

PROJECT CODE	PRODUCT DESIGNATION	REFERENCE
NA	BIO SYNEX COVID-19 BSS	SW40005

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I. CLINICAL STUDY 1

Report dated: 2020.02.28

➤ Objective

Investigate the application of the product in the market via evaluating amounts of clinical samples.

➤ Material

- ✓ Description of component

COVID-19 IgG/IgM rapid test

Lot No.: COV2002003-S

- ✓ Samples

Sample from Confirmed Population of nCOV Pneumonia

Sample from Suspected Population of nCOV Pneumonia

Sample from Healthy People

All samples confirmed according to China's Novel Coronavirus Pneumonia Diagnosis and Treatment Plan (Version 5th)

➤ Protocol / Method

The COVID-19 IgG/IgM rapid test was parallel compared with Clinical Diagnostic Result and PCR Testing Result.

Draw the serum/plasma/whole blood specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Read results at 10 minutes. Do not interpret results after 20 minutes.

➤ Results

1. For confirmed samples

Item n°	Type of sample	Clinical symptom	PCR testing result	Testing result with the COVID-19 IgG/IgM rapid test	
				IgG	IgM
1	serum	confirmed case	positive	+	+
2	serum	confirmed case	positive	+	+
3	serum	confirmed case	positive	+	+
4	serum	confirmed case	positive	+	+
5	serum	confirmed case	positive	+	+
6	serum	confirmed case	positive	+	+
7	serum	confirmed case	positive	+	-
8	serum	confirmed case	positive	+	+
9	serum	confirmed case	positive	+	+
10	serum	confirmed case	positive	+	+
11	serum	confirmed case	positive	+	-
12	serum	confirmed case	positive	+	+
13	serum	confirmed case	positive	+	-
14	serum	confirmed case	positive	+	+

Item n°	Type of sample	Clinical symptom	PCR testing result	Testing result with the COVID-19 IgG/IgM rapid test	
				IgG	IgM
15	serum	confirmed case	positive	+	+
16	serum	confirmed case	positive	+	-
17	serum	confirmed case	positive	+	+
18	serum	confirmed case	positive	+	+
19	serum	confirmed case	positive	+	+
20	serum	confirmed case	positive	+	+
21	serum	confirmed case	positive	+	+
22	serum	confirmed case	positive	+	-
23	serum	confirmed case	positive	+	+
24	serum	confirmed case	positive	+	+
25	serum	confirmed case	positive	+	+
26	serum	confirmed case	positive	+	+
27	serum	confirmed case	positive	-	+
28	serum	confirmed case	positive	+	+
29	serum	confirmed case	positive	+	+
30	serum	confirmed case	positive	+	+
31	serum	confirmed case	positive	+	+
32	serum	confirmed case	positive	+	+
33	serum	confirmed case	positive	+	+
34	serum	confirmed case	positive	+	+
35	serum	confirmed case	positive	+	+
36	serum	confirmed case	positive	+	+
37	serum	confirmed case	positive	+	+
38	serum	confirmed case	positive	+	+

2. For suspected samples and negative samples

Item n°	Type of sample	Clinical symptom	PCR testing result	Testing result with the COVID-19 IgG/IgM rapid test	
				IgG	IgM
1	serum	suspected case	negative	-	-
2	serum	suspected case	negative	-	-
3	serum	suspected case	negative	-	-
4	serum	suspected case	negative	-	-
5	serum	suspected case	negative	-	-
6	serum	suspected case	negative	-	-
7	serum	suspected case	negative	-	-
8	serum	suspected case	negative	-	-
9	serum	suspected case	negative	-	-
10	serum	suspected case	negative	-	-
11	serum	healthy	negative	-	-
12	serum	healthy	negative	-	-

