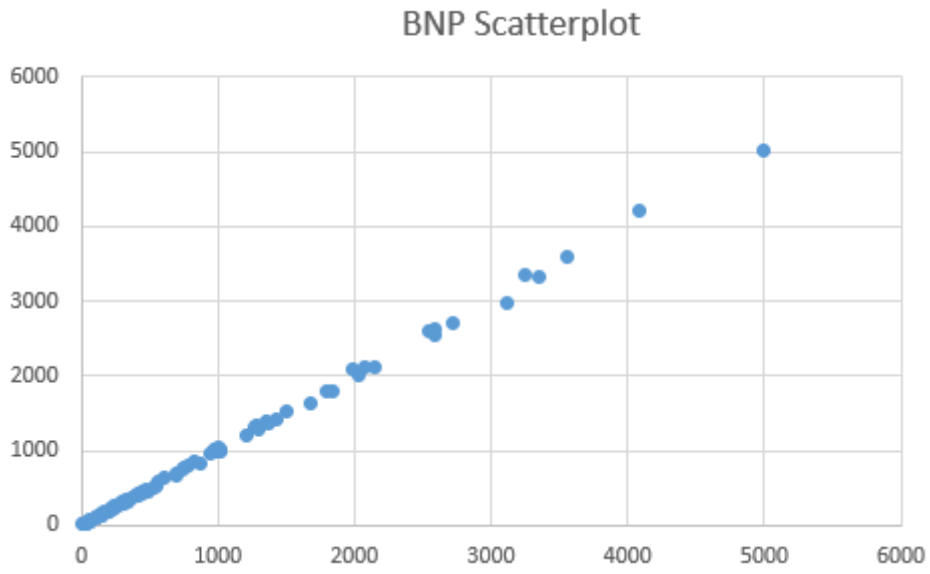
12	416.45	409.43
13	374.21	368.25
14	2584.95	2534.26
15	1507.30	1529.28
16	243.68	239.77
17	70.97	70.46
18	278.09	290.68
19	103.66	101.65
20	989.11	992.52
21	1801.69	1797.51
22	17.70	16.97
23	28.04	28.64
24	213.58	216.78
25	62.60	61.36
26	141.65	137.67
27	1211.24	1211.83
28	688.43	708.34
29	67.23	69.19
30	52.66	52.72
31	172.54	173.41
32	48.29	49.69
33	789.32	792.6
34	114.42	114.86
35	544.60	542.69
36	57.67	60.36
37	1286.74	1329.31
38	195.79	189.98
39	441.59	430.47
40	529.15	514.4
41	325.49	341.59
42	236.16	228.23
43	142.22	142.03
44	977.39	1009
45	152.60	149.24
46	107.99	102.6
47	443.71	444.91
48	945.77	952.97
49	189.37	190.71
50	31.71	33.11
51	227.01	223.11

52	35.86	34.7
53	1007.07	1046
54	347.42	345.48
55	176.02	180.15
56	223.46	228.37
57	272.05	263.98
58	244.00	251.17
59	175.80	177.96
60	130.10	132.12
61	409.95	428.95
62	1261.06	1307.06
63	311.10	302.65
64	198.34	198.3
65	2535.99	2592.48
66	3343.94	3313.23
67	868.11	825.21
68	1370.12	1355.41
69	425.50	427.15
70	304.25	310.79
71	3114.22	2981.61
72	3244.42	3359.22
73	337.58	332.43
74	25.62	25.34
75	554.86	531.88
76	156.84	158.95
77	1838.24	1796.85
78	17.80	18.21
79	215.70	206.8
80	4987.33	5007.49
81	2033.43	2009.32
82	753.69	783.25
83	608.72	638.65
84	3550.93	3601.93
85	399.06	397.07
86	699.97	680.67
87	1674.68	1627.76
88	2145.95	2126.61
89	1349.90	1380.73
90	2589.83	2638.19
91	1016.74	998.5

92	833.46	855.4
93	2079.03	2108.53
94	567.65	587.98
95	481.90	492.43
96	4079.47	4209.79
97	1427.71	1411.39
98	745.48	748.42
99	1989.15	2102.71
100	1291.47	1277.31

