

Performance test report COVID-19 IgG/IgM Rapid Test Kit			Prepared by	XueMei Bao
			Checked by	Lingling Su
Doc. No.	EGENS/CE- Appendix 4		Approved by	WeiJun Ou
Effective date	2020.5.10	Ver. A/2	Pages	14

Performance Test Report

I. Precision/Reproducibility/Cut-Off Value Study Protocol

To establish cut off value of COVID-19 IgG/IgM Rapid Test Kit, negative blood specimens were spiked with varying COVID-19 IgG/IgM (COVID-19 IgG/IgM Antibody Internal Reference Substance) concentrations. The spiked samples were measured in 3 replicates using 3 different lots.

standards		Lot 1 20200217		Lot 2 20200218		Lot 3 20200219	
		# of negative	# of positive	# of negative	# of positive	# of negative	# of positive
IgG 1:5	IgG	0	3	0	3	0	3
	IgM	3	0	3	0	3	0
IgG 1:10	IgG	0	3	0	3	0	3
	IgM	3	0	3	0	3	0
IgG 1:25	IgG	0	3	0	3	0	3
	IgM	3	0	3	0	3	0
IgG 1:50	IgG	0	3	0	3	0	3
	IgM	3	0	3	0	3	0
IgG 1:100	IgG	1	2	0	3	0	3
	IgM	3	0	3	0	3	0
IgG 1:200	IgG	3	0	3	0	3	0
	IgM	3	0	3	0	3	0
IgM 1:5	IgG	0	0	0	0	0	0
	IgM	0	3	0	3	0	3
IgM 1:10	IgG	0	0	0	0	0	0
	IgM	0	3	0	3	0	3
IgM 1:20	IgG	0	0	0	0	0	0
	IgM	0	3	0	3	0	3
IgM 1:40	IgG	0	0	0	0	0	0
	IgM	0	3	0	3	0	3
IgM 1:80	IgG	0	0	0	0	0	0
	IgM	0	3	0	3	0	3
IgM 1:160	IgG	0	0	0	0	0	0
	IgM	3	0	3	0	3	0

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Lots of Product Used for Each Format: Three

Numbers of Operators: Three

Result:

Results will be filled in the following form:

Lot No.:20200217

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:5	+	—	+	—	+	—
002		+	—	+	—	+	—
003		+	—	+	—	+	—

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:10	+	—	+	—	+	—
002		+	—	+	—	+	—
003		+	—	+	—	+	—

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:25	+	—	+	—	+	—
002		+	—	+	—	+	—
003		+	—	+	—	+	—

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:50	+	—	+	—	+	—
002		+	—	+	—	+	—
003		+	—	+	—	+	—

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:100	+	—	+	—	+	—
002		—	—	+	—	—	—
003		+	—	+	—	+	—

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:200	—	—	—	—	—	—

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002		—	—	—	—	—	—
003		—	—	—	—	—	—

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:5	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:10	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:20	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:40	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:80	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:160	—	—	—	—	—	—
002		—	—	—	—	—	—
003		—	—	—	—	—	—

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Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:5	+	-	+	-	+	-
002		+	-	+	-	+	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:10	+	-	+	-	+	-
002		+	-	+	-	+	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:25	+	-	+	-	+	-
002		+	-	+	-	+	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:50	+	-	+	-	+	-
002		+	-	+	-	+	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:100	+	-	+	-	+	-
002		-	-	+	-	-	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:200	-	-	-	-	-	-
002		-	-	-	-	-	-
003		-	-	-	-	-	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:5	-	+	-	+	-	+

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002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:10	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:20	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:40	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:80	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:160	—	—	—	—	—	—
002		—	—	—	—	—	—
003		—	—	—	—	—	—

Lot No.:20200219

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:5	+	—	+	—	+	—
002		+	—	+	—	+	—
003		+	—	+	—	+	—

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Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:10	+	-	+	-	+	-
002		+	-	+	-	+	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:25	+	-	+	-	+	-
002		+	-	+	-	+	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:50	+	-	+	-	+	-
002		+	-	+	-	+	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:100	+	-	+	-	+	-
002		-	-	+	-	-	-
003		+	-	+	-	+	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgG 1:200	-	-	-	-	-	-
002		-	-	-	-	-	-
003		-	-	-	-	-	-

