

Clinical Study Report of 2019-nCoV IgG/IgM Rapid Test Cassette

Ref.: BNCP-402/BNCP-402S

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1. Purpose

Do clinical studies of 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) with the 2019-nCoV positive specimen and negative specimen which confirmed with PCR method.

2. Materials

← 2019-nCoV Rapid Test Cassette
←

Lot: COV20020001-R

← 2019-nCoV Rapid Test Cassette single use kit

Lot: COV20020002-R

← 20 2019-nCoV clinical positive specimen

← 50 2019-nCoV clinical negative specimen

3. Operation Method

- 3.1. Place the cassette on a clean and level surface. Hold the dropper vertically, transfer 10 μ L serum, plasma specimen or 20 μ L whole blood specimen to the sample well(S). Then add 2 drops of buffer (approximately 80 L) and start the timer.
- 3.2. Read the results at 10 minutes, do not interpret the results after 20 minutes.

4. Test Results

Table- Test Results of BNCP-402

No.	Gender	Age	Result		
			AllTest Kit		PCR Results
			IgG	IgM	
1	Female	45	+	+	+
2	Female	34	+	+	+
3	Male	31	+	+	+
4	Male	36	+	+	+
5	Female	55	+	+	+
6	Female	63	+	+	+
7	Female	38	+	+	+
8	Male	74	+	+	+
9	Male	74	+	-	+
10	Male	51	+	+	+
11	Male	83	+	-	+
12	Female	65	+	+	+
13	Female	59	+	+	+
14	Female	48	+	+	+
15	Male	36	+	+	+
16	Female	81	+	-	+
17	Male	85	+	+	+
18	Male	39	+	+	+
19	Female	84	+	+	+
20	Male	91	+	+	+

21	Male	39	-	-	-
22	Female	80	-	-	-
23	Female	96	-	-	-
24	Male	85	-	-	-
25	Female	77	-	-	-
26	Female	71	-	-	-
27	Male	51	-	-	-
28	Female	73	-	+	-
29	Male	74	-	-	-
30	Female	26	-	-	-
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

Table- Test Results of BNCP-402S

No.	Gender	Age	Result		
			AllTest Kit		PCR Results
			IgG	IgM	
1	Female	45	+	+	+
2	Female	34	+	+	+
3	Male	31	+	+	+
4	Male	36	+	+	+
5	Female	55	+	+	+
6	Female	63	+	+	+
7	Female	38	+	+	+
8	Male	74	+	+	+
9	Male	74	+	-	+
10	Male	51	+	+	+
11	Male	83	+	-	+
12	Female	65	+	+	+
13	Female	59	+	+	+
14	Female	48	+	+	+
15	Male	36	+	+	+
16	Female	81	+	-	+
17	Male	85	+	+	+
18	Male	39	+	+	+
19	Female	84	+	+	+
20	Male	91	+	+	+
21	Male	39	-	-	-
22	Female	80	-	-	-
23	Female	96	-	-	-
24	Male	85	-	-	-
25	Female	77	-	-	-
26	Female	71	-	-	-
27	Male	51	-	-	-
28	Female	73	-	+	-
29	Male	74	-	-	-
30	Female	26	-	-	-

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
	Results	Positive	Negative	
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	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
	Results	Positive	Negative	
2019-nCoV IgG/IgM Rapid Test Cassette (WB/S/P)	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
	Results	Positive	Negative	
2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood)	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
	Results	Positive	Negative	
2019-nCoV IgG/IgM Rapid Test Cassette (Fingerstick Whole Blood)	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.