



# Nantong Egens Biotechnology Co., Ltd

Building 15 & building 12(west) No.1692 xinghu avenue,  
Nantong Economy & Technology Dev. Zone,  
Jiangsu Province,226010,P.R.China

## Clinical performance

### Name and Lot No. of the kit

Name: COVID-19 IgM / IgG rapid test cassette

Lot No.: 20200520

### Hospitals

Wuhan Hangyun Hospital

The First Affiliated Hospital of Guangzhou medical university

The Third People's Hospital of Hubei Province

	Signature	Date
Experiment Date	-	2020.05.25~2020.06.10
Prepared by	Juan zhang	2020.6.12
Reviewed by	Yipin sun	2020.6.12
Report Date	-	2020.6.12

## 1. Objective

Entrusted by Nantong Egens Biotechnology Co., Ltd. (hereinafter referred to as “Egens”), Clinical Cooperative hospital implemented clinical test on COVID-19 IgM/IgG Rapid Test cassette researched and produced by Nantong Egens Biotechnology Co., Ltd. according to *Guiding Principle for Clinical Research Technology of In Vitro Diagnostics Reagent* (CFDA MD(2014) 16).

The kit to be evaluated uses immunochromatography and the principle of Capture to qualitatively detect COVID-19 IgM/IgG Antibodies in human serum (and plasma ) for clinical auxiliary diagnosis. The test kit is produced by Nantong Egens Biotechnology Co., Ltd. The purpose of COVID-19 IgM/IgG Rapid Test cassette clinical trial is to verify the accuracy of this product in clinical test by verifying a certain number of confirmed samples of novel coronavirus, so as to judge whether the safety and effectiveness requirements of the marketed products have been met.



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## 2. Acceptance Criteria

The COVID-19 IgM/IgG Rapid Test cassette is developed and produced by Nantong Egens Biotechnology Co., Ltd., and the clinical evaluation was conducted by Clinical Cooperative hospital.

Before implementation of the test, Nantong Egens Biotechnology Co., Ltd. and representatives of Clinical Cooperative hospital should discuss together. According to relevant regulations of “*Clinical Research Technical Guidelines and Rules of IVD Reagents*” etc., both parties should sign clinical test protocol and design clinical test scheme to clarify test purpose, content and responsibilities of both parties.

Before the start of clinical research, participants in the research must be familiar with and master the operation of the product, technical performance, etc., so as to do their utmost to take control of the experimental error as well as unify record method and judgment standard; Researcher should fill in every item in detail and faithfully according to record chart to make sure content of record chart is complete, true and reliable; all observed results should be verified to ensure every conclusion in clinical trial is derived from the original records; there should be corresponding data management measures in clinical trial and data processing phases.

During the clinical research any other situation outside the scheme shall be settled by the parties through negotiation.

## 3. Test Protocol

A comparison study between Colloidal gold device and BGI Genomics Co. Ltd Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019- nCoV Nucleic acid test method is conducted in Wuhan Hangyun Hospital, The First Affiliated Hospital of Guangzhou medical university, The Third People's Hospital of Hubei Province.

### 3.1. Selection of test subjects

- 1) Age and gender are not limited
- 2) Can provide enough test specimens as required
- 3) Confirmed samples of novel coronavirus
- 4) Consider cases of suspected influenza, respiratory syncytial virus, enterovirus, adenovirus and other viral infections

### 3.2. Information of the test reagent

The test reagent is COVID-19 IgM/IgG Rapid Test cassette produced by Nantong Egens Biotechnology Co., Ltd.

Cassette type: specification is 25t/box; batch number is 20200520, valid for 2 years , the preservation condition is 2-30 ° C, dry and light-avoiding.

### 3.3. Sample collection and serial number

Serum samples were collected intravenously in the conventional way. The samples to be tested within five days can be stored at 2-8°C, and the samples can be stored at -20°C for at least three months. Avoid repeated freezing-thawing of samples as far as possible.

Sample No.

In Wuhan Hangyun Hospital, 135 samples (No.01-135) were selected and the results were detected with nucleic acid.

In the First Affiliated Hospital of Guangzhou Medical University, 135 samples (No.01-135) were selected and the results were detected with nucleic acid.

In the Third People's Hospital of Hubei Province, 130 samples (No.01-130) were selected and the results were detected with nucleic acid.