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:5	-	+	-	+	-	+
002		-	+	-	+	-	+
003		-	+	-	+	-	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:10	-	+	-	+	-	+
002		-	+	-	+	-	+

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003		—	+	—	+	—	+
-----	--	---	---	---	---	---	---

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:20	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:40	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:80	—	+	—	+	—	+
002		—	+	—	+	—	+
003		—	+	—	+	—	+

Sample Numbers	Concentration	Viewer A		Viewer B		Viewer C	
		IgG	IgM	IgG	IgM	IgG	IgM
001	IgM 1:160	—	—	—	—	—	—
002		—	—	—	—	—	—
003		—	—	—	—	—	—

Conclusion:

Based on the results, the cut-off value of IgG is 1:100 (L2), the cut-off value of IgM is 1:80 (L5).

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II. Specificity

To evaluate cross-reactivity with Flu A, Flu B, EV71, CA16, RSV(respiratory syncytial virus) and ADV, each sample was tested by 3 different lots and 3 different operators.

Lot No.:20200217

Samples	Viewer A		Viewer B		Viewer C	
	IgG	IgM	IgG	IgM	IgG	IgM
anti-Flu A antibody	—	—	—	—	—	—
anti-Flu B antibody	—	—	—	—	—	—
anti-RSV antibody	—	—	—	—	—	—
anti-ADV antibody	—	—	—	—	—	—
anti-B group of Coxsackie virus antibody	—	—	—	—	—	—

Lot No.:20200218

Samples	Viewer A		Viewer B		Viewer C	
	IgG	IgM	IgG	IgM	IgG	IgM
anti-Flu A antibody	—	—	—	—	—	—
anti-Flu B antibody	—	—	—	—	—	—
anti-RSV antibody	—	—	—	—	—	—
anti-ADV antibody	—	—	—	—	—	—
anti-B group of Coxsackie virus antibody	—	—	—	—	—	—

Lot No.:20200219

Samples	Viewer A		Viewer B		Viewer C	
	IgG	IgM	IgG	IgM	IgG	IgM
anti-Flu A antibody	—	—	—	—	—	—
anti-Flu B antibody	—	—	—	—	—	—
anti-RSV antibody	—	—	—	—	—	—
anti-ADV antibody	—	—	—	—	—	—
anti-B group of Coxsackie virus antibody	—	—	—	—	—	—

Conclusion:

There' s no cross-reactivity observed with anti-Flu A antibody, anti-Flu B antibody, anti-RSV antibody(respiratory syncytial virus), anti-ADV antibody, and anti-B group of Coxsackie virus antibody.

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2) Interferants

To evaluate potential interference from certain exogenous compounds, we use the following compounds to test.

Lot 1:20200217 Lot 2: 20200218 Lot 3:20200219

Interferants		Lot 1		Lot 2		Lot 3	
		IgG	IgM	IgG	IgM	IgG	IgM
Triglycerides	1mmol/L	—	—	—	—	—	—
	2mmol/L	—	—	—	—	—	—
	3mmol/L	+	+	+	+	+	+
	4mmol/L	+	+	+	+	+	+
	5mmol/L	+	+	+	+	+	+
Cholesterol(2.3mmol/mL)		—	—	—	—	—	—
total bilirubin(169.8 μ mol/L)		—	—	—	—	—	—
Jaundice(34.2 μ mol/L)		—	—	—	—	—	—

Conclusion:

The test of Triglycerides indicates, when the concentration of Triglycerides is above 2mmol/L, it will influence the result, getting an error conclusions.

The Cholesterol(2.3mmol/mL), total bilirubin(169.8μmol/L) and Jaundice(34.2μmol/L) exhibited no cross reactivity.

3) Repeatability

To evaluate the repeatability of COVID-19 IgG/IgM Rapid Test Kit, use CV1 and CV2 to test, the result is as following:

Lot 1:20200217

	1		2		3		4		5		6		7		8		9		10	
	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M
CV1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
CV2	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Lot 2: 20200218

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	1		2		3		4		5		6		7		8		9		10	
	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M
CV1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
CV2	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Lot 3:20200219

	1		2		3		4		5		6		7		8		9		10	
	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M	Ig G	Ig M
CV1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
CV2	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

Conclusion:

Use CV1 and CV2 to test, the result of IgG shall be positive at 10 minutes, and the ten times test results are uniform.