Item n°	Type of sample	Clinical symptom	PCR testing result	Testing result with the COVID-19 IgG/IgM rapid test	
				IgG	IgM
13	serum	healthy	negative	-	-
14	serum	healthy	negative	+	+
15	serum	healthy	negative	-	-
16	serum	healthy	negative	-	-
17	serum	healthy	negative	-	-
18	serum	healthy	negative	-	-
19	serum	healthy	negative	-	-
20	serum	healthy	negative	-	-
21	serum	healthy	negative	-	-
22	serum	healthy	negative	-	+
23	serum	healthy	negative	-	-
24	serum	healthy	negative	-	-
25	serum	healthy	negative	-	-
26	serum	healthy	negative	-	-
27	serum	healthy	negative	-	-
28	serum	healthy	negative	-	-
29	serum	healthy	negative	-	-
30	serum	healthy	negative	-	-
31	serum	healthy	negative	-	-
32	serum	healthy	negative	-	-
33	serum	healthy	negative	-	-
34	serum	healthy	negative	-	-
35	serum	healthy	negative	-	-
36	serum	healthy	negative	-	-
37	serum	healthy	negative	-	-
38	serum	healthy	negative	-	-
39	serum	healthy	negative	-	-
40	serum	healthy	negative	-	-
41	serum	healthy	negative	-	-
42	serum	healthy	negative	-	-
43	serum	healthy	negative	-	-
44	serum	healthy	negative	-	-
45	serum	healthy	negative	-	-
46	serum	healthy	negative	-	-
47	serum	healthy	negative	-	-
48	serum	healthy	negative	-	-
49	serum	healthy	negative	-	-
50	serum	healthy	negative	-	-
51	serum	healthy	negative	-	-
52	serum	healthy	negative	-	-
53	serum	healthy	negative	-	-

Item n°	Type of sample	Clinical symptom	PCR testing result	Testing result with the COVID-19 IgG/IgM rapid test	
				IgG	IgM
54	serum	healthy	negative	-	-
55	serum	healthy	negative	-	-
56	serum	healthy	negative	-	-
57	serum	healthy	negative	-	-
58	serum	healthy	negative	-	-
59	serum	healthy	negative	-	-
60	serum	healthy	negative	-	-
61	serum	healthy	negative	-	-
62	serum	healthy	negative	-	-
63	serum	healthy	negative	-	-
64	serum	healthy	negative	-	-
65	serum	healthy	negative	-	-
66	serum	healthy	negative	-	-
67	serum	healthy	negative	-	-
68	serum	healthy	negative	-	-
69	serum	healthy	negative	-	-
70	serum	healthy	negative	-	-
71	serum	healthy	negative	-	-
72	serum	healthy	negative	-	-
73	serum	healthy	negative	-	-
74	serum	healthy	negative	-	-
75	serum	healthy	negative	-	-
76	serum	healthy	negative	-	-
77	serum	healthy	negative	-	-
78	serum	healthy	negative	-	-
79	serum	healthy	negative	-	-
80	serum	healthy	negative	-	-
81	serum	healthy	negative	-	-
82	serum	healthy	negative	-	-
83	serum	healthy	negative	-	-
84	serum	healthy	negative	-	-
85	serum	healthy	negative	-	-
86	serum	healthy	negative	-	-
87	serum	healthy	negative	-	-
88	serum	healthy	negative	-	-
89	serum	healthy	negative	-	-
90	serum	healthy	negative	-	-
91	serum	healthy	negative	-	-
92	serum	healthy	negative	-	-
93	serum	healthy	negative	-	-
94	serum	healthy	negative	-	-

Item n°	Type of sample	Clinical symptom	PCR testing result	Testing result with the COVID-19 IgG/IgM rapid test	
				IgG	IgM
95	serum	healthy	negative	-	-
96	serum	healthy	negative	-	-
97	serum	healthy	negative	-	-
98	serum	healthy	negative	-	-
99	serum	healthy	negative	-	-
100	serum	healthy	negative	-	-
101	serum	healthy	negative	-	-
102	serum	healthy	negative	-	-
103	serum	healthy	negative	-	-
104	serum	healthy	negative	-	-
105	serum	healthy	negative	-	-
106	serum	healthy	negative	-	-
107	serum	healthy	negative	-	-
108	serum	healthy	negative	-	-
109	serum	healthy	negative	-	-
110	serum	healthy	negative	-	-
111	serum	healthy	negative	-	-
112	serum	healthy	negative	-	-
113	serum	healthy	negative	-	-
114	serum	healthy	negative	-	-
115	serum	healthy	negative	-	-
116	serum	healthy	negative	-	-
117	serum	healthy	negative	-	-
118	serum	healthy	negative	-	-
119	serum	healthy	negative	-	-
120	serum	healthy	negative	-	-
121	serum	healthy	negative	-	-
122	serum	healthy	negative	-	-
123	serum	healthy	negative	-	-

Comment: - means negative results. + means positive results.

