

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

Ref.: INCP-402/INCP-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

• 2019-nCoV Rapid Test Cassette single use kit

• 20 2019-nCoV clinical positive specimen

• 50 2019-nCoV clinical negative specimen

Lot: COV20020001-R

Lot: COV20020002-R

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

				Result			
No.	Age	Gender	AllTe	st Kit	DCD D I		
			IgG	IgM*	PCR Results		
1	45	Female	+	+	+		
2	34	Female	44	+5	+		
3	31	Male	+ =	+	+		
4	36	Male	+	+	+		
5	55	Female	+	+	+		
6	63	Female	+	+ /	七個外公		
7	38	Female	+	+/	My that She		
8	74	Male	+	+	+ 800		
9	74	Male	+	4	18008		
10	51	Male	+	+	+ 288		
11	83	Male	+	- / 3	X X X X		
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	+	+	+		



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	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	- N	-	-
	41	66	Female	_ le	, - s	
	42	17	Female	data v. -	-	<u>-</u>
	43	85	Female	7.5		
	44	31	Male	- 32	_	H-//
	45	68	Female			《有限公司》
	46	59	Male	-	-/	- 3
	47	71	Female	-	- 4	
	48	36	Male	-	- +	R P
	49	39	Male	-	+	- L
	50	82	Male	-	-	水茶草州
	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

				Result			
No.	Age	Gender	AllTe	est Kit	PCR Results		
		\$7.00	IgG	IgM	1 CR Results		
1	45	Female	+	+	+		
2	34	Female	+	+	+		
3	31	Male	+	+	+		
4	36	Male	+	+	+		
5	55	Female	+	+	+		
6	63	Female	+	+	+		
7	38	Female	+	+	+		
8	74	Male	+	y+ _s	+		
9	74	Male	+	-	+		
10	51	Male	+	+	+		
11	83	Male	400	-	+///		
12	65	Female	+	4			
13	59	Female	+	+	发展+/>		
14	48	Female	+	+ / 5	H2111 + 3		
15	36	Male	+	+ 4	D T		
16	81	Female	+	- 4	Z P		
17	85	Male	+	+ +	+ .0		
18	39	Male	+	+ 1	" 交 承 采 <i>州</i> 。		
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		_	- 19 ²		
28	73	Female	-	+	-		
29	74	Male	-	-	_		



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30	26	Female	-	-	-
31	60	Female	-	_	_
32	67	Male	-	- 72°	ne real English
33	38	Male	-	-	-
34	82	Male	-	-	
35	63	Female	_	-	-
36	90	Male		_	-
37	69	Female	_	9 S - S	_
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	_3	_	-
47	71	Female	-	_	
48	36	Male	- 5	_	-
49	39	Male		+	-
50	82	Male	<u> </u>	y - s	-
51	49	Female		-	-
52	62	Male		_	-
53	71	Male	- 140	-	
54	38	Female		-	
55	82	Male	-	-	米明儿
56	63	Female		_	成有限公司
57	74	Male	_	- 1	1
58	69	Male	_	-	K
59	56	Male	_	_	节 一
60	68	Female	_	_	My Such City
61	59	Male	-	-	李素與州
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	PC	Total Results		
2019-nCoV IgG/IgM	Results	Positive	Negative	Total Results
Rapid Test Cassette	Positive	20	1	21
(WB/S/P)	Negative	0	49	49
Total Resu	lts	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	Total Results			
2019-nCoV IgG/IgM	Results	Positive	Negative	Total Results
Rapid Test Cassette	Positive	17	2	19
(WB/S/P)	Negative	3	48	51
Total Resu	lts	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		
Results	Positive	Negative	Total Results	
Positive	20	1	24周八	
Negative	0	49	The state of the s	
Total Results		50	1×70 -	
	Positive Negative	Results Positive Positive 20 Negative 0	Results Positive Negative Positive 20 1 Negative 0 49	

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	Results	Positive	Negative	Total Results
Rapid Test Cassette	Positive	17	2	19
(Fingerstick Whole Blood)	Negative	3	48	51
Total Resu	lts	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.