Use CV1 and CV2 to test, the result of IgM shall be positive at 10 minutes, and the ten times test results are uniform

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III. Method Comparison Protocol

The clinical trial was conducted in three hospitals, each of which collected 60 samples. The Test results of Egens COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) were compared with nucleic acid test results to determine the accuracy of Egens products. The nucleic acid detection kit used was the BGI Genomics Co. Ltd Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV Nucleic acid test.

Result:

The results will be filled in the following Tables.

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	Number of days
					S-serum P-plasma W-whole blood	IgG	IgM			
01	2004100402	45	female	2020/4/8	serum	—	+	2020/3/17	+	22
02	2004081252	59	female	2020/3/23	serum	—	—	2020/3/17	+	6
03	2004081258	70	female	2020/4/8	serum	+	+	2020/3/17	+	22
04	2004110236	25	female	2020/4/11	serum	+	+	2020/3/17	+	25
05	2004110239	69	female	2020/3/27	serum	+	—	2020/3/17	+	10
06	2004110237	59	female	2020/3/27	serum	+	—	2020/3/17	+	10
07	2004110238	32	male	2020/4/14	serum	+	+	2020/3/17	+	28
08	2004081262	31	female	2020/3/29	serum	+	+	2020/3/17	+	12
09	2004090146	56	male	2020/3/23	serum	—	—	2020/3/17	+	6
10	2004081278	69	male	2020/4/14	serum	+	—	2020/3/17	+	28
11	2004081259	87	male	2020/3/29	serum	—	—	2020/3/17	+	12
12	2004081241	25	female	2020/4/10	serum	+	+	2020/3/17	+	24
13	2004081254	31	female	2020/4/10	serum	—	+	2020/3/17	+	24

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14	200408 1260	45	male	2020/4/ 10	serum	+	—	2020/3/ 17	+	24
15	200408 1270	47	male	2020/3/ 22	serum	—	—	2020/3/ 17	+	5
16	200408 1274	62	male	2020/4/ 12	serum	+	+	2020/3/ 17	+	26
17	200408 1233	66	male	2020/4/ 12	serum	—	+	2020/3/ 17	+	26
18	200408 1255	83	female	2020/3/ 30	serum	+	+	2020/3/ 17	+	13
19	200410 0399	73	female	2020/4/ 12	serum	+	—	2020/3/ 17	+	26
20	200410 0408	69	female	2020/3/ 30	serum	—	—	2020/3/ 17	+	13
21	200407 0401	69	male	2020/3/ 30	serum	—	+	2020/3/ 17	+	13
22	200407 0485	65	female	2020/3/ 23	serum	—	—	2020/3/ 17	+	6
23	200407 0352	43	female	2020/3/ 23	serum	—	—	2020/3/ 17	+	6
24	200407 0647	96	male	2020/4/ 9	serum	+	+	2020/3/ 17	+	23
25	200407 0611	61	male	2020/3/ 22	serum	+	+	2020/3/ 17	+	5
26	200407 0653	26	male	2020/3/ 28	serum	+	+	2020/3/ 17	+	11
27	200407 0398	43	female	2020/4/ 9	serum	+	+	2020/3/ 17	+	23
28	200407 0582	53	female	2020/4/ 9	serum	+	—	2020/3/ 17	+	23
29	200407 0430	49	male	2020/3/ 28	serum	+	+	2020/3/ 17	+	11
30	200407 0562	36	female	2020/3/ 28	serum	+	—	2020/3/ 17	+	11
31	200407 0554	24	female	2020/3/ 23	serum	+	—	2020/3/ 17	+	6
32	200407 0416	25	female	2020/4/ 11	serum	+	+	2020/3/ 17	+	25
33	200407 0368	56	male	2020/4/ 9	serum	—	—	2020/3/ 17	+	5

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34	200407 0396	47	male	2020/3/ 29	serum	—	+	2020/3/ 17	+	12
35	200407 0342	53	female	2020/4/ 9	serum	+	—	2020/3/ 17	+	23
36	200407 0549	44	female	2020/3/ 28	serum	+	—	2020/3/ 17	+	11
37	200407 0585	64	male	2020/4/ 9	serum	+	—	2020/3/ 17	+	23
38	200407 0492	68	female	2020/3/ 28	serum	+	+	2020/3/ 17	+	11
39	200407 0418	33	male	2020/3/ 29	serum	—	—	2020/3/ 17	+	12
40	200407 0629	89	female	2020/4/ 11	serum	+	—	2020/3/ 17	+	25
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	—	

