

Method Comparison 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 Wu han hangyun hospital, Hubei 3RD Person's Hospital and The First Affiliated Hospital of Guangzhou medical university. Each was operated by three experimenters.

Sample:

In Wu han hangyun hospital

60 samples (No.01-60) were selected and the results were detected with nucleic acid.

In The First Affiliated Hospital of Guanzhou medical university

60 samples (No.01-60) were selected and the results were detected with nucleic acid.

In The Third People's Hospital of Hubei Province

60 samples (No.01-60) were selected and the results were detected with nucleic acid.

Testing Procedure:

Use Egens COVID-19 IgG/IgM Rapid Test Kit to test the samples, the result compares with the result of nucleic acid.

Lots of Product Used for Each Format: One

Result:

In Wu han 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	IgG	IgM		
					P-plasma W-whole blood				
01	200410 0402	45	female	2020/4/8	serum	+	+	2020/3/17	+
02	200408 1252	59	female	2020/3/23	serum	+	+	2020/3/17	+
03	200408 1258	70	female	2020/4/8	serum	+	+	2020/3/17	+
04	200411 0236	25	female	2020/4/11	serum	+	+	2020/3/17	+

05	200411 0239	69	female	2020/3/27	serum	+	+	2020/3/17	+
06	200411 0237	59	female	2020/3/27	serum	+	+	2020/3/17	+
07	200411 0238	32	male	2020/4/14	serum	+	+	2020/3/17	+
08	200408 1262	31	female	2020/3/29	serum	+	+	2020/3/17	+
09	200409 0146	56	male	2020/3/23	serum	+	+	2020/3/17	+
10	200408 1278	69	male	2020/4/14	serum	+	+	2020/3/17	+
11	200408 1259	87	male	2020/3/29	serum	—	+	2020/3/17	+
12	200408 1241	25	female	2020/4/10	serum	+	—	2020/3/17	+
13	200408 1254	31	female	2020/4/10	serum	+	+	2020/3/17	+
14	200408 1260	45	male	2020/4/10	serum	+	+	2020/3/17	+
15	200408 1270	47	male	2020/3/22	serum	+	—	2020/3/17	+
16	200408 1274	62	male	2020/4/12	serum	+	+	2020/3/17	+
17	200408 1233	66	male	2020/4/12	serum	+	—	2020/3/17	+
18	200408 1255	83	female	2020/3/30	serum	+	—	2020/3/17	+
19	200410 0399	73	female	2020/4/12	serum	+	+	2020/3/17	+

20	200410 0408	69	female	2020/3/30	serum	+	—	2020/3/17	+
21	200407 0401	69	male	2020/3/30	serum	+	—	2020/3/17	+
22	200407 0485	65	female	2020/3/23	serum	+	+	2020/3/17	+
23	200407 0352	43	female	2020/3/23	serum	+	+	2020/3/17	+
24	200407 0647	96	male	2020/4/9	serum	+	+	2020/3/17	+
25	200407 0611	61	male	2020/3/22	serum	+	+	2020/3/17	+
26	200407 0653	26	male	2020/3/28	serum	+	+	2020/3/17	+
27	200407 0398	43	female	2020/4/9	serum	+	+	2020/3/17	+
28	200407 0582	53	female	2020/4/9	serum	+	+	2020/3/17	+
29	200407 0430	49	male	2020/3/28	serum	+	+	2020/3/17	+
30	200407 0562	36	female	2020/3/28	serum	+	—	2020/3/17	+
31	200407 0554	24	female	2020/3/23	serum	+	+	2020/3/17	+
32	200407 0416	25	female	2020/4/11	serum	+	+	2020/3/17	+
33	200407 0368	56	male	2020/4/9	serum	+	+	2020/3/17	+
34	200407 0396	47	male	2020/3/29	serum	+	+	2020/3/17	+