## 4. Data

### 4.1 Arrangement and analysis of the results in the Wuhan Hangyun Hospital:

No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
01	2004100402	45	female	2020/6/10	serum	-	-	2020/5/27	-
02	2004081252	59	female	2020/6/3	serum	-	-	2020/5/27	-
03	2004081258	70	female	2020/6/8	serum	-	-	2020/5/27	-
04	2004110236	25	female	2020/6/10	serum	+	+	2020/5/27	+
05	2004110239	69	female	2020/6/3	serum	-	-	2020/5/27	-
06	2004110237	59	female	2020/6/3	serum	-	-	2020/5/27	-
07	2004110238	32	male	2020/6/10	serum	+	+	2020/5/27	+
08	2004081262	31	female	2020/6/3	serum	+	+	2020/5/27	+
09	2004090146	56	male	2020/6/3	serum	-	-	2020/5/27	-
10	2004081278	69	male	2020/6/10	serum	-	-	2020/5/27	-
11	2004081259	87	male	2020/6/3	serum	-	-	2020/5/27	-
12	2004081241	25	female	2020/6/10	serum	+	+	2020/5/27	+
13	2004081254	31	female	2020/6/10	serum	+	+	2020/5/27	+
14	2004081260	45	male	2020/6/10	serum	-	-	2020/5/27	-
15	2004081270	47	male	2020/6/5	serum	+	-	2020/5/27	-
16	2004081274	62	male	2020/6/10	serum	-	-	2020/5/27	-
17	2004081233	66	male	2020/6/10	serum	-	-	2020/5/27	-
18	2004081255	83	female	2020/6/5	serum	-	-	2020/5/27	-



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
19	2004100399	73	female	2020/6/10	serum	-	-	2020/5/27	-
20	2004100408	69	female	2020/6/5	serum	-	-	2020/5/27	-
21	2004070401	69	male	2020/6/5	serum	-	-	2020/5/27	-
22	2004070485	65	female	2020/6/3	serum	-	-	2020/5/27	-
23	2004070352	43	female	2020/6/3	serum	-	-	2020/5/27	-
24	2004070647	96	male	2020/6/10	serum	-	-	2020/5/27	-
25	2004070611	61	male	2020/6/5	serum	-	-	2020/5/27	-
26	2004070653	26	male	2020/6/5	serum	+	+	2020/5/27	+
27	2004070398	43	female	2020/6/10	serum	-	-	2020/5/27	-
28	2004070582	53	female	2020/6/10	serum	-	-	2020/5/27	-
29	2004070430	49	male	2020/6/5	serum	-	-	2020/5/27	-
30	2004070562	36	female	2020/6/5	serum	-	-	2020/5/27	-
31	2004070554	24	female	2020/6/3	serum	+	+	2020/5/27	+
32	2004070416	25	female	2020/6/10	serum	+	+	2020/5/27	+
33	2004070368	56	male	2020/6/10	serum	-	-	2020/5/27	-
34	2004070396	47	male	2020/6/6	serum	-	-	2020/5/27	-
35	2004070342	53	female	2020/6/10	serum	-	-	2020/5/27	-
36	2004070549	44	female	2020/6/6	serum	-	-	2020/5/27	-
37	2004070585	64	male	2020/6/10	serum	-	-	2020/5/27	-
38	2004070492	68	female	2020/6/5	serum	-	-	2020/5/27	-
39	2004070418	33	male	2020/6/5	serum	+	+	2020/5/27	+
40	2004070629	89	female	2020/6/1	serum	-	-	2020/6/1	-
41	2004090136	49	male	2020/6/1	serum	-	-	2020/6/1	-
42	2004100017	47	male	2020/6/1	serum	-	-	2020/6/1	-
43	2004100019	45	male	2020/6/1	serum	-	-	2020/6/1	-
44	2004081250	32	male	2020/6/1	serum	+	+	2020/6/1	+
45	2004081247	46	female	2020/6/1	serum	-	-	2020/6/1	-
46	2004081251	34	female	2020/6/1	serum	+	+	2020/6/1	+
47	2004081257	56	male	2020/6/1	serum	-	-	2020/6/1	-
48	2004081265	48	female	2020/6/1	serum	-	-	2020/6/1	-
49	2004081239	52	male	2020/6/1	serum	-	-	2020/6/1	-
50	2004081244	28	female	2020/6/1	serum	+	+	2020/6/1	+
51	2004081237	53	male	2020/6/1	serum	-	-	2020/6/1	-
52	2004100398	50	female	2020/6/1	serum	-	-	2020/6/1	-