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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**

Days post symptom onset	PCR Total positive	Candidate Device		
		of positive results	PPA	95%CI
≤7	8	2	25.00%	7.15%~59.07%
8-14	14	9	64.29%	38.76%~83.66%
≥15	18	15	83.33%	60.78%~94.16%

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

For IgM

Days post symptom onset	PCR Total positive	Candidate Device		
		of positive results	PPA	95%CI
≤7	8	1	12.50%	2.24%~47.09%
8-14	14	7	50.00%	26.80%~73.20%
≥15	18	11	61.11%	38.62%~79.70%

PCR Total Negative	Candidate Device

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Results	of negative results	NPA	95%CI
20	20	100%	83.89%~100.00%

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	Number of days
					S-serum P-plasma W-whole blood	IgG	IgM			
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	2004070472	22	female	2020/3/21	serum	-	-	2020/3/21	—	
06	2004070387	26	male	2020/3/21	serum	-	-	2020/3/21	—	
07	2004070529	28	male	2020/4/12	serum	+	-	2020/3/21	+	22
08	2004070659	47	male	2020/3/27	serum	-	-	2020/3/21	+	6
09	2004070354	43	female	2020/3/27	serum	+	-	2020/3/21	+	6
10	2004070428	31	female	2020/3/21	serum	-	-	2020/3/21	—	
11	2004070553	42	male	2020/3/21	serum	-	-	2020/3/21	—	
12	2004070456	51	female	2020/3/21	serum	-	-	2020/3/21	—	
13	2004070367	35	female	2020/4/2	serum	+	+	2020/3/21	+	12
14	2004070644	43	male	2020/3/21	serum	-	-	2020/3/21	—	
15	2004070432	49	female	2020/4/2	serum	-	-	2020/3/21	+	12

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16	200407 0615	52	female	2020/3/ 26	serum	-	+	2020/3/ 21	+	5
17	200407 0483	27	male	2020/4/ 15	serum	-	+	2020/3/ 21	+	25
18	200407 0353	37	female	2020/3/ 27	serum	+	-	2020/3/ 21	+	6
19	200407 0517	45	female	2020/4/ 4	serum	+	+	2020/3/ 21	+	14
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	A2474 8674	42	female	2020/4/ 14	serum	-	+	2020/3/ 21	+	24
31	200410 0398	40	male	2020/4/ 3	serum	+	-	2020/3/ 21	+	13
32	200408 1238	44	female	2020/4/ 14	serum	+	-	2020/3/ 21	+	24
33	A6989 7955	57	male	2020/4/ 14	serum	+	-	2020/3/ 21	+	24
34	20200 40806 24	66	female	2020/3/ 27	serum	-	-	2020/3/ 21	+	6
35	20200	36	male	2020/3/	serum	-	-	2020/3/	+	5

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	40802 80			26				21		
36	20041 00247	56	male	2020/3/ 26	serum	-	-	2020/3/ 21	+	5
37	20200 02665	47	male	2020/4/ 16	serum	+	+	2020/3/ 21	+	26
38	20040 80605	53	male	2020/3/ 31	serum	+	+	2020/3/ 21	+	10
39	20040 81238	44	male	2020/4/ 18	serum	+	-	2020/3/ 21	+	28
40	20040 81081	64	male	2020/4/ 2	serum	-	-	2020/3/ 21	+	12
41	20040 80563	68	male	2020/3/ 31	serum	+	-	2020/3/ 21	+	10
42	20040 81556	50	male	2020/3/ 31	serum	+	+	2020/3/ 21	+	10
43	20040 80577	35	male	2020/4/ 16	serum	+	+	2020/3/ 21	+	26
44	20040 81069	29	male	2020/3/ 27	serum	-	-	2020/3/ 21	+	6
45	20040 81293	50	male	2020/4/ 16	serum	+	+	2020/3/ 21	+	26
46	20041 00557	39	female	2020/3/ 26	serum	-	-	2020/3/ 21	+	5
47	20041 00552	46	male	2020/4/ 17	serum	+	+	2020/3/ 21	+	27
48	20041 00555	87	female	2020/4/ 17	serum	+	+	2020/3/ 21	+	27
49	20041 00560	25	female	2020/4/ 3	serum	-	-	2020/3/ 21	+	13
50	20040 70828	31	male	2020/4/ 18	serum	+	-	2020/3/ 21	+	28
51	200409 0137	45	male	2020/3/ 30	serum	+	-	2020/3/ 21	+	9
52	200410 0018	47	male	2020/3/ 30	serum	+	-	2020/3/ 21	+	9
53	200410 0020	29	male	2020/4/ 2	serum	-	+	2020/3/ 21	+	12
54	200408 1249	49	female	2020/3/ 25	serum	-	-	2020/3/ 21	+	4