35	200407 0342	53	female	2020/4/9	serum	+	+	2020/3/17	+
36	200407 0549	44	female	2020/3/28	serum	+	+	2020/3/17	+
37	200407 0585	64	male	2020/4/9	serum	+	+	2020/3/17	+
38	200407 0492	68	female	2020/3/28	serum	+	+	2020/3/17	+
39	200407 0418	33	male	2020/3/29	serum	+	+	2020/3/17	+
40	200407 0629	89	female	2020/4/11	serum	+	—	2020/3/17	+
41	200409 0136	49	male	2020/4/11	serum	—	—	2020/4/11	—
42	200410 0017	47	male	2020/4/11	serum	—	—	2020/4/11	—
43	200410 0019	45	male	2020/4/11	serum	—	—	2020/4/11	—
44	200408 1250	32	male	2020/4/11	serum	—	—	2020/4/11	—
45	200408 1247	46	female	2020/4/11	serum	—	—	2020/4/11	—
46	200408 1251	34	female	2020/4/11	serum	—	—	2020/4/11	—
47	200408 1257	56	male	2020/4/11	serum	—	—	2020/4/11	—
48	200408 1265	48	female	2020/4/11	serum	—	—	2020/4/11	—
49	200408 1239	52	male	2020/4/11	serum	—	—	2020/4/11	—

50	200408 1244	28	female	2020/4/11	serum	—	—	2020/4/11	—
51	200408 1237	53	male	2020/4/11	serum	+	—	2020/4/11	—
52	200410 0398	50	female	2020/4/11	serum	—	—	2020/4/11	—
53	200410 0405	53	male	2020/4/11	serum	—	—	2020/4/11	—
54	200408 1256	29	female	2020/4/11	serum	—	—	2020/4/11	—
55	200408 1263	50	female	2020/4/11	serum	—	—	2020/4/11	—
56	200411 0240	46	female	2020/4/11	serum	—	—	2020/4/11	—
57	200411 0243	49	male	2020/4/11	serum	—	—	2020/4/11	—
58	200411 0241	39	male	2020/4/11	serum	—	—	2020/4/11	—
59	200411 0242	62	female	2020/4/11	serum	—	—	2020/4/11	—
60	200408 1266	59	male	2020/4/11	serum	—	—	2020/4/11	—

Summary

For IgG

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
40	39	97.50%	87.12%~99.56%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
20	19	95.00%	76.39%~99.11%

For IgM

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
40	32	80.00%	65.24%~89.50%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
20	20	100%	83.89%~100.00%

In The First Affiliated Hospital of Guanzhou 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	W-whole blood		
01	2004070373	45	female	2020/3/21	serum	-	-	2020/3/21	—
02	2004070441	58	male	2020/3/21	serum	-	-	2020/3/21	—
03	2004070542	46	male	2020/3/21	serum	-	-	2020/3/21	—
04	2004070496	48	male	2020/3/21	serum	-	-	2020/3/21	—

05	200407 0472	22	female	2020/3/21	serum	-	-	2020/3/21	—
06	200407 0387	26	male	2020/3/21	serum	-	-	2020/3/21	—
07	200407 0529	28	male	2020/4/12	serum	+	+	2020/3/21	+
08	200407 0659	47	male	2020/3/27	serum	+	+	2020/3/21	+
09	200407 0354	43	female	2020/3/27	serum	+	+	2020/3/21	+
10	200407 0428	31	female	2020/3/21	serum	-	-	2020/3/21	—
11	200407 0553	42	male	2020/3/21	serum	-	-	2020/3/21	—
12	200407 0456	51	female	2020/3/21	serum	+	-	2020/3/21	—
13	200407 0367	35	female	2020/4/2	serum	+	+	2020/3/21	+
14	200407 0644	43	male	2020/3/21	serum	-	-	2020/3/21	—
15	200407 0432	49	female	2020/4/2	serum	+	+	2020/3/21	+
16	200407 0615	52	female	2020/3/26	serum	+	-	2020/3/21	+
17	200407 0483	27	male	2020/4/15	serum	+	+	2020/3/21	+
18	200407 0353	37	female	2020/3/27	serum	+	+	2020/3/21	+
19	200407 0517	45	female	2020/4/4	serum	+	+	2020/3/21	+

20	200407 0400	47	female	2020/3/21	serum	-	-	2020/3/21	—
21	200407 0460	32	male	2020/3/21	serum	-	-	2020/3/21	—
22	200407 0506	44	male	2020/3/21	serum	-	-	2020/3/21	—
23	200407 0390	26	male	2020/3/21	serum	-	-	2020/3/21	—
24	200407 0450	44	female	2020/3/21	serum	-	-	2020/3/21	—
25	200407 0451	45	male	2020/3/21	serum	-	-	2020/3/21	—
26	200407 0323	45	male	2020/3/21	serum	-	-	2020/3/21	—
27	200407 0547	35	female	2020/3/21	serum	-	-	2020/3/21	—
28	200407 0579	40	female	2020/3/21	serum	-	-	2020/3/21	—
29	200407 0564	24	male	2020/3/21	serum	-	-	2020/3/21	—
30	A24748 674	42	female	2020/4/14	serum	+	-	2020/3/21	+
31	200410 0398	40	male	2020/4/3	serum	+	+	2020/3/21	+
32	200408 1238	44	female	2020/4/14	serum	+	+	2020/3/21	+
33	A69897 955	57	male	2020/4/14	serum	+	+	2020/3/21	+
34	2020040 80624	66	female	2020/3/27	serum	+	+	2020/3/21	+

