

31	Female	60	-	-	-
32	Male	67	-	-	-
33	Male	38	-	-	-
34	Male	82	-	-	-
35	Female	63	-	-	-
36	Male	90	-	-	-
37	Female	69	-	-	-
38	Male	56	-	-	-
39	Male	68	+	-	-
40	Male	59	-	-	-
41	Female	66	-	-	-
42	Female	17	-	-	-
43	Female	85	-	-	-
44	Male	31	-	-	-
45	Female	68	-	-	-
46	Male	59	-	-	-
47	Female	71	-	-	-
48	Male	36	-	-	-
49	Male	39	-	+	-
50	Male	82	-	-	-
51	Female	49	-	-	-
52	Male	62	-	-	-
53	Male	71	-	-	-
54	Female	38	-	-	-
55	Male	82	-	-	-
56	Female	63	-	-	-
57	Male	74	-	-	-
58	Male	69	-	-	-
59	Male	56	-	-	-
60	Female	68	-	-	-
61	Male	59	-	-	-
62	Female	46	-	-	-
63	Female	17	-	-	-
64	Male	85	-	-	-
65	Female	31	-	-	-
66	Male	68	-	-	-
67	Male	52	-	-	-
68	Female	81	-	-	-
69	Male	66	-	-	-
70	Female	27	-	-	-

Note: "+" mean positive result, "-" mean negative result

5. Result Analysis

Table: Clinical study result of BNCP-402

IgG Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Results		20	50	70

Relative Sensitivity: >99.9% (95%CI*: 86%-100%)

Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)

Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

*Confidence Intervals

IgM Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Results		20	50	70

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

*Confidence Intervals

Table: Clinical study result of BNCP-402S

IgG Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood)	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Results		20	50	70

Relative Sensitivity: >99.9% (95%CI*: 86%-100%)

Relative Specificity: 98.0% (95%CI*: 89.4%-99.9%)

Accuracy: 98.6% (95%CI*: 92.3%-99.96%)

*Confidence Intervals

IgM Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood)	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Results		20	50	70

Relative Sensitivity: 85.0% (95%CI*: 62.1%-96.8%)

Relative Specificity: 96.0% (95%CI*: 86.3%-99.5%)

Accuracy: 92.9% (95%CI*: 84.1%-97.6%)

*Confidence Intervals

6. Conclusion

The relative sensitivity of 2019-nCoV IgG/IgM Rapid Test Cassette (BNCP-402 and BNCP-402S) was more than 99.9% for IgG and 85.0% for IgM, the relative specificity was 98.0% for IgG and 96.0% for IgM compare with PCR result.

