

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

Ref.: INCP-402/INCP-402B

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## 1. Purpose

Do clinical studies of 2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) with the SARS-COV-2 antibody positive specimen and negative specimen from patients which confirmed with clinical diagnosis.

## 2. Materials

- 2019-nCoV IgG/IgM Rapid Test Cassette Lot: NCP20030001CA-T
- 64 SARS-COV-2 antibody clinical positive specimen
- 294 SARS-COV-2 antibody clinical negative specimen

## 3. Operation Method

- 3.1. Place the Cassette on a clean and level surface. Hold the dropper vertically, transfer 10µ L serum, plasma specimen or 20µ L whole blood specimen to the sample well(S). Then add 2 drops of buffer (approximately 80µ 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/INCP-402B

No.	Age	Gender	Specimen	Result		
				ACRO Kit		PCR+Clinical Diagnosis
				IgG	IgM	
1	65	Male	Serum/Plasma /WB	+	-	+
2	55	Male	Serum/Plasma /WB	+	+	+
3	14	Male	Serum/Plasma /WB	+	-	+
4	71	Male	Serum/Plasma /WB	+	+	+
5	31	Female	Serum	+	+	+
6	57	Female	Serum/Plasma /WB	+	-	+
7	48	Male	Serum/Plasma /WB	+	+	+
8	66	Male	Serum/Plasma /WB	+	+	+
9	53	Male	Serum/Plasma /WB	+	+	+
10	36	Male	Serum/Plasma /WB	+	-	+
11	35	Male	Serum/Plasma /WB	+	-	+

12	25	Female	Serum/Plasma /WB	+	-	+
13	56	Female	Serum/Plasma /WB	+	+	+
14	67	Female	Serum/Plasma /WB	+	+	+
15	57	Male	Serum/Plasma /WB	+	+	+
16	30	Female	Serum/Plasma /WB	+	+	+
17	58	Female	Serum/Plasma /WB	+	+	+
18	40	Male	Serum	+	-	+
19	60	Female	Serum/Plasma /WB	+	+	+
20	48	Female	Serum	+	-	+
21	49	Female	Serum/Plasma /WB	+	-	+
22	31	Female	Serum/Plasma /WB	+	+	+
23	30	Male	Serum/Plasma /WB	+	+	+
24	54	Female	Serum/Plasma /WB	+	-	+
25	56	Male	Serum/Plasma /WB	+	-	+
26	67	Male	Serum/Plasma /WB	+	-	+
27	52	Female	Serum/Plasma /WB	+	+	+
28	63	Male	Serum/Plasma /WB	+	-	+
29	49	Male	Serum/Plasma /WB	+	+	+
30	31	Male	Serum/Plasma /WB	+	+	+
31	40	Female	Serum/Plasma /WB	+	+	+
32	58	Male	Serum/Plasma /WB	+	-	+
33	49	Male	Serum/Plasma /WB	+	-	+
34	53	Male	Serum/Plasma	+	+	+

			/WB			
35	45	Male	Serum/Plasma /WB	+	+	+
36	37	Male	Serum/Plasma /WB	+	-	+
37	40	Female	Serum/Plasma /WB	+	-	+
38	81	Female	Serum/Plasma /WB	+	+	+
39	39	Female	Serum	-	-	+
40	61	Male	Serum	+	+	+
41	82	Female	Serum/Plasma /WB	+	+	+
42	72	Male	Serum/Plasma /WB	+	+	+
43	66	Female	Serum/Plasma /WB	+	-	+
44	91	Male	Serum/Plasma /WB	+	+	+
45	84	Female	Serum/Plasma /WB	+	-	+
46	75	Male	Serum/Plasma /WB	-	-	+
47	91	Male	Serum/Plasma /WB	+	-	+
48	60	Male	Serum/Plasma /WB	+	-	+
49	71	Male	Serum/Plasma /WB	+	-	+
50	62	Male	Serum/Plasma /WB	+	+	+
51	52	Male	Serum/Plasma /WB	+	+	+
52	34	Female	Serum/Plasma /WB	+	+	+
53	30	Male	Serum/Plasma /WB	+	+	+
54	44	Female	Serum/Plasma /WB	-	+	+
55	63	Female	Serum/Plasma /WB	+	-	+
56	68	Female	Serum/Plasma /WB	+	-	+