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
						S-serum P-plasma	IgG		
53	2004100405	53	male	2020/6/1	serum	-	-	2020/6/1	-
54	2004081256	29	female	2020/6/1	serum	+	+	2020/6/1	+
55	2004081263	50	female	2020/6/1	serum	-	-	2020/6/1	-
56	2004110240	46	female	2020/6/1	serum	-	-	2020/6/1	-
57	2004110243	49	male	2020/6/1	serum	-	-	2020/6/1	-
58	2004110241	39	male	2020/6/1	serum	-	-	2020/6/1	-
59	2004110242	62	female	2020/6/1	serum	-	-	2020/6/1	-
60	2004081266	59	male	2020/6/1	serum	-	-	2020/6/1	-
61	5331131	49	male	2020/6/5	serum	-	-	2020/5/27	-
62	5306523	30	male	2020/6/5	serum	+	+	2020/5/27	+
63	5312683	37	male	2020/6/5	serum	-	-	2020/5/27	-
64	5312705	51	male	2020/6/5	serum	-	-	2020/5/27	-
65	5331862	37	female	2020/6/5	serum	-	-	2020/5/27	-
66	534304	41	female	2020/6/5	serum	-	-	2020/5/27	-
67	5346059	48	male	2020/6/5	serum	-	-	2020/5/27	-
68	5258928	44	female	2020/6/5	serum	-	-	2020/5/27	-
69	5258872	50	male	2020/6/5	serum	-	-	2020/5/27	-
70	5342415	44	female	2020/6/5	serum	-	-	2020/5/27	-
71	5255237	45	male	2020/6/5	serum	-	-	2020/5/27	-
72	5291586	45	female	2020/6/5	serum	-	-	2020/5/27	-
73	5346998	35	female	2020/6/5	serum	-	-	2020/5/27	-
74	5347367	40	male	2020/6/5	serum	-	-	2020/5/27	-
75	5248184	24	female	2020/6/5	serum	-	+	2020/5/27	+
76	5305910	42	female	2020/6/5	serum	-	-	2020/5/27	-
77	5343195	53	female	2020/6/5	serum	-	-	2020/5/27	-
78	5339610	44	male	2020/6/5	serum	-	-	2020/5/27	-
79	5334403	64	female	2020/6/5	serum	-	-	2020/5/27	-
80	5347745	68	male	2020/6/5	serum	-	-	2020/5/27	-
81	5334987	50	female	2020/6/5	serum	-	-	2020/5/27	-
82	5363381	35	female	2020/6/5	serum	-	-	2020/5/27	-
83	5348896	29	male	2020/6/5	serum	+	+	2020/5/27	+
84	30136744	50	female	2020/6/5	serum	-	-	2020/5/27	-
85	5329096	39	male	2020/6/5	serum	-	-	2020/5/27	-
86	5249751	29	male	2020/6/5	serum	+	+	2020/5/27	+



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
87	5296399	50	male	2020/6/5	serum	-	-	2020/5/27	-
88	5284291	39	male	2020/6/5	serum	-	-	2020/5/27	-
89	5372066	46	female	2020/6/5	serum	-	-	2020/5/27	-
90	5372212	52	female	2020/6/5	serum	-	-	2020/5/27	-
91	54966	47	male	2020/6/5	serum	-	-	2020/5/27	-
92	5394173	33	female	2020/6/5	serum	+	+	2020/5/27	+
93	5349680	89	male	2020/6/5	serum	-	-	2020/5/27	-
94	5250837	49	female	2020/6/5	serum	-	-	2020/5/27	-
95	5297189	47	male	2020/6/5	serum	-	-	2020/5/27	-
96	ZZ00001009	45	male	2020/6/5	serum	-	-	2020/5/27	-
97	5350325	43	male	2020/6/5	serum	-	-	2020/5/27	-
98	5246398	49	male	2020/6/5	serum	-	-	2020/5/27	-
99	5374276	52	male	2020/6/5	serum	-	-	2020/5/27	-
100	5365577	27	male	2020/6/5	serum	+	+	2020/5/27	+
101	26596	74	male	2020/6/5	serum	-	-	2020/5/27	-
102	26772	53	female	2020/6/5	serum	-	-	2020/5/27	-
103	26237	28	female	2020/6/5	serum	+	+	2020/5/27	+
104	27871	43	female	2020/6/5	serum	-	-	2020/5/27	-
105	27601	37	female	2020/6/5	serum	-	-	2020/5/27	-
106	26934	53	male	2020/6/5	serum	-	-	2020/5/27	-
107	29642	40	male	2020/6/5	serum	-	-	2020/5/27	-
108	25107	30	female	2020/6/5	serum	+	+	2020/5/27	+
109	29821	65	female	2020/6/5	serum	-	-	2020/5/27	-
110	27365	63	female	2020/6/5	serum	-	-	2020/5/27	-
111	25149	55	female	2020/6/5	serum	-	-	2020/5/27	-
112	28379	53	female	2020/6/5	serum	-	-	2020/5/27	-
113	28897	43	female	2020/6/5	serum	-	-	2020/5/27	-
114	25315	75	male	2020/6/5	serum	-	-	2020/5/27	-
115	27819	35	female	2020/6/5	serum	+	+	2020/5/27	+
116	29621	27	female	2020/6/5	serum	+	+	2020/5/27	+
117	29496	55	male	2020/6/5	serum	-	-	2020/5/27	-
118	27876	22	male	2020/6/5	serum	+	+	2020/5/27	+
119	25379	68	male	2020/6/5	serum	-	-	2020/5/27	-
120	26714	69	male	2020/6/5	serum	-	-	2020/5/27	-