35	2020040 80280	36	male	2020/3/26	serum	+	-	2020/3/21	+
36	2004100 247	56	male	2020/3/26	serum	+	+	2020/3/21	+
37	2020002 665	47	male	2020/4/16	serum	+	+	2020/3/21	+
38	2004080 605	53	male	2020/3/31	serum	+	+	2020/3/21	+
39	2004081 238	44	male	2020/4/18	serum	+	+	2020/3/21	+
40	2004081 081	64	male	2020/4/2	serum	+	+	2020/3/21	+
41	2004080 563	68	male	2020/3/31	serum	+	+	2020/3/21	+
42	2004081 556	50	male	2020/3/31	serum	+	+	2020/3/21	+
43	2004080 577	35	male	2020/4/16	serum	+	-	2020/3/21	+
44	2004081 069	29	male	2020/3/27	serum	+	+	2020/3/21	+
45	2004081 293	50	male	2020/4/16	serum	+	+	2020/3/21	+
46	2004100 557	39	female	2020/3/26	serum	+	+	2020/3/21	+
47	2004100 552	46	male	2020/4/17	serum	+	+	2020/3/21	+
48	2004100 555	87	female	2020/4/17	serum	+	+	2020/3/21	+
49	2004100 560	25	female	2020/4/3	serum	+	-	2020/3/21	+

50	2004070 828	31	male	2020/4/18	serum	+	+	2020/3/21	+
51	200409 0137	45	male	2020/3/30	serum	+	+	2020/3/21	+
52	200410 0018	47	male	2020/3/30	serum	+	+	2020/3/21	+
53	200410 0020	29	male	2020/4/2	serum	+	-	2020/3/21	+
54	200408 1249	49	female	2020/3/25	serum	+	+	2020/3/21	+
55	200408 1248	57	female	2020/4/11	serum	+	+	2020/3/21	+
56	200408 1253	87	female	2020/4/3	serum	+	+	2020/3/21	+
57	200408 1261	70	male	2020/3/26	serum	+	+	2020/3/21	+
58	200408 1265	92	male	2020/4/18	serum	+	-	2020/3/21	+
59	200408 1240	67	female	2020/3/27	serum	+	+	2020/3/21	+
60	200408 1245	45	male	2020/3/31	serum	+	+	2020/3/21	+

Summary

For IgG

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
40	40	97.50%	91.24%~100%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
20	19	95.00%	76.39%~99.11%

For IgM

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
40	33	82.50%	68.05%~91.25%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
20	20	100%	83.89%~100.00%

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 W-whole blood	IgG	IgM		
01	202004100130	24	female	2020/4/20	serum	+	—	2020/4/10	+
02	202004100193	43	female	2020/4/20	serum	+	+	2020/4/10	+
03	2004090081	51	male	2020/4/20	serum	+	+	2020/4/10	+
04	2004081168	30	male	2020/4/10	serum	+	+	2020/4/10	+

05	2004081 405	57	male	2020/5/4	serum	+	—	2020/4/10	+
06	2004090 269	34	male	2020/5/4	serum	+	+	2020/4/10	+
07	A80099 92X	62	male	2020/4/22	serum	+	+	2020/4/11	+
08	2020041 10024	67	male	2020/4/22	serum	+	+	2020/4/11	+
09	9007892 71	66	female	2020/5/5	serum	+	—	2020/4/11	+
10	2020041 10099	37	female	2020/5/5	serum	+	+	2020/4/11	+
11	2020041 10116	37	male	2020/4/22	serum	+	+	2020/4/11	+
12	2020041 00065	47	female	2020/4/22	serum	—	+	2020/4/11	+
13	2004100 129	56	male	2020/5/5	serum	+	+	2020/4/11	+
14	2004100 374	57	male	2020/4/22	serum	+	+	2020/4/11	+
15	2004100 246	59	male	2020/4/22	serum	+	+	2020/4/11	+
16	2004100 077	22	female	2020/4/22	serum	+	+	2020/4/11	+
17	2020002 663	29	male	2020/4/17	serum	+	+	2020/4/11	+
18	2004080 604	27	male	2020/4/17	serum	+	—	2020/4/11	+
19	2004050 010	27	male	2020/4/16	serum	+	+	2020/4/11	+