3. Testing results about serum, paired plasma, paired fingerstick blood and venous blood

Item n°	Clinical symptoms	PCR testing results	Testing results with the COVID-19 IgG/IgM rapid test											
			Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM
124	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
125	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
126	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-

Item n°	Clinical symptoms	PCR testing results	Testing results with the COVID-19 IgG/IgM rapid test											
			Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM
127	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
128	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
129	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
130	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
131	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
132	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
133	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
134	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
135	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
136	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
137	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
138	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
139	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
140	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
141	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
142	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
143	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
144	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
145	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
146	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
147	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
148	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
149	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
150	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
151	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
152	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
153	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
154	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-

Item n°	Clinical symptoms	PCR testing results	Testing results with the COVID-19 IgG/IgM rapid test											
			Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM
155	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
156	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
157	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
158	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
159	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
160	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
161	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
162	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
163	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
164	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
165	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
166	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
167	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
168	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
169	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
170	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
171	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
172	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-
173	healthy	negative	serum	-	-	plasma	-	-	VWB	-	-	FWB	-	-

Comment: - means negative results. VWB means venous whole blood. FWB means fingerstick whole blood.

➤ Conclusion

1. Compared with clinical diagnostic result

IgG results:

Method		Clinical diagnostic result		Total result
COVID-19 IgG/IgM rapid test for IgG	Result	Confirmed case	Suspected case and healthy case	
	Positive	37	1	38
	Negative	1	172	173
Total result		38	173	211

Sensitivity: 97.4% (95%CI: 86.2%~99.9%)*

Specificity: 99.4% (95%CI: 96.8%~100.0%)*

Accuracy: 99.1% (95%CI: 96.6%~99.9%)*

*Confidence interval

IgM results:

Method		Clinical diagnostic result		Total result
COVID-19 IgG/IgM rapid test for IgM	Result	Confirmed case	Suspected case and healthy case	
	Positive	33	2	35
	Negative	5	171	176
Total result		38	173	211

Sensitivity: 86.8% (95%CI:71.9%-95.6%)*

Specificity: 98.8% (95%CI:95.9%~99.9%)*

Accuracy: 96.7% (95%CI: 93.2%~98.7%)*

*Confidence interval

2. Compared with commercial PCR test

IgG results:

Method		PCR		Total result
COVID-19 IgG/IgM rapid test for IgG	Result	Confirmed case	Suspected case and healthy case	
	Positive	37	1	38
	Negative	1	172	173
Total result		38	173	211

Sensitivity: 97.4% (95%CI: 86.2%~99.9%)*

Specificity: 99.4% (95%CI: 96.8%~100.0%)*

Accuracy: 99.1% (95%CI: 96.6%~99.9%)*

*Confidence Interval

IgM results :

Method		PCR		Total result
COVID-19 IgG/IgM rapid test for IgM	Result	Confirmed case	Suspected case and healthy case	
	Positive	33	2	35
	Negative	5	171	176
Total result		38	173	211

Sensitivity: 86.8% (95%CI:71.9%-95.6%)*

Specificity: 98.8% (95%CI:95.9%~99.9%)*

Accuracy: 96.7% (95%CI: 93.2%~98.7%)*

*Confidence interval

General conclusion:

Samples from 38 confirmed cases and 173 suspected cases and healthy population were performed with the COVID-19 IgG/IgM Rapid Test. The COVID-19 IgG/IgM Rapid Test products have been

compared to a leading commercial PCR test using clinical specimens. The results show that relative to leading product tests, the COVID-19 IgG/IgM Rapid Test shows 97.4% relative sensitivity and 99.4% relative specificity for IgG and 86.8% relative sensitivity and 98.8% relative specificity for IgM.

II. CLINICAL STUDY 2

Report dated: 2020.03.14

➤ Objective

Investigate the application of the product in the market via evaluating amounts of clinical samples.