57	46	Female	Serum/Plasma /WB	+	-	+
58	36	Female	Serum/Plasma /WB	+	+	+
59	54	Male	Serum/Plasma /WB	+	+	+
60	31	Male	Serum/Plasma /WB	+	-	+
61	63	Male	Serum/Plasma /WB	+	-	+
62	71	Male	Serum/Plasma /WB	+	-	+
63	55	Male	Serum/Plasma /WB	+	+	+
64	37	Male	Serum/Plasma /WB	+	+	+
65	26	Female	Serum	-	-	-
66	29	Female	Serum	-	-	-
67	33	Male	Serum	-	-	-
68	58	Male	Serum	-	-	-
69	30	Male	Serum	-	-	-
70	29	Female	Serum	-	-	-
71	32	Male	Serum	-	-	-
72	25	Male	Serum	-	-	-
73	24	Male	Serum	-	-	-
74	37	Female	Serum	-	-	-
75	61	Female	Serum	-	-	-
76	27	Female	Serum	-	-	-
77	39	Male	Serum	-	-	-
78	68	Male	Serum	-	-	-
79	34	Female	Serum	-	-	-
80	72	Male	Serum	-	-	-
81	63	Male	Serum	-	-	-
82	50	Female	Serum	-	-	-
83	75	Female	Serum	-	-	-
84	55	Male	Serum	-	-	-
85	69	Female	Serum	-	-	-
86	53	Female	Serum	-	-	-
87	57	Male	Serum	-	-	-
88	55	Male	Serum	-	-	-
89	67	Male	Serum	-	-	-
90	68	Female	Serum	-	-	-
91	73	Female	Serum	-	-	-

92	34	Female	Serum	-	-	-
93	35	Female	Serum	-	-	-
94	88	Female	Serum	-	-	-
95	9	Male	Serum	-	-	-
96	33	Male	Serum	-	-	-
97	79	Female	Serum	-	-	-
98	80	Male	Serum	-	-	-
99	32	Male	Serum	-	-	-
100	53	Male	Serum	-	-	-
101	72	Female	Serum	-	-	-
102	59	Male	Serum	-	-	-
103	65	Male	Serum	-	-	-
104	26	Female	Serum	-	-	-
105	66	Female	Serum/Plasma /WB	-	-	-
106	48	Male	Serum	-	-	-
107	62	Female	Serum	-	-	-
108	81	Male	Serum	-	-	-
109	38	Male	Serum	-	-	-
110	59	Female	Serum/Plasma /WB	-	-	-
111	71	Male	Serum/Plasma /WB	-	-	-
112	56	Male	Serum/Plasma /WB	-	-	-
113	76	Male	Serum/Plasma /WB	-	-	-
114	60	Female	Serum/Plasma /WB	-	-	-
115	39	Female	Serum/Plasma /WB	-	-	-
116	49	Female	Serum	-	-	-
117	32	Male	Serum	-	-	-
118	19	Female	Serum/Plasma /WB	-	-	-
119	58	Female	Serum	-	-	-
120	46	Male	Serum/Plasma /WB	-	-	-
121	82	Male	Serum/Plasma /WB	-	-	-
122	45	Male	Serum	-	-	-
123	67	Male	Serum	-	-	-
124	27	Female	Serum/Plasma	-	-	-

			/WB			
125	64	Male	Serum/Plasma /WB	-	-	-
126	76	Female	Serum/Plasma /WB	-	-	-
127	62	Male	Serum	-	-	-
128	55	Male	Serum	-	-	-
129	58	Female	Serum	-	-	-
130	33	Female	Serum/Plasma /WB	-	-	-
131	58	Female	Serum/Plasma /WB	-	-	-
132	50	Male	Serum/Plasma /WB	-	-	-
133	74	Male	Serum/Plasma /WB	-	-	-
134	54	Male	Serum	-	-	-
135	56	Male	Serum/Plasma /WB	-	-	-
136	52	Female	Serum	-	-	-
137	49	Female	Serum	-	+	-
138	33	Male	Serum	-	-	-
139	27	Male	Serum/Plasma /WB	-	-	-
140	63	Female	Serum	-	-	-
141	33	Male	Serum/Plasma /WB	-	-	-
142	56	Male	Serum	-	-	-
143	29	Female	Serum/Plasma /WB	-	-	-
144	58	Female	Serum	-	-	-
145	53	Female	Serum/Plasma /WB	-	-	-
146	57	Female	Serum/Plasma /WB	-	-	-
147	74	Female	Serum	-	-	-
148	52	Male	Serum/Plasma /WB	-	-	-
149	70	Male	Serum/Plasma /WB	-	-	-
150	64	Male	Serum/Plasma /WB	-	-	-
151	60	Male	Serum/Plasma	-	-	-