No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
121	29501	23	male	2020/6/5	serum	+	+	2020/5/27	+
122	27412	57	male	2020/6/5	serum	-	-	2020/5/27	-
123	25527	59	female	2020/6/5	serum	-	-	2020/5/27	-
124	25940	67	female	2020/6/5	serum	-	-	2020/5/27	-
125	26903	66	male	2020/6/5	serum	-	-	2020/5/27	-
126	29947	35	female	2020/6/5	serum	-	-	2020/5/27	-
127	27150	25	male	2020/6/5	serum	+	+	2020/5/27	+
128	25265	43	female	2020/6/5	serum	-	-	2020/5/27	-
129	26808	43	female	2020/6/5	serum	-	-	2020/5/27	-
130	28712	66	female	2020/6/5	serum	-	-	2020/5/27	-
131	29826	68	male	2020/6/5	serum	-	-	2020/5/27	-
132	26213	74	male	2020/6/5	serum	-	-	2020/5/27	-
133	27640	47	female	2020/6/5	serum	-	-	2020/5/27	-
134	25888	59	male	2020/6/5	serum	-	-	2020/5/27	-
135	27980	64	male	2020/6/5	serum	-	-	2020/5/27	-

4.2 Arrangement and analysis of the results in the First Affiliated Hospital of Guangzhou Medical University:

No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
01	2004070373	45	female	2020/6/6	serum	-	-	2020/5/28	-
02	2004070441	58	male	2020/6/6	serum	-	-	2020/5/28	-
03	2004070542	46	male	2020/6/6	serum	+	-	2020/5/28	-
04	2004070496	48	male	2020/6/6	serum	-	-	2020/5/28	-
05	2004070472	22	female	2020/6/6	serum	+	+	2020/5/28	+
06	2004070387	26	male	2020/6/6	serum	+	+	2020/5/28	+
07	2004070529	28	male	2020/6/9	serum	+	+	2020/5/28	+
08	2004070659	47	male	2020/6/9	serum	-	-	2020/5/28	-
09	2004070354	43	female	2020/6/9	serum	-	-	2020/5/28	-
10	2004070428	31	female	2020/6/6	serum	+	+	2020/5/28	+
11	2004070553	42	male	2020/6/6	serum	-	-	2020/5/28	-
12	2004070456	51	female	2020/6/6	serum	-	-	2020/5/28	-





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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
13	2004070367	35	female	2020/6/9	serum	—	—	2020/5/28	—
14	2004070644	43	male	2020/6/1	serum	—	—	2020/5/28	—
15	2004070432	49	female	2020/6/9	serum	—	—	2020/5/28	—
16	2004070615	52	female	2020/6/1	serum	—	—	2020/5/28	—
17	2004070483	27	male	2020/6/9	serum	—	—	2020/5/28	+
18	2004070353	37	female	2020/6/1	serum	—	—	2020/5/28	—
19	2004070517	45	female	2020/6/6	serum	—	—	2020/5/28	—
20	2004070400	47	female	2020/6/6	serum	—	—	2020/5/28	—
21	2004070460	32	male	2020/6/6	serum	+	+	2020/5/28	+
22	2004070506	44	male	2020/6/6	serum	—	—	2020/5/28	—
23	2004070390	26	male	2020/6/6	serum	—	—	2020/5/28	+
24	2004070450	44	female	2020/6/6	serum	—	—	2020/5/28	—
25	2004070451	45	male	2020/6/6	serum	—	—	2020/5/28	—
26	2004070323	45	male	2020/6/6	serum	—	—	2020/5/28	—
27	2004070547	35	female	2020/6/6	serum	—	—	2020/5/28	—
28	2004070579	40	female	2020/6/6	serum	—	—	2020/5/28	—
29	2004070564	24	male	2020/6/6	serum	+	+	2020/5/28	+
30	A24748674	42	female	2020/6/9	serum	—	—	2020/5/28	—
31	2004100398	40	male	2020/6/9	serum	—	—	2020/5/28	—
32	2004081238	44	female	2020/6/9	serum	—	—	2020/5/28	—
33	A69897955	57	male	2020/6/9	serum	—	—	2020/5/28	—
34	202004080624	66	female	2020/6/9	serum	—	—	2020/5/28	—
35	202004080280	36	male	2020/6/9	serum	—	—	2020/5/28	—
36	2004100247	56	male	2020/6/9	serum	—	—	2020/5/28	—
37	2020002665	47	male	2020/6/9	serum	—	—	2020/5/28	—
38	2004080605	53	male	2020/6/9	serum	—	—	2020/5/28	—
39	2004081238	44	male	2020/6/9	serum	—	—	2020/5/28	—
40	2004081081	64	male	2020/6/9	serum	—	—	2020/5/28	—
41	2004080563	68	male	2020/6/6	serum	—	—	2020/5/28	—
42	2004081556	50	male	2020/6/6	serum	—	—	2020/5/28	—
43	2004080577	35	male	2020/6/6	serum	—	—	2020/5/28	—
44	2004081069	29	male	2020/6/6	serum	+	+	2020/5/28	+
45	2004081293	50	male	2020/6/9	serum	—	—	2020/5/28	—
46	2004100557	39	female	2020/6/6	serum	—	—	2020/5/28	—
47	2004100552	46	male	2020/6/9	serum	—	—	2020/5/28	—