➤ Material

- ✓ Description of component

COVID-19 IgG/IgM rapid test

Lot No.: COV2002003-T

- ✓ Samples

Sample from Confirmed Population of nCOV Pneumonia

Sample from Suspected Population of nCOV Pneumonia

Sample from Healthy People

All sample confirmed according to China's Novel Coronavirus Pneumonia Diagnosis and Treatment Plan (Version 7th)

➤ Method

COVID-19 IgG/IgM rapid test was compared with Clinical Diagnostic Result.

Direction for Use :

Draw the serum/plasma/whole blood specimen up to the Fill Line (approximately 10µl), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Read results at 10 minutes. Do not interpret results after 20 minutes.

➤ Results

1. For confirmed samples

Item n°	Type of sample	Clinical symptom	Testing result with COVID-19 IgG/IgM rapid test		Comment
			IgG	IgM	
1	Serum	Confirmed Case	+	+	N/A
2	Serum	Confirmed Case	+	+	N/A
3	Serum	Confirmed Case	+	+	N/A
4	Serum	Confirmed Case	+	+	N/A
5	Serum	Confirmed Case	+	+	N/A
6	Serum	Confirmed Case	+	+	N/A
7	Serum	Confirmed Case	+	-	N/A
8	Serum	Confirmed Case	+	+	N/A
9	Serum	Confirmed Case	+	+	N/A
10	Serum	Confirmed Case	+	+	N/A
11	Serum	Confirmed Case	+	-	N/A
12	Serum	Confirmed Case	+	+	N/A
13	Serum	Confirmed Case	-	-	Primary Infection
14	Serum	Confirmed Case	+	+	N/A
15	Serum	Confirmed Case	+	+	N/A

16	Serum	Confirmed Case	-	-	Primary Infection
17	Serum	Confirmed Case	+	+	N/A
18	Serum	Confirmed Case	+	+	N/A
19	Serum	Confirmed Case	+	+	N/A
20	Serum	Confirmed Case	+	+	N/A
21	Serum	Confirmed Case	+	+	N/A
22	Serum	Confirmed Case	-	-	Primary Infection
23	Serum	Confirmed Case	+	+	N/A
24	Serum	Confirmed Case	+	+	N/A
25	Serum	Confirmed Case	+	+	N/A
26	Serum	Confirmed Case	+	+	N/A
27	Serum	Confirmed Case	-	+	Primary Infection
28	Serum	Confirmed Case	+	+	N/A
29	Serum	Confirmed Case	+	+	N/A
30	Serum	Confirmed Case	+	+	N/A
31	Serum	Confirmed Case	+	+	N/A
32	Serum	Confirmed Case	+	+	N/A
33	Serum	Confirmed Case	+	+	N/A
34	Serum	Confirmed Case	+	+	N/A
35	Serum	Confirmed Case	+	+	N/A
36	Serum	Confirmed Case	+	+	N/A
37	Serum	Confirmed Case	+	+	N/A
38	Serum	Confirmed Case	+	+	N/A
39	Serum	Confirmed Case	+	+	N/A
40	Serum	Confirmed Case	+	+	N/A
41	Serum	Confirmed Case	+	+	N/A
42	Serum	Confirmed Case	+	+	N/A
43	Serum	Confirmed Case	+	+	N/A
44	Serum	Confirmed Case	+	+	N/A
45	Serum	Confirmed Case	+	+	N/A
46	Serum	Confirmed Case	+	+	N/A
47	Serum	Confirmed Case	+	+	N/A
48	Serum	Confirmed Case	+	+	N/A
49	Serum	Confirmed Case	+	+	N/A
50	Serum	Confirmed Case	+	+	N/A
51	Serum	Confirmed Case	+	+	N/A
52	Serum	Confirmed Case	+	+	N/A
53	Serum	Confirmed Case	+	+	N/A
54	Serum	Confirmed Case	+	+	N/A
55	Serum	Confirmed Case	+	+	N/A
56	Serum	Confirmed Case	+	+	N/A
57	Serum	Confirmed Case	-	-	Primary Infection
58	Serum	Confirmed Case	+	+	N/A
59	Serum	Confirmed Case	+	+	N/A
60	Serum	Confirmed Case	+	+	N/A
61	Serum	Confirmed Case	+	+	N/A
62	Serum	Confirmed Case	-	-	Primary Infection
63	Serum	Confirmed Case	-	+	Primary Infection
64	Serum	Confirmed Case	+	+	N/A
65	Serum	Confirmed Case	+	+	N/A
66	Serum	Confirmed Case	+	+	N/A
67	Serum	Confirmed Case	+	+	N/A
68	Serum	Confirmed Case	+	+	N/A