			/WB			
152	81	Male	Serum/Plasma /WB	-	-	-
153	33	Male	Serum/Plasma /WB	-	-	-
153	38	Female	Serum/Plasma /WB	-	+	-
155	61	Male	Serum/Plasma /WB	-	-	-
156	78	Male	Serum	-	-	-
157	74	Male	Serum/Plasma /WB	-	-	-
158	66	Female	Serum	-	-	-
159	58	Male	Serum/Plasma /WB	-	-	-
160	73	Female	Serum	-	+	-
161	60	Male	Serum/Plasma /WB	-	-	-
162	57	Female	Serum	-	-	-
163	35	Male	Serum/Plasma /WB	-	-	-
164	39	Male	Serum	-	-	-
165	53	Male	Serum	-	-	-
166	56	Male	Serum	-	-	-
167	59	Male	Serum/Plasma /WB	-	-	-
168	47	Female	Serum/Plasma /WB	-	-	-
169	60	Male	Serum	-	-	-
170	42	Male	Serum/Plasma /WB	-	-	-
171	53	Male	Serum/Plasma /WB	-	-	-
172	57	Male	Serum	-	-	-
173	45	Male	Serum/Plasma /WB	-	-	-
174	59	Male	Serum/Plasma /WB	-	-	-
175	47	Male	Serum	-	-	-
176	66	Female	Serum/Plasma /WB	+	+	-
177	69	Female	Serum	-	-	-
178	77	Male	Serum	-	-	-

179	52	Female	Serum	-	-	-
180	55	Female	Serum	-	-	-
181	89	Male	Serum	-	-	-
182	56	Male	Serum	-	-	-
183	72	Female	Serum	-	-	-
184	52	Male	Serum	+	+	-
185	35	Male	Serum	-	-	-
186	68	Male	Serum	-	-	-
187	52	Male	Serum	-	-	-
188	55	Female	Serum	-	-	-
189	44	Male	Serum	-	-	-
190	60	Female	Serum	-	-	-
191	30	Male	Serum	-	-	-
192	49	Male	Serum	-	-	-
193	58	Female	Serum	-	-	-
194	62	Male	Serum	-	-	-
195	36	Male	Serum	+	-	-
196	68	Female	Serum	-	-	-
197	61	Male	Serum	-	-	-
198	67	Male	Serum	-	-	-
199	60	Female	Serum	-	-	-
200	32	Female	Serum	-	-	-
201	42	Female	Serum	-	-	-
202	44	Male	Serum	-	-	-
203	54	Male	Serum	-	-	-
204	65	Female	Serum	-	-	-
205	50	Female	Serum	-	-	-
206	53	Male	Serum	-	-	-
207	30	Female	Serum	-	-	-
208	85	Male	Serum	-	-	-
209	23	Female	Serum	-	-	-
210	69	Male	Serum	-	-	-
211	62	Female	Serum/Plasma /WB	-	-	-
212	63	Female	Serum	-	-	-
213	60	Female	Serum	-	-	-
214	35	Male	Serum	-	-	-
215	57	Male	Serum	-	-	-
216	74	Male	Serum	-	-	-
217	63	Male	Serum	-	-	-
218	73	Male	Serum	-	-	-
219	69	Female	Serum	-	-	-

220	56	Male	Serum	-	-	-
221	67	Male	Serum	-	-	-
222	66	Female	Serum	-	-	-
223	68	Female	Serum	-	-	-
224	53	Male	Serum	-	-	-
225	50	Female	Serum	-	-	-
226	68	Male	Serum	-	-	-
227	66	Female	Serum	-	-	-
228	61	Male	Serum	-	-	-
229	81	Male	Serum	-	-	-
230	73	Male	Serum	-	-	-
231	71	Male	Serum	-	-	-
232	30	Female	Serum	-	-	-
233	66	Female	Serum	-	-	-
234	51	Male	Serum	-	-	-
235	58	Male	Serum	-	-	-
236	70	Female	Serum	-	-	-
237	65	Female	Serum	-	-	-
238	52	Female	Serum	-	-	-
239	62	Male	Serum	-	-	-
240	64	Male	Serum	-	-	-
241	43	Female	Serum	-	-	-
242	60	Female	Serum	-	-	-
243	43	Male	Serum	-	-	-
244	81	Male	Serum	-	-	-
245	34	Female	Serum	+	-	-
246	74	Male	Serum	-	-	-
247	70	Male	Serum	-	-	-
248	60	Male	Serum	-	-	-
249	31	Male	Serum	-	-	-
250	62	Female	Serum	-	-	-
251	48	Male	Serum	-	-	-
252	61	Male	Serum	-	+	-
253	37	Female	Serum	-	-	-
254	24	Female	Serum	-	-	-
255	80	Male	Serum	-	-	-
256	32	Male	Serum	-	-	-
257	42	Male	Serum	-	-	-
258	64	Female	Serum	-	-	-
259	31	Female	Serum	-	-	-
260	62	Male	Serum	-	-	-
261	55	Male	Serum	-	-	-