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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
48	2004100555	87	female	2020/6/9	serum	—	—	2020/5/28	—
49	2004100560	25	female	2020/6/9	serum	+	+	2020/5/28	+
50	2004070828	31	male	2020/6/6	serum	+	+	2020/5/28	+
51	2004090137	45	male	2020/6/1	serum	—	—	2020/5/28	—
52	2004100018	47	male	2020/6/1	serum	—	—	2020/5/28	—
53	2004100020	29	male	2020/6/6	serum	+	+	2020/5/28	+
54	2004081249	49	female	2020/6/3	serum	—	—	2020/5/28	—
55	2004081248	57	female	2020/6/6	serum	—	—	2020/5/28	—
56	2004081253	87	female	2020/6/6	serum	—	—	2020/5/28	—
57	2004081261	70	male	2020/6/3	serum	—	—	2020/5/28	—
58	2004081265	92	male	2020/6/6	serum	—	—	2020/5/28	—
59	2004081240	67	female	2020/6/3	serum	—	—	2020/5/28	—
60	2004081245	45	male	2020/6/3	serum	—	—	2020/5/28	—
61	5382959	63	male	2020/6/6	serum	—	—	2020/5/28	—
62	5374759	43	male	2020/6/6	serum	—	—	2020/5/28	—
63	5410093	63	female	2020/6/6	serum	—	—	2020/5/28	—
64	5395856	47	female	2020/6/6	serum	—	—	2020/5/28	—
65	5316450	63	male	2020/6/6	serum	—	—	2020/5/28	—
66	5316558	51	female	2020/6/6	serum	—	—	2020/5/28	—
67	5316887	54	female	2020/6/6	serum	—	—	2020/5/28	—
68	5317093	51	male	2020/6/6	serum	—	—	2020/5/28	—
69	56062	27	male	2020/6/6	serum	+	+	2020/5/28	+
70	5383978	50	male	2020/6/6	serum	—	—	2020/5/28	—
71	30146735	30	male	2020/6/6	serum	+	+	2020/5/28	+
72	5375986	22	male	2020/6/6	serum	+	+	2020/5/28	+
73	5396851	42	male	2020/6/6	serum	—	—	2020/5/28	—
74	5367203	45	male	2020/6/6	serum	—	—	2020/5/28	—
75	5400751	58	female	2020/6/6	serum	—	—	2020/5/28	—
76	5317292	46	male	2020/6/6	serum	+	—	2020/5/28	—
77	5357218	55	female	2020/6/6	serum	—	—	2020/5/28	—
78	5367689	49	female	2020/6/6	serum	—	—	2020/5/28	—
79	5357289	24	male	2020/6/6	serum	+	—	2020/5/28	+
80	5406597	50	male	2020/6/6	serum	—	—	2020/5/28	—
81	5411620	41	female	2020/6/6	serum	—	—	2020/5/28	—
82	5439060	27	female	2020/6/6	serum	+	+	2020/5/28	+



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
83	5317726	46	female	2020/6/6	serum	—	—	2020/5/28	—
84	5401651	28	male	2020/6/6	serum	+	+	2020/5/28	+
85	100129766	53	female	2020/6/6	serum	—	—	2020/5/28	—
86	5414699	50	male	2020/6/6	serum	—	—	2020/5/28	—
87	541504	53	male	2020/6/6	serum	—	—	2020/5/28	—
88	5368961	29	male	2020/6/6	serum	+	+	2020/5/28	+
89	5397580	50	female	2020/6/6	serum	—	—	2020/5/28	—
90	5397613	46	female	2020/6/6	serum	—	—	2020/5/28	—
91	5420701	26	male	2020/6/6	serum	+	+	2020/5/28	+
92	5377334	43	male	2020/6/6	serum	—	—	2020/5/28	—
93	5369197	53	female	2020/6/6	serum	—	—	2020/5/28	—
94	5290859	49	female	2020/6/6	serum	—	—	2020/5/28	—
95	5294801	36	male	2020/6/6	serum	—	—	2020/5/28	—
96	5332307	24	male	2020/6/6	serum	+	+	2020/5/28	+
97	5193991	25	male	2020/6/6	serum	+	+	2020/5/28	+
98	5115170	87	female	2020/6/6	serum	—	—	2020/5/28	—
99	5333118	25	female	2020/6/6	serum	+	+	2020/5/28	+
100	5333386	31	male	2020/6/6	serum	+	+	2020/5/28	+
101	28746	51	female	2020/6/6	serum	—	—	2020/5/28	—
102	29450	50	male	2020/6/6	serum	—	—	2020/5/28	—
103	25861	67	male	2020/6/6	serum	—	—	2020/5/28	—
104	25879	44	female	2020/6/6	serum	—	—	2020/5/28	—
105	28905	45	male	2020/6/6	serum	—	—	2020/5/28	—
106	27217	67	male	2020/6/6	serum	—	—	2020/5/28	—
107	27810	54	male	2020/6/6	serum	—	—	2020/5/28	—
108	25412	41	male	2020/6/6	serum	—	—	2020/5/28	—
109	25155	67	male	2020/6/6	serum	—	—	2020/5/28	—
110	28109	44	male	2020/6/6	serum	—	—	2020/5/28	—
111	29296	33	female	2020/6/6	serum	+	+	2020/5/28	+
112	26280	71	female	2020/6/6	serum	—	—	2020/5/28	—
113	28668	41	male	2020/6/6	serum	—	—	2020/5/28	—
114	29761	57	female	2020/6/6	serum	—	—	2020/5/28	—
115	26865	55	male	2020/6/6	serum	—	—	2020/5/28	—
116	26730	48	male	2020/6/6	serum	—	—	2020/5/28	—
117	29159	44	male	2020/6/6	serum	—	—	2020/5/28	—