69	Serum	Confirmed Case	-	+	Primary Infection
70	Serum	Confirmed Case	+	+	N/A
71	Serum	Confirmed Case	+	+	N/A
72	Serum	Confirmed Case	-	+	Primary Infection
73	Serum	Confirmed Case	+	+	N/A
74	Serum	Confirmed Case	+	+	N/A
75	Serum	Confirmed Case	+	+	N/A
76	Serum	Confirmed Case	+	+	N/A
77	Serum	Confirmed Case	-	+	Primary Infection
78	Serum	Confirmed Case	+	+	N/A
79	Serum	Confirmed Case	+	+	N/A
80	Serum	Confirmed Case	+	+	N/A
81	Serum	Confirmed Case	+	+	N/A
82	Serum	Confirmed Case	+	+	N/A
83	Serum	Confirmed Case	+	+	N/A
84	Serum	Confirmed Case	+	+	N/A
85	Serum	Confirmed Case	+	+	N/A

2. For suspected samples and negative samples

Item n°	Type of sample	Clinical symptom	PCR testing result	Testing result with COBID-19 IgG/IgM rapid test	
				IgG	IgM
1	Serum	Suspected Case	Negative	-	-
2	Serum	Suspected Case	Negative	-	-
3	Serum	Suspected Case	Negative	-	-
4	Serum	Suspected Case	Negative	-	-
5	Serum	Suspected Case	Negative	-	-
6	Serum	Suspected Case	Negative	-	-
7	Serum	Suspected Case	Negative	-	-
8	Serum	Suspected Case	Negative	-	-
9	Serum	Suspected Case	Negative	-	-
10	Serum	Suspected Case	Negative	-	-
11	Serum	Healthy	Negative	-	-
12	Serum	Healthy	Negative	-	-
13	Serum	Healthy	Negative	-	-
14	Serum	Healthy	Negative	+	+
15	Serum	Healthy	Negative	-	-
16	Serum	Healthy	Negative	-	-
17	Serum	Healthy	Negative	-	-
18	Serum	Healthy	Negative	-	-
19	Serum	Healthy	Negative	-	-
20	Serum	Healthy	Negative	-	-
21	Serum	Healthy	Negative	-	-
22	Serum	Healthy	Negative	-	+
23	Serum	Healthy	Negative	-	-
24	Serum	Healthy	Negative	-	-
25	Serum	Healthy	Negative	-	-
26	Serum	Healthy	Negative	-	-
27	Serum	Healthy	Negative	-	-
28	Serum	Healthy	Negative	-	-
29	Serum	Healthy	Negative	-	-
30	Serum	Healthy	Negative	-	-
31	Serum	Healthy	Negative	-	-