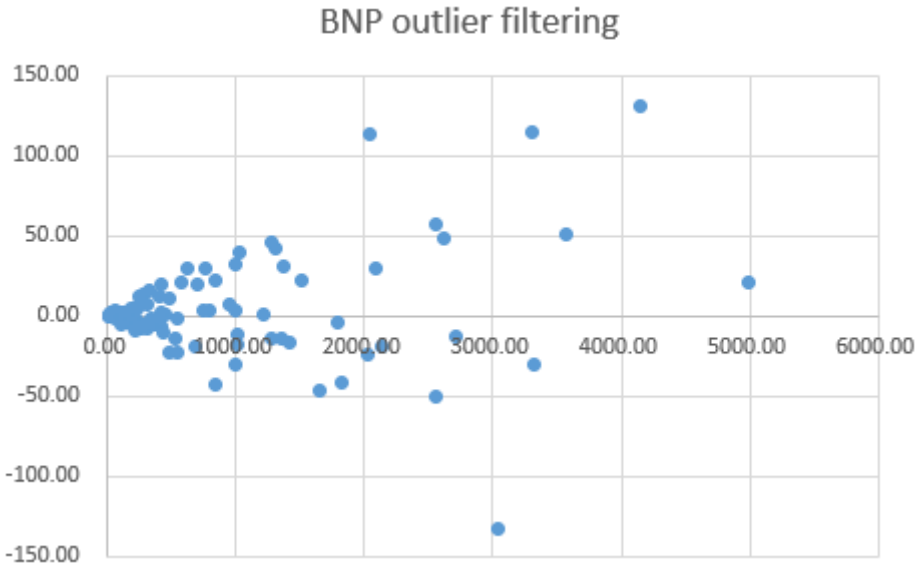
4. 2 Data analysis

（1）The comparison reagent is X, and the reagent to be evaluated is Y to make a scatter diagram.

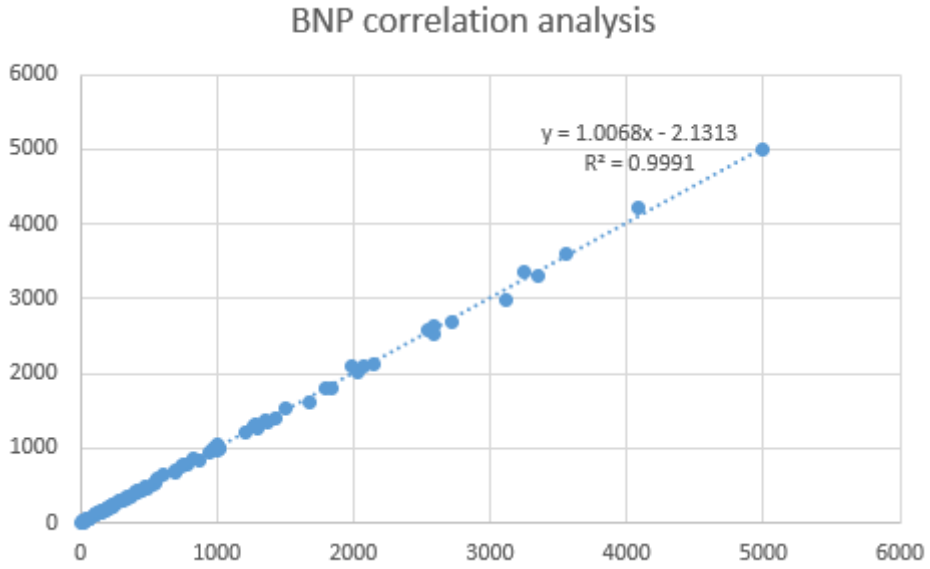


No obvious outliers were found by visual judgment.

（2）The average value of the reagent to be evaluated and the comparison reagent is X, and the difference between the reagent to be evaluated and the comparison reagent is Y, and the graph is drawn.



（3）With the reagent to be evaluated as the dependent variable and the comparative reagent as the independent variable, linear regression fitting was performed, and the linear results are as follows:



The R^2=0.9991 of the test results of the reagent to be evaluated and the comparison reagent, the linear equation of the two is: y =1.0068x-2.1313, the test results of the two groups are highly correlated.

5 Conclusion

Through the comparative analysis of this clinical trial, there is no significant difference in the test results of the reagent to be evaluated compared with the test results of the reagent to be evaluated, which can be regarded as consistent in the results.

Since the reagent to be evaluated is an in vitro diagnostic reagent used to assist in the diagnosis of diseases, the diagnosis of the disease also depends on the comprehensive judgment of clinical symptoms and other test results. Therefore, a certain deviation between the reagent to be evaluated and the comparison reagent is acceptable. The results of this clinical evaluation show that the test results of the reagent to be evaluated and the comparison reagent have little deviation, which can be regarded as equivalent to the detection of clinical

samples, and can be used in clinical practice as an auxiliary diagnosis.