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
118	28969	47	male	2020/6/6	serum	—	—	2020/5/28	—
119	29886	51	female	2020/6/6	serum	—	—	2020/5/28	—
120	28352	29	female	2020/6/6	serum	+	+	2020/5/28	+
121	25999	71	male	2020/6/6	serum	—	—	2020/5/28	—
122	26853	70	female	2020/6/6	serum	—	—	2020/5/28	—
123	28315	75	male	2020/6/6	serum	—	—	2020/5/28	—
124	29539	44	male	2020/6/6	serum	—	—	2020/5/28	—
125	25831	30	female	2020/6/6	serum	+	+	2020/5/28	+
126	28994	61	male	2020/6/6	serum	—	—	2020/5/28	—
127	25696	55	female	2020/6/6	serum	—	—	2020/5/28	—
128	27796	24	male	2020/6/6	serum	+	+	2020/5/28	+
129	27598	33	male	2020/6/6	serum	+	+	2020/5/28	+
130	26649	30	female	2020/6/6	serum	+	+	2020/5/28	+
131	25345	36	male	2020/6/6	serum	—	—	2020/5/28	—
132	28699	29	female	2020/6/6	serum	+	+	2020/5/28	+
133	29981	32	female	2020/6/6	serum	+	+	2020/5/28	+
134	27252	22	female	2020/6/6	serum	+	+	2020/5/28	+
135	29437	31	male	2020/6/6	serum	+	+	2020/5/28	+

#### 4.3 Arrangement and analysis of the results in the Third People's Hospital of Hubei Province:

No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
01	202004100130	24	female	2020/6/5	serum	+	—	2020/5/30	+
02	202004100193	43	female	2020/6/5	serum	—	—	2020/5/30	—
03	2004090081	51	male	2020/6/5	serum	—	—	2020/5/30	—
04	2004081168	30	male	2020/6/5	serum	+	+	2020/5/30	+
05	2004081405	57	male	2020/6/5	serum	—	—	2020/5/30	—
06	2004090269	34	male	2020/6/5	serum	+	+	2020/5/30	+
07	A8009992X	62	male	2020/6/5	serum	—	—	2020/6/1	—
08	202004110024	67	male	2020/6/5	serum	—	—	2020/6/1	—
09	900789271	66	female	2020/6/5	serum	—	—	2020/6/1	—
10	202004110099	37	female	2020/6/5	serum	—	—	2020/6/1	—
11	202004110116	37	male	2020/6/5	serum	—	—	2020/6/1	—