32	Serum	Healthy	Negative	-	-
33	Serum	Healthy	Negative	-	-
34	Serum	Healthy	Negative	-	-
35	Serum	Healthy	Negative	-	-
36	Serum	Healthy	Negative	-	-
37	Serum	Healthy	Negative	-	-
38	Serum	Healthy	Negative	-	-
39	Serum	Healthy	Negative	-	-
40	Serum	Healthy	Negative	-	-
41	Serum	Healthy	Negative	-	-
42	Serum	Healthy	Negative	-	-
43	Serum	Healthy	Negative	-	-
44	Serum	Healthy	Negative	-	-
45	Serum	Healthy	Negative	-	-
46	Serum	Healthy	Negative	-	-
47	Serum	Healthy	Negative	-	-
48	Serum	Healthy	Negative	-	-
49	Serum	Healthy	Negative	-	-
50	Serum	Healthy	Negative	-	-
51	Serum	Healthy	Negative	-	-
52	Serum	Healthy	Negative	-	-
53	Serum	Healthy	Negative	-	-
54	Serum	Healthy	Negative	-	-
55	Serum	Healthy	Negative	-	-
56	Serum	Healthy	Negative	-	-
57	Serum	Healthy	Negative	-	-
58	Serum	Healthy	Negative	-	-
59	Serum	Healthy	Negative	-	-
60	Serum	Healthy	Negative	-	-
61	Serum	Healthy	Negative	-	-
62	Serum	Healthy	Negative	-	-
63	Serum	Healthy	Negative	-	-
64	Serum	Healthy	Negative	-	-
65	Serum	Healthy	Negative	-	-
66	Serum	Healthy	Negative	-	-
67	Serum	Healthy	Negative	-	-
68	Serum	Healthy	Negative	-	-
69	Serum	Healthy	Negative	-	-
70	Serum	Healthy	Negative	-	-
71	Serum	Healthy	Negative	-	-
72	Serum	Healthy	Negative	-	-
73	Serum	Healthy	Negative	-	-
74	Serum	Healthy	Negative	-	-
75	Serum	Healthy	Negative	-	-
76	Serum	Healthy	Negative	-	-
77	Serum	Healthy	Negative	-	-
78	Serum	Healthy	Negative	-	-
79	Serum	Healthy	Negative	-	-
80	Serum	Healthy	Negative	-	-
81	Serum	Healthy	Negative	-	-
82	Serum	Healthy	Negative	-	-
83	Serum	Healthy	Negative	-	-
84	Serum	Healthy	Negative	-	-
85	Serum	Healthy	Negative	-	-
86	Serum	Healthy	Negative	-	-
87	Serum	Healthy	Negative	-	-
88	Serum	Healthy	Negative	-	-
89	Serum	Healthy	Negative	-	-

90	Serum	Healthy	Negative	-	-
91	Serum	Healthy	Negative	-	-
92	Serum	Healthy	Negative	-	-
93	Serum	Healthy	Negative	-	-
94	Serum	Healthy	Negative	-	-
95	Serum	Healthy	Negative	-	-
96	Serum	Healthy	Negative	-	-
97	Serum	Healthy	Negative	-	-
98	Serum	Healthy	Negative	-	-
99	Serum	Healthy	Negative	-	-
100	Serum	Healthy	Negative	-	-
101	Serum	Healthy	Negative	-	-
102	Serum	Healthy	Negative	-	-
103	Serum	Healthy	Negative	-	-
104	Serum	Healthy	Negative	-	-
105	Serum	Healthy	Negative	-	-
106	Serum	Healthy	Negative	-	-
107	Serum	Healthy	Negative	-	-
108	Serum	Healthy	Negative	-	-
109	Serum	Healthy	Negative	-	-
110	Serum	Healthy	Negative	-	-
111	Serum	Healthy	Negative	-	-
112	Serum	Healthy	Negative	-	-
113	Serum	Healthy	Negative	-	-
114	Serum	Healthy	Negative	-	-
115	Serum	Healthy	Negative	-	-
116	Serum	Healthy	Negative	-	-
117	Serum	Healthy	Negative	-	-
118	Serum	Healthy	Negative	-	-
119	Serum	Healthy	Negative	-	-
120	Serum	Healthy	Negative	-	-
121	Serum	Healthy	Negative	-	-
122	Serum	Healthy	Negative	-	-
123	Serum	Healthy	Negative	-	-
124	Serum	Healthy	N/A	-	-
125	Serum	Healthy	N/A	-	-
126	Serum	Healthy	N/A	-	-
127	Serum	Healthy	N/A	-	-
128	Serum	Healthy	N/A	-	-
129	Serum	Healthy	N/A	-	-
130	Serum	Healthy	N/A	-	-
131	Serum	Healthy	N/A	-	-
132	Serum	Healthy	N/A	-	-
133	Serum	Healthy	N/A	-	-
134	Serum	Healthy	N/A	-	-
135	Serum	Healthy	N/A	-	-
136	Serum	Healthy	N/A	-	-
137	Serum	Healthy	N/A	-	-
138	Serum	Healthy	N/A	-	-
139	Serum	Healthy	N/A	-	-
140	Serum	Healthy	N/A	-	-
141	Serum	Healthy	N/A	-	-
142	Serum	Healthy	N/A	-	-
143	Serum	Healthy	N/A	-	-
144	Serum	Healthy	N/A	-	-
145	Serum	Healthy	N/A	-	-
146	Serum	Healthy	N/A	-	-
147	Serum	Healthy	N/A	-	-