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55	200408 1248	57	female	2020/4/ 11	serum	+	+	2020/3/ 21	+	21
56	200408 1253	87	female	2020/4/ 3	serum	-	-	2020/3/ 21	+	13
57	200408 1261	70	male	2020/3/ 26	serum	-	-	2020/3/ 21	+	5
58	200408 1265	92	male	2020/4/ 18	serum	+	+	2020/3/ 21	+	28
59	200408 1240	67	female	2020/3/ 27	serum	+	+	2020/3/ 21	+	6
60	200408 1245	45	male	2020/3/ 31	serum	-	+	2020/3/ 21	+	10

Summary

For IgG

Days post symptom onset	PCR Total positive	Candidate Device		
		of positive results	PPA	95%CI
≤7	12	3	25.00%	8.89%~53.23%
8-14	14	8	57.14%	32.59%~78.62%
≥15	14	12	85.71%	60.06%~95.99%

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

For IgM

Days post symptom onset	PCR Total positive	Candidate Device		
		of positive results	PPA	95%CI
≤7	12	2	16.67%	4.70%~44.80%
8-14	14	6	42.86%	21.38%~67.41%
≥15	14	9	64.29%	38.76%~83.66%

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

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No	Specimen Number	Age	Gender	Serum Specimen Collection Date	Specimen Type* S-serum P-plasma W-whole blood	Antibody Test Kit Result		PCR confirmation time	PCR confirmation Result	Number of days
						IgG	IgM			
01	202004100130	24	female	2020/4/20	serum	+	—	2020/4/10	+	10
02	202004100193	43	female	2020/4/20	serum	—	+	2020/4/10	+	10
03	2004090081	51	male	2020/4/20	serum	+	+	2020/4/10	+	10
04	2004081168	30	male	2020/4/10	serum	—	—	2020/4/10	+	6
05	2004081405	57	male	2020/5/4	serum	+	+	2020/4/10	+	24
06	2004090269	34	male	2020/5/4	serum	+	+	2020/4/10	+	24
07	A8009992X	62	male	2020/4/22	serum	+	—	2020/4/11	+	11
08	202004110024	67	male	2020/4/22	serum	+	—	2020/4/11	+	11
09	900789271	66	female	2020/5/5	serum	+	—	2020/4/11	+	25
10	202004110099	37	female	2020/5/5	serum	+	+	2020/4/11	+	25
11	202004110116	37	male	2020/4/22	serum	—	+	2020/4/11	+	11
12	202004100065	47	female	2020/4/22	serum	+	+	2020/4/11	+	11
13	2004100129	56	male	2020/5/5	serum	+	—	2020/4/11	+	25
14	2004100374	57	male	2020/4/22	serum	+	+	2020/4/11	+	11

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15	20041 00246	59	male	2020/4/2 2	serum	+	—	2020/4/1 1	+	11
16	20041 00077	22	female	2020/4/2 2	serum	+	+	2020/4/1 1	+	11
17	20200 02663	29	male	2020/4/1 7	serum	—	—	2020/4/1 1	+	6
18	20040 80604	27	male	2020/4/1 7	serum	—	—	2020/4/1 1	+	6
19	20040 50010	27	male	2020/4/1 6	serum	+	+	2020/4/1 1	+	5
20	20200 41200 35	71	female	2020/4/1 7	serum	—	—	2020/4/1 2	+	6
21	20200 41200 34	43	male	2020/5/9	serum	+	—	2020/4/1 2	+	27
22	20200 41200 07	53	male	2020/5/9	serum	+	+	2020/4/1 2	+	27
23	20200 41200 51	29	female	2020/5/9	serum	—	+	2020/4/1 2	+	27
24	A2474 8673	49	female	2020/5/9	serum	—	—	2020/4/1 2	+	27
25	20200 41201 11	57	male	2020/5/9	serum	+	+	2020/4/1 2	+	27
26	20200 02419	87	female	2020/5/9	serum	+	+	2020/4/1 2	+	27
27	20200 40701 85	70	male	2020/5/9	serum	+	—	2020/4/1 2	+	27
28	20200 02269	92	male	2020/4/2 4	serum	+	+	2020/4/1 2	+	12
29	A7602 380X	27	female	2020/4/2 4	serum	+	+	2020/4/1 2	+	12
30	20200 41101 39	40	female	2020/5/8	serum	+	+	2020/4/1 2	+	26
31	A3202	30	male	2020/4/1	serum	—	—	2020/4/1	+	5