262	68	Male	Serum	-	-	-
263	74	Female	Serum	-	-	-
264	55	Female	Serum	-	-	-
265	27	Male	Serum	-	-	-
266	72	Female	Serum	-	-	-
267	60	Female	Serum	-	-	-
268	50	Female	Serum	-	-	-
269	58	Female	Serum	-	-	-
270	51	Male	Serum	-	-	-
271	69	Male	Serum	-	-	-
272	60	Male	Serum	-	-	-
273	74	Male	Serum	-	-	-
274	68	Male	Serum	-	-	-
275	60	Male	Serum	-	-	-
276	84	Male	Serum	-	-	-
277	31	Male	Serum	-	-	-
278	64	Male	Serum	-	-	-
279	71	Male	Serum	-	-	-
280	75	Female	Serum	-	-	-
281	48	Male	Serum	-	-	-
282	48	Male	Serum	-	-	-
283	51	Male	Serum	-	-	-
284	57	Male	Serum	-	-	-
285	70	Male	Serum	-	-	-
286	30	Male	Serum	-	-	-
287	54	Female	Serum	-	-	-
288	57	Male	Serum	-	-	-
289	77	Male	Serum	-	-	-
290	50	Male	Serum	-	-	-
291	82	Female	Serum	-	-	-
292	66	Male	Serum	-	-	-
293	76	Female	Serum	-	-	-
294	56	Male	Serum	-	-	-
295	73	Female	Serum	-	-	-
296	66	Female	Serum	-	-	-
297	23	Female	Serum	-	-	-
298	65	Male	Serum	-	-	-
299	25	Female	Serum	-	-	-
300	74	Female	Serum	-	+	-
301	37	Female	Serum	-	-	-
302	56	Male	Serum	-	-	-
303	55	Male	Serum	-	-	-

304	57	Female	Serum	-	-	-
305	69	Male	Serum	-	-	-
306	66	Male	Serum	-	+	-
307	67	Male	Serum	-	-	-
308	72	Male	Serum	-	-	-
309	56	Male	Serum	-	-	-
310	70	Male	Serum	-	-	-
311	61	Male	Serum	-	-	-
312	29	Male	Serum	-	-	-
313	70	Male	Serum	-	-	-
314	60	Female	Serum	-	-	-
315	53	Male	Serum	-	-	-
316	67	Male	Serum	-	-	-
317	55	Male	Serum	-	-	-
318	62	Male	Serum	-	-	-
319	71	Male	Serum	-	-	-
320	44	Male	Serum	-	-	-
321	67	Male	Serum	-	-	-
322	58	Male	Serum	-	-	-
323	32	Male	Serum	-	-	-
324		Male	Serum	-	-	-
325	71	Female	Serum	-	-	-
326	92	Female	Serum	-	-	-
327	62	Female	Serum	-	-	-
328	32	Male	Serum	-	-	-
329	55	Male	Serum	-	-	-
330	78	Male	Serum	-	-	-
331	53	Male	Serum	-	-	-
332	73	Male	Serum	-	-	-
333	40	Female	Serum	-	-	-
334	72	Male	Serum	-	-	-
335	71	Female	Serum	-	-	-
336	46	Female	Serum	-	-	-
337	69	Female	Serum	-	-	-
338	64	Male	Serum	-	-	-
339	67	Male	Serum	-	+	-
340	31	Female	Serum	-	-	-
341	30	Male	Serum	-	-	-
342	30	Female	Serum	-	-	-
343	102	Male	Serum	-	-	-
344	54	Male	Serum	-	-	-
345	71	Female	Serum	-	-	-

346	41	Female	Serum	-	-	-
347	88	Male	Serum	-	-	-
348	56	Male	Serum	-	-	-
349	75	Male	Serum	-	-	-
350	68	Male	Serum	-	-	-
351	45	Male	Serum	-	-	-
352	85	Female	Serum	-	-	-
353	60	Female	Serum	-	-	-
354	65	Female	Serum	-	-	-
355	77	Male	Serum	-	-	-
356	2	Male	Serum	-	-	-
357	6	Male	Serum	-	-	-
358	15	Female	Serum	-	-	-

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

## 5. Result Analysis

**Table: Clinical study result of INCP-402/INCP-402B**

Method		Clinical diagnosis	
		Positive	Negative
2019-nCoV IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	Positive	IgM	1
		IgG+IgM	33
		IgG	28
	IgG+IgM Negative		2
Totally Results		64	294

Relative Sensitivity:  $(1+33+28)/(1+33+28+2) \times 100\% = 96.9\%$  (95%CI\*: 88.7%-99.8%)

Relative Specificity:  $283/(283+11) \times 100\% = 96.3\%$  (95%CI\*: 93.4%-98.0%)

Accuracy:  $(1+33+28+283)/(1+33+28+2+283+11) = 96.4\%$  (95%CI\*: 93.8%-97.9%)

\*Confidence Interval

## 6. Conclusion

The relative sensitivity of 2019-nCoV IgG/IgM Rapid Test Cassette (INCP-402) was 96.9%, the relative specificity was 96.3% compare with clinical diagnosis result.