148	Serum	Healthy	N/A	-	-
149	Serum	Healthy	N/A	-	-
150	Serum	Healthy	N/A	-	-
151	Serum	Healthy	N/A	-	-
152	Serum	Healthy	N/A	-	-
153	Serum	Healthy	N/A	-	-
154	Serum	Healthy	N/A	-	-
155	Serum	Healthy	N/A	-	-
156	Serum	Healthy	N/A	-	-
157	Serum	Healthy	N/A	-	-
158	Serum	Healthy	N/A	-	-
159	Serum	Healthy	N/A	-	-
160	Serum	Healthy	N/A	-	-
161	Serum	Healthy	N/A	-	-
162	Serum	Healthy	N/A	-	-
163	Serum	Healthy	N/A	-	-
164	Serum	Healthy	N/A	-	-
165	Serum	Healthy	N/A	-	-
166	Serum	Healthy	N/A	-	-
167	Serum	Healthy	N/A	-	-
168	Serum	Healthy	N/A	-	-
169	Serum	Healthy	N/A	-	-
170	Serum	Healthy	N/A	-	-
171	Serum	Healthy	N/A	-	-
172	Serum	Healthy	N/A	-	-
173	Serum	Healthy	N/A	-	-
174	Serum	Healthy	N/A	-	-
175	Serum	Healthy	N/A	-	-
176	Serum	Healthy	N/A	-	-
177	Serum	Healthy	N/A	-	-
178	Serum	Healthy	N/A	-	-
179	Serum	Healthy	N/A	-	-
180	Serum	Healthy	N/A	-	-
181	Serum	Healthy	N/A	-	-
182	Serum	Healthy	N/A	-	-
183	Serum	Healthy	N/A	-	-
184	Serum	Healthy	N/A	-	-
185	Serum	Healthy	N/A	-	-
186	Serum	Healthy	N/A	-	-
187	Serum	Healthy	N/A	-	-
188	Serum	Healthy	N/A	-	-
189	Serum	Healthy	N/A	-	-
190	Serum	Healthy	N/A	-	-
191	Serum	Healthy	N/A	-	-
192	Serum	Healthy	N/A	-	-
193	Serum	Healthy	N/A	-	-
194	Serum	Healthy	N/A	-	-
195	Serum	Healthy	N/A	-	-
196	Serum	Healthy	N/A	-	-
197	Serum	Healthy	N/A	-	-
198	Serum	Healthy	N/A	-	-
199	Serum	Healthy	N/A	-	-
200	Serum	Healthy	N/A	-	-
201	Serum	Healthy	N/A	-	-
202	Serum	Healthy	N/A	-	-
203	Serum	Healthy	N/A	-	-
204	Serum	Healthy	N/A	-	-
205	Serum	Healthy	N/A	-	-