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	494X			7				2		
32	A2386 8585	34	female	2020/5/5	serum	+	—	2020/4/9	+	26
33	90207 7373	56	female	2020/4/1 4	serum	—	—	2020/4/9	+	5
34	A6070 8708	34	male	2020/4/2 1	serum	—	—	2020/4/9	+	12
35	20200 40902 48	62	male	2020/5/4	serum	+	+	2020/4/9	+	25
36	A7338 401X	63	female	2020/4/1 5	serum	+	—	2020/4/9	+	6
37	20040 70826	43	female	2020/4/1 5	serum	—	—	2020/4/9	+	6
38	20200 41002 38	63	female	2020/5/5	serum	—	+	2020/4/1 0	+	25
39	20041 00558	47	female	2020/5/5	serum	+	—	2020/4/1 0	+	25
40	20200 40901 34	63	female	2020/4/2 5	serum	—	—	2020/4/9	+	16
41	20040 81068	51	male	2020/4/1 4	serum	—	—	2020/4/1 0	+	4
42	20041 00554	54	female	2020/4/2 0	serum	—	—	2020/4/1 0	+	10
43	20041 00556	51	female	2020/4/1 0	serum	—	—	2020/4/1 0	—	
44	20041 00553	52	male	2020/4/1 0	serum	—	—	2020/4/1 0	—	
45	A8439 2381	69	female	2020/4/1 2	serum	—	—	2020/4/1 2	—	
46	200410 0155	37	male	2020/4/1 1	serum	—	—	2020/4/1 1	—	
47	200410 0217	54	male	2020/4/1 1	serum	—	—	2020/4/1 1	—	
48	200410 0231	50	male	2020/4/1 1	serum	—	—	2020/4/1 1	—	
49	200410 0203	35	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	

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50	200410 0215	29	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
51	200410 0244	50	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
52	200410 0297	39	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
53	200410 0278	46	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
54	200410 0260	52	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
55	200410 0226	47	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
56	200410 0262	48	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
57	200410 0361	31	male	2020/4/1 1	serum	—	—	2020/4/1 1	—	
58	200410 0209	27	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
59	200410 0280	50	female	2020/4/1 1	serum	—	—	2020/4/1 1	—	
60	200410 0370	30	male	2020/4/1 1	serum	—	—	2020/4/1 1	—	

Summary

For IgG

Days post symptom onset	PCR Total positive	Candidate Device		
		of positive results	PPA	95%CI
≤7	10	2	20.00%	5.67%~50.98%
8-14	15	10	66.67%	41.71%~84.82%
≥15	17	14	82.35%	58.97%~93.81%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
18	18	100%	82.41%~100.00%

For IgM

Days post	PCR Total	Candidate Device
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symptom onset	positive	of positive results	PPA	95%CI
≤7	10	1	10.00%	1.79%~40.42%
8-14	15	8	53.33%	30.12%~75.19%
≥15	17	10	58.82%	36.01%~78.39%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
18	18	100%	82.41%~100.00%

Summary for all results

For IgG

Days post symptom onset	PCR Total positive	Candidate Device		
		of positive results	PPA	95%CI
≤7	30	7	23.33%	11.79%~40.93%
8-14	43	27	62.79%	47.86%~75.62%
≥15	49	41	83.67%	70.96%~91.49%

For IgM

Days post symptom onset	PCR Total positive	Candidate Device		
		of positive results	PPA	95%CI
≤7	30	4	13.33%	5.31%~29.68%
8-14	43	21	48.84%	34.62%~63.25%
≥15	49	30	61.22%	47.25%~73.57%

PCR Total Negative Results	Candidate Device		
	of negative results	NPA	95%CI
58	58	100%	93.79%~100.00%