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
12	202004100065	47	female	2020/6/5	serum	-	-	2020/6/1	-
13	2004100129	56	male	2020/6/5	serum	-	-	2020/6/1	-
14	2004100374	57	male	2020/6/5	serum	-	-	2020/6/1	-
15	2004100246	59	male	2020/6/5	serum	-	-	2020/6/1	-
16	2004100077	22	female	2020/6/5	serum	+	+	2020/6/1	+
17	2020002663	29	male	2020/6/5	serum	+	+	2020/6/1	+
18	2004080604	27	male	2020/6/5	serum	+	+	2020/6/1	+
19	2004050010	27	male	2020/6/5	serum	+	+	2020/6/1	+
20	202004120035	71	female	2020/6/5	serum	-	-	2020/5/30	-
21	202004120034	43	male	2020/6/5	serum	-	-	2020/5/30	-
22	202004120007	53	male	2020/6/5	serum	-	-	2020/5/30	-
23	202004120051	29	female	2020/6/5	serum	+	+	2020/5/30	+
24	A24748673	49	female	2020/6/5	serum	-	-	2020/5/30	-
25	202004120111	57	male	2020/6/5	serum	-	-	2020/5/30	-
26	2020002419	87	female	2020/6/5	serum	-	-	2020/5/30	-
27	202004070185	70	male	2020/6/5	serum	-	-	2020/5/30	-
28	2020002269	92	male	2020/6/5	serum	-	-	2020/5/30	-
29	A7602380X	27	female	2020/6/5	serum	+	+	2020/5/30	+
30	202004110139	40	female	2020/6/5	serum	-	-	2020/5/30	-
31	A3202494X	30	male	2020/6/5	serum	+	+	2020/5/30	+
32	A23868585	34	female	2020/6/7	serum	+	+	2020/5/29	+
33	902077373	56	female	2020/6/7	serum	-	-	2020/5/29	-
34	A60708708	34	male	2020/6/7	serum	+	+	2020/5/29	+
35	202004090248	62	male	2020/6/7	serum	-	-	2020/5/29	-
36	A7338401X	63	female	2020/6/7	serum	-	-	2020/5/29	-
37	2004070826	43	female	2020/6/7	serum	-	-	2020/5/29	-
38	202004100238	63	female	2020/6/7	serum	-	-	2020/5/29	-
39	2004100558	47	female	2020/6/7	serum	-	-	2020/5/29	-
40	202004090134	63	female	2020/6/7	serum	-	-	2020/5/29	-
41	2004081068	51	male	2020/6/7	serum	-	-	2020/5/29	-
42	2004100554	54	female	2020/6/7	serum	-	-	2020/5/29	-
43	2004100556	51	female	2020/6/7	serum	-	-	2020/5/29	-
44	2004100553	52	male	2020/6/7	serum	-	-	2020/5/29	-
45	A84392381	69	female	2020/6/9	serum	-	-	2020/5/30	-
46	2004100155	37	male	2020/6/9	serum	-	-	2020/5/30	-
47	2004100217	54	male	2020/6/9	serum	-	-	2020/5/30	-



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
48	2004100231	50	male	2020/6/9	serum	-	-	2020/5/30	-
49	2004100203	35	female	2020/6/9	serum	-	-	2020/5/30	-
50	2004100215	29	female	2020/6/9	serum	+	+	2020/5/30	+
51	2004100244	50	female	2020/6/9	serum	-	-	2020/5/30	-
52	2004100297	39	female	2020/6/9	serum	-	-	2020/5/30	-
53	2004100278	46	female	2020/6/9	serum	-	-	2020/5/30	-
54	2004100260	52	female	2020/6/9	serum	-	-	2020/5/30	-
55	2004100226	47	female	2020/6/9	serum	-	-	2020/5/30	-
56	2004100262	48	female	2020/6/9	serum	-	-	2020/5/30	-
57	2004100361	31	male	2020/6/9	serum	+	+	2020/5/30	+
58	2004100209	27	female	2020/6/9	serum	+	+	2020/5/30	+
59	2004100280	50	female	2020/6/9	serum	-	-	2020/5/30	-
60	2004100370	30	male	2020/6/9	serum	+	+	2020/5/30	+
61	5333788	34	female	2020/6/7	serum	+	+	2020/5/29	+
62	5362994	62	male	2020/6/7	serum	-	-	2020/5/29	-
63	5472304	67	female	2020/6/7	serum	-	-	2020/5/29	-
64	30125864	66	male	2020/6/7	serum	-	-	2020/5/29	-
65	140047242	37	female	2020/6/7	serum	-	-	2020/5/29	-
66	5249927	37	male	2020/6/7	serum	-	-	2020/5/29	-
67	5249986	47	male	2020/6/9	serum	-	-	2020/5/30	-
68	5197421	56	male	2020/6/9	serum	-	-	2020/5/30	-
69	5353341	57	male	2020/6/9	serum	-	-	2020/5/30	-
70	5329901	70	female	2020/6/9	serum	-	-	2020/5/30	-
71	5349523	25	female	2020/6/9	serum	+	+	2020/5/30	+
72	5418482	69	male	2020/6/9	serum	-	-	2020/5/30	-
73	5321741	59	male	2020/6/9	serum	-	-	2020/5/30	-
74	5246471	32	female	2020/6/9	serum	+	+	2020/5/30	+
75	5365524	46	female	2020/6/9	serum	-	-	2020/5/30	-
76	5374793	52	male	2020/6/9	serum	-	-	2020/5/30	-
77	5355156	47	male	2020/6/9	serum	-	-	2020/5/30	-
78	5400003	48	female	2020/6/9	serum	-	-	2020/5/30	-
79	5390558	31	female	2020/6/9	serum	+	+	2020/5/30	+
80	5400074	27	male	2020/6/9	serum	+	+	2020/6/1	+
81	5356206	50	male	2020/6/9	serum	-	-	2020/6/1	-
82	5375189	30	female	2020/6/9	serum	+	+	2020/6/1	+
83	5375226	49	female	2020/6/9	serum	-	-	2020/6/1	-