20	2020041 20035	71	female	2020/4/17	serum	+	+	2020/4/12	+
21	2020041 20034	43	male	2020/5/9	serum	+	+	2020/4/12	+
22	2020041 20007	53	male	2020/5/9	serum	+	+	2020/4/12	+
23	2020041 20051	29	female	2020/5/9	serum	+	+	2020/4/12	+
24	A24748 673	49	female	2020/5/9	serum	+	+	2020/4/12	+
25	2020041 20111	57	male	2020/5/9	serum	+	+	2020/4/12	+
26	2020002 419	87	female	2020/5/9	serum	+	—	2020/4/12	+
27	2020040 70185	70	male	2020/5/9	serum	+	+	2020/4/12	+
28	2020002 269	92	male	2020/4/24	serum	+	+	2020/4/12	+
29	A76023 80X	27	female	2020/4/24	serum	+	+	2020/4/12	+
30	2020041 10139	40	female	2020/5/8	serum	+	+	2020/4/12	+
31	A32024 94X	30	male	2020/4/17	serum	+	+	2020/4/12	+
32	A23868 585	34	female	2020/5/5	serum	+	+	2020/4/9	+
33	9020773 73	56	female	2020/4/14	serum	+	+	2020/4/9	+
34	A60708 708	34	male	2020/4/21	serum	+	—	2020/4/9	+

35	2020040 90248	62	male	2020/5/4	serum	+	+	2020/4/9	+
36	A73384 01X	63	female	2020/4/15	serum	+	+	2020/4/9	+
37	2004070 826	43	female	2020/4/15	serum	+	+	2020/4/9	+
38	2020041 00238	63	female	2020/5/5	serum	+	+	2020/4/10	+
39	2004100 558	47	female	2020/5/5	serum	+	+	2020/4/10	+
40	2020040 90134	63	female	2020/4/25	serum	+	—	2020/4/9	+
41	2004081 068	51	male	2020/4/14	serum	—	—	2020/4/10	—
42	2004100 554	54	female	2020/4/20	serum	—	—	2020/4/10	—
43	2004100 556	51	female	2020/4/10	serum	—	—	2020/4/10	—
44	2004100 553	52	male	2020/4/10	serum	—	—	2020/4/10	—
45	A84392 381	69	female	2020/4/12	serum	—	—	2020/4/12	—
46	200410 0155	37	male	2020/4/11	serum	—	—	2020/4/11	—
47	200410 0217	54	male	2020/4/11	serum	—	—	2020/4/11	—
48	200410 0231	50	male	2020/4/11	serum	—	—	2020/4/11	—
49	200410 0203	35	female	2020/4/11	serum	—	—	2020/4/11	—

50	200410 0215	29	female	2020/4/11	serum	—	—	2020/4/11	—
51	200410 0244	50	female	2020/4/11	serum	—	—	2020/4/11	—
52	200410 0297	39	female	2020/4/11	serum	—	—	2020/4/11	—
53	200410 0278	46	female	2020/4/11	serum	—	—	2020/4/11	—
54	200410 0260	52	female	2020/4/11	serum	—	—	2020/4/11	—
55	200410 0226	47	female	2020/4/11	serum	—	—	2020/4/11	—
56	200410 0262	48	female	2020/4/11	serum	—	—	2020/4/11	—
57	200410 0361	31	male	2020/4/11	serum	—	—	2020/4/11	—
58	200410 0209	27	female	2020/4/11	serum	—	—	2020/4/11	—
59	200410 0280	50	female	2020/4/11	serum	—	—	2020/4/11	—
60	200410 0370	30	male	2020/4/11	serum	—	—	2020/4/11	—

Summary

For IgG

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
40	39	97.50%	87.12%~99.56%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
20	20	100%	83.89%~100.00%

For IgM

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
40	33	82.50%	68.05%~91.25%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
20	20	100%	83.89%~100.00%

Conclusion:

For IgG

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
120	118	98.33%	94.13%~99.54%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
60	58	96.67%	88.64%~99.08%

For IgM

PCR Total positive Results	Candidate Device		
	of positive results	PPA	95%CI
120	98	81.67%	73.80%~87.57%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
60	60	100%	93.79%~100.00%