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

Ref.: INCP-402/INCP-402S

	Name	Department	Date
Prepared by	Tony Peng	R&D	2020.02.13
Reviewed by	Kael Chen	R&D	2020.02.13

Content

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 10µL serum, plasma specimen or 20µL 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 INCP-402

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

21	39	Male	-	-	-
22	80	Female	-	-	-
23	96	Female	-	-	-
24	85	Male	-	-	-
25	77	Female	-	-	-
26	71	Female	-	-	-
27	51	Male	-	-	-
28	73	Female	-	+	-
29	74	Male	-	-	-
30	26	Female	-	-	-
31	60	Female	-	-	-
32	67	Male	-	-	-
33	38	Male	-	-	-
34	82	Male	-	-	-
35	63	Female	-	-	-
36	90	Male	-	-	-
37	69	Female	-	-	-
38	56	Male	-	-	-
39	68	Male	+	-	-
40	59	Male	-	-	-
41	66	Female	-	-	-
42	17	Female	-	-	-
43	85	Female	-	-	-
44	31	Male	-	-	-
45	68	Female	-	-	-
46	59	Male	-	-	-
47	71	Female	-	-	-
48	36	Male	-	-	-
49	39	Male	-	+	-
50	82	Male	-	-	-
51	49	Female	-	-	-
52	62	Male	-	-	-
53	71	Male	-	-	-
54	38	Female	-	-	-
55	82	Male	-	-	-
56	63	Female	-	-	-
57	74	Male	-	-	-
58	69	Male	-	-	-
59	56	Male	-	-	-
60	68	Female	-	-	-
61	59	Male	-	-	-
62	46	Female	-	-	-

63	17	Female	-	-	-
64	85	Male	-	-	-
65	31	Female	-	-	-
66	68	Male	-	-	-
67	52	Male	-	-	-
68	81	Female	-	-	-
69	66	Male	-	-	-
70	27	Female	-	-	-

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

Table- Test Results of INCP-402S

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

5

30	26	Female	-	-	-
31	60	Female	-	-	-
32	67	Male	-	-	-
33	38	Male	-	-	-
34	82	Male	-	-	-
35	63	Female	-	-	-
36	90	Male	-	-	-
37	69	Female	-	-	-
38	56	Male	-	-	-
39	68	Male	+	-	-
40	59	Male	-	-	-
41	66	Female	-	-	-
42	17	Female	-	-	-
43	85	Female	-	-	-
44	31	Male	-	-	-
45	68	Female	-	-	-
46	59	Male	-	-	-
47	71	Female	-	-	-
48	36	Male	-	-	-
49	39	Male	-	+	-
50	82	Male	-	-	-
51	49	Female	-	-	-
52	62	Male	-	-	-
53	71	Male	-	-	-
54	38	Female	-	-	-
55	82	Male	-	-	-
56	63	Female	-	-	-
57	74	Male	-	-	-
58	69	Male	-	-	-
59	56	Male	-	-	-
60	68	Female	-	-	-
61	59	Male	-	-	-
62	46	Female	-	-	-
63	17	Female	-	-	-
64	85	Male	-	-	-
65	31	Female	-	-	-
66	68	Male	-	-	-
67	52	Male	-	-	-
68	81	Female	-	-	-
69	66	Male	-	-	-
70	27	Female	-	-	-

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

5. Result Analysis

Table: Clinical study result of INCP-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 INCP-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 (INCP-402 and INCP-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.