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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
84	5375139	47	male	2020/6/9	serum	-	-	2020/6/1	-
85	5316982	45	female	2020/6/9	serum	-	-	2020/6/1	-
86	5375493	32	female	2020/6/9	serum	+	+	2020/6/1	+
87	5375520	46	male	2020/6/9	serum	-	-	2020/6/1	-
88	5396384	34	female	2020/6/9	serum	+	+	2020/6/1	+
89	5438297	45	male	2020/6/9	serum	-	-	2020/6/1	-
90	5406531	58	male	2020/6/9	serum	-	-	2020/6/1	-
91	5323444	46	male	2020/6/9	serum	-	-	2020/6/1	-
92	5376519	48	female	2020/6/9	serum	-	-	2020/6/1	-
93	5323630	22	female	2020/6/9	serum	+	+	2020/6/1	+
94	5420274	26	female	2020/6/9	serum	+	+	2020/6/1	+
95	5427001	28	female	2020/6/9	serum	-	-	2020/6/1	+
96	5358483	47	female	2020/6/9	serum	-	-	2020/6/1	-
97	5301832	43	female	2020/6/9	serum	-	-	2020/6/1	-
98	5415523	32	male	2020/6/9	serum	+	+	2020/6/1	+
99	5407175	46	male	2020/6/9	serum	-	-	2020/6/1	-
100	5398250	34	male	2020/6/9	serum	+	+	2020/5/30	+
101	25656	31	female	2020/6/9	serum	+	+	2020/5/30	+
102	29971	52	male	2020/6/9	serum	-	-	2020/5/30	-
103	29753	63	male	2020/6/9	serum	-	-	2020/5/30	-
104	25850	67	female	2020/6/9	serum	-	-	2020/5/30	-
105	28720	40	male	2020/6/9	serum	-	-	2020/5/30	-
106	25331	74	male	2020/6/9	serum	-	-	2020/5/30	-
107	26303	55	female	2020/6/9	serum	-	-	2020/5/30	-
108	25313	32	male	2020/6/9	serum	+	+	2020/5/30	+
109	27110	42	male	2020/6/9	serum	-	-	2020/5/30	-
110	25198	59	female	2020/6/9	serum	-	-	2020/5/30	-
111	27840	73	female	2020/6/9	serum	-	-	2020/5/30	-
112	27909	36	female	2020/6/9	serum	-	-	2020/5/30	-
113	26254	61	female	2020/6/9	serum	-	-	2020/5/30	-
114	27562	22	female	2020/6/9	serum	+	+	2020/5/30	+
115	28499	59	male	2020/6/9	serum	-	-	2020/5/30	-
116	25404	35	male	2020/6/9	serum	+	+	2020/5/30	+
117	25726	46	male	2020/6/9	serum	-	-	2020/5/30	-
118	29845	18	female	2020/6/9	serum	+	+	2020/5/30	+
119	26315	26	male	2020/6/9	serum	+	+	2020/5/30	+

No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type*	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result
					S-serum P-plasma	IgG	IgM		
120	25122	69	male	2020/6/9	serum	-	-	2020/5/30	-
121	26780	34	male	2020/6/9	serum	+	+	2020/5/30	+
122	27517	34	female	2020/6/9	serum	+	+	2020/5/30	+
123	29377	38	male	2020/6/9	serum	-	-	2020/5/30	-
124	29955	64	male	2020/6/9	serum	-	-	2020/5/30	-
125	29407	69	female	2020/6/9	serum	-	-	2020/5/30	-
126	29719	36	male	2020/6/9	serum	-	-	2020/5/30	-
127	27476	40	male	2020/6/9	serum	-	-	2020/5/30	-
128	25266	30	female	2020/6/9	serum	+	+	2020/5/30	+
129	29515	18	female	2020/6/9	serum	+	+	2020/5/30	+
130	26390	31	male	2020/6/9	serum	+	+	2020/5/30	+

## 5. Result analysis:

	Nucleic acid test results		Total
	Positive	Negative	
IgM+/IgG+	94	0	94
IgM+/IgG-	1	0	1
IgM-/IgG+	2	3	5
IgM-/IgG-	3	297	300
Total	100	300	400

Measure	Estimate	95% Confidence interval
IgM sensitivity	95.0% (95/100)	(88.8%;97.9%)
IgM specificity	100% (300/300)	(98.7%;100%)
IgG sensitivity	96.0% (96/100)	(90.2%;98.4%)
IgG specificity	99.0% (297/300)	(97.1%;99.7%)
Combined sensitivity	97.0% (97/100)	(91.5%;98.9%)
Combined specificity	99.0% (297/300)	(97.1%;99.7%)
Combined coincidence rate	97.8% (391/400)	(95.8%;98.8%)
PPV	96.9% (94/97)	---
NPV	98.0% (297/303)	---