

CLINICAL STUDY REPORT

2019-nCoV IgG/IgM Rapid Test Cassette (1-360-K025)

PURPOSE

Clinical studies of 2019-nCoV IgG/IgM Rapid Test Cassette with the 2019-nCoV positive specimen and negative specimen which confirmed with PCR method.

METHOD

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 specimen well. Then add 2 drops of buffer and start the timer. Read results at 10 minutes. Do not interpret the result after 20 minutes.

RESULTS

No.	Age	Gender	Result		
			2019-nCoV IgG/IgM Rapid Test Cassette		PCR Result
			IgG	IgM	
1	45	Female	+	+	+
2	34	Female	+	+	+
3	34	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

RESULT ANALYSIS

IgG Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	Positive	Negative	
	Positive	20	1	21
	Negative	0	49	49
Total Result		20	50	70

Relative Sensitivity: >99,9% (95%CI*: 86.0%-100%) *Confidence Interval

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

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

IgM Result

Method		PCR		Total Results
2019-nCoV IgG/IgM Rapid Test	Results	Positive	Negative	
	Positive	17	2	19
	Negative	3	48	51
Total Result		20	50	70

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

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

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

CONCLUSION

The relative sensitivity of 2019-nCoV IgG/IgM Rapid Test Cassette was more than 99,9% for IgG and 85,0% for IgM. The relative specificity is 98.0% for IgG and 96.0% for IgM compare with PCR result.