

*Clinical study Report of 2019-nCoV IgG/IgM Rapid  
Test Casette  
Ref.: INCP-402/  
INCP-402S*

## 1. Purpose

To 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. COV 20020001-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 microlitres of serum, plasma specimen or 20 microlitres whole blood specimen to the sample well (S). Then add 2 drops of buffer (approx. 80 microlitres) and start the timer.

3.2 Read the results at 10 minutes, do not interpret the results after 20 minutes or more.

## 4. Test results

Table – Test Results of INCP-402

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

25	77	F	-	-	-
26	71	F	-	-	-
27	51	M	-	-	-
28	73	F	-	+	-
29	74	M	-	-	-
30	26	F	-	-	-
31	60	F	-	-	-
32	67	M	-	-	-
33	38	M	-	-	-
34	82	M	-	-	-
35	63	F	-	-	-
36	90	M	--	-	-
37	69	F	-	-	-
38	56	M	-	-	-
39	68	M	+	-	-
40	59	M	-	-	-
41	66	F	-	-	-
42	17	F	-	-	-
43	85	F	-	-	-
44	31	M	-	-	-
45	68	F	-	-	-
46	59	M	-	-	-
47	71	F	-	-	-
48	36	M	-	-	-
49	39	M	-	+	-
50	82	M	-	-	-
51	49	F	-	-	-
52	62	M	-	-	-
53	71	M	-	-	-
54	38	F	-	-	-
55	82	M	-	-	-
56	63	F	-	-	-
57	74	M	-	-	-
58	69	M	-	-	-
59	56	M	-	-	-
60	68	F	-	-	-
61	59	M	-	-	-
62	46	F	-	-	-
63	17	F	-	-	-
64	85	M	-	-	-
65	31	F	-	-	-
66	68	M	-	-	-
67	52	M	-	-	-
68	81	F	-	-	-
69	66	M	-	-	-
70	27	F	-	-	-

Note: "+" means positive results, "-" means negative result

Table-Test Results of INCP-402S

No.	Age	Gender	Results		
			IgG	IgM	PCR Results
1	45	F	+	+	+
2	34	F	+	+	+
3	31	M	+	+	+
4	36	M	+	+	+
5	55	F	+	+	+
6	63	F	+	+	+
7	38	F	+	+	+
8	74	M	+	+	+
9	74	M	+	+	+
10	51	M	+	+	+
11	83	M	+	-	+
12	65	F	+	+	+
13	59	F	+	+	+
14	48	F	+	+	+
15	36	M	+	+	+
16	81	F	+	+	+
17	85	M	+	+	+
18	39	M	+	+	+
19	84	F	+	+	+
20	91	M	+	+	+
21	39	M	-	-	-
22	80	F	-	-	-
23	96	F	-	-	-
24	85	M	-	-	-
25	77	F	-	-	-
26	71	F	-	-	-
27	51	M	-	-	-
28	73	F	-	+	-
29	74	M	-	-	-
30	26	F	-	-	-
31	60	F	-	-	-
32	67	M	-	-	-
33	38	M	-	-	-
34	82	M	-	-	-
35	63	F	-	-	-
36	90	M	-	-	-
37	69	F	-	-	-
38	56	M	-	-	-
39	68	M	+	-	-
40	59	M	-	-	-
41	66	F	-	-	-
42	17	F	-	-	-
43	85	F	-	-	-
44	31	M	-	-	-
45	68	F	-	-	-

46	59	M	-	-	-
47	71	F	-	-	-
48	36	M	-	-	-
49	39	M	-	+	-
50	82	M	-	-	-
51	49	F	-	-	-
52	62	M	-	-	-
53	71	M	-	-	-
54	38	F	-	-	-
55	82	M	-	-	-
56	63	F	-	-	-
57	74	M	-	-	-
58	69	M	-	-	-
59	56	M	-	-	-
60	68	F	-	-	-
61	59	M	-	-	-
62	46	F	-	-	-
63	17	F	-	-	-
64	85	M	-	-	-
65	31	F	-	-	-
66	68	M	-	-	-
67	52	M	-	-	-
68	81	F	-	-	-
69	66	M	-	-	-
70	27	F	-	-	-

## 5. Result Analysis

## IgG Result

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

Relative Sensitivity: &gt;99,9% (95%CI\*: 86-100%)

Relative Specificity: 98% (95%CI\*: 89,4%-99,9%)

Accuracy: 98,6% (95%CI\*:92,3-99,96%)

## IgM Result

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

Relative Sensivity: 85%% (95%CI\*: 62,1-96,8%)

Relative Specificity: 96% (95%CI\*: 86,3-99,5%)

Accuracy: 92,9% (95%CI\*:84,1-97,6%)

Table: Clinical study result of INCP-402S

### IgG Result

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

Relative Sensivity: >99,9% (95%CI\*: 86-100%)

Relative Specificity: 98% (95%CI\*: 89,4%-99,9%)

Accuracy: 98,6% (95%CI\*:92,3-99,96%)

### IgM Result

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

Relative Sensivity: 85%% (95%CI\*: 62,1-96,8%)

Relative Specificity: 96% (95%CI\*: 86,3-99,5%)

Accuracy: 92,9% (95%CI\*:84,1-97,6%)

### 6. Conclusion

The relative sensivity of 2019-nCoV IgG/IgM Rapid Test Casette (INCP-402 and INCP-402S) was more than 99,9% for IgG and 85% for IgM, the relative sppecificity was 98% for IgG and 96% for IgM comparing with PCR results.