206	Serum	Healthy	N/A	-	-
207	Serum	Healthy	N/A	-	-
208	Serum	Healthy	N/A	-	-
209	Serum	Healthy	N/A	-	-
210	Serum	Healthy	N/A	-	-
211	Serum	Healthy	N/A	-	-
212	Serum	Healthy	N/A	-	-
213	Serum	Healthy	N/A	-	-
214	Serum	Healthy	N/A	-	-
215	Serum	Healthy	N/A	-	-
216	Serum	Healthy	N/A	-	-
217	Serum	Healthy	N/A	-	-
218	Serum	Healthy	N/A	-	-
219	Serum	Healthy	N/A	-	-
220	Serum	Healthy	N/A	-	-
221	Serum	Healthy	N/A	-	-
222	Serum	Healthy	N/A	-	-
223	Serum	Healthy	N/A	-	-
224	Serum	Healthy	N/A	-	-
225	Serum	Healthy	N/A	-	-
226	Serum	Healthy	N/A	-	-
227	Serum	Healthy	N/A	-	-
228	Serum	Healthy	N/A	-	-
229	Serum	Healthy	N/A	-	-
230	Serum	Healthy	N/A	-	-
231	Serum	Healthy	N/A	-	-
232	Serum	Healthy	N/A	-	-
233	Serum	Healthy	N/A	-	-
234	Serum	Healthy	N/A	-	-
235	Serum	Healthy	N/A	-	-
236	Serum	Healthy	N/A	-	-
237	Serum	Healthy	N/A	-	-
238	Serum	Healthy	N/A	-	-
239	Serum	Healthy	N/A	-	-
240	Serum	Healthy	N/A	-	-
241	Serum	Healthy	N/A	-	-
242	Serum	Healthy	N/A	-	-
243	Serum	Healthy	N/A	-	-
244	Serum	Healthy	N/A	-	-
245	Serum	Healthy	N/A	-	-
246	Serum	Healthy	N/A	-	-
247	Serum	Healthy	N/A	-	-
248	Serum	Healthy	N/A	-	-
249	Serum	Healthy	N/A	-	-
250	Serum	Healthy	N/A	-	-
251	Serum	Healthy	N/A	-	-
252	Serum	Healthy	N/A	-	-
253	Serum	Healthy	N/A	-	-
254	Serum	Healthy	N/A	-	-
255	Serum	Healthy	N/A	-	-
256	Serum	Healthy	N/A	-	-
257	Serum	Healthy	N/A	-	-
258	Serum	Healthy	N/A	-	-
259	Serum	Healthy	N/A	-	-
260	Serum	Healthy	N/A	-	-
261	Serum	Healthy	N/A	-	-
262	Serum	Healthy	N/A	-	-
263	Serum	Healthy	N/A	-	-

264	Serum	Healthy	N/A	-	-
265	Serum	Healthy	N/A	-	-
266	Serum	Healthy	N/A	-	-
267	Serum	Healthy	N/A	-	-
268	Serum	Healthy	N/A	-	-
269	Serum	Healthy	N/A	-	-
270	Serum	Healthy	N/A	-	-
271	Serum	Healthy	N/A	-	-
272	Serum	Healthy	N/A	-	-
273	Serum	Healthy	N/A	-	-
274	Serum	Healthy	N/A	-	-
275	Serum	Healthy	N/A	-	-
276	Serum	Healthy	N/A	-	-
277	Serum	Healthy	N/A	-	-
278	Serum	Healthy	N/A	-	-
279	Serum	Healthy	N/A	-	-
280	Serum	Healthy	N/A	-	-
281	Serum	Healthy	N/A	-	-
282	Serum	Healthy	N/A	-	-
283	Serum	Healthy	N/A	-	-
284	Serum	Healthy	N/A	-	-
285	Serum	Healthy	N/A	-	-
286	Serum	Healthy	N/A	-	-
287	Serum	Healthy	N/A	-	-
288	Serum	Healthy	N/A	-	-
289	Serum	Healthy	N/A	-	-
290	Serum	Healthy	N/A	-	-
291	Serum	Healthy	N/A	-	-
292	Serum	Healthy	N/A	-	-
293	Serum	Healthy	N/A	-	-
294	Serum	Healthy	N/A	-	-
295	Serum	Healthy	N/A	-	-
296	Serum	Healthy	N/A	+	+
297	Serum	Healthy	N/A	-	-
298	Serum	Healthy	N/A	-	-
299	Serum	Healthy	N/A	-	-
300	Serum	Healthy	N/A	-	-
301	Serum	Healthy	N/A	-	-
302	Serum	Healthy	N/A	-	-
303	Serum	Healthy	N/A	-	-
304	Serum	Healthy	N/A	-	-
305	Serum	Healthy	N/A	-	-
306	Serum	Healthy	N/A	-	-
307	Serum	Healthy	N/A	-	-
308	Serum	Healthy	N/A	-	-
309	Serum	Healthy	N/A	-	-
310	Serum	Healthy	N/A	-	-
311	Serum	Healthy	N/A	-	-
312	Serum	Healthy	N/A	-	-
313	Serum	Healthy	N/A	-	-
314	Serum	Healthy	N/A	-	-
315	Serum	Healthy	N/A	-	-
316	Serum	Healthy	N/A	-	-
317	Serum	Healthy	N/A	-	-
318	Serum	Healthy	N/A	-	-
319	Serum	Healthy	N/A	-	-
320	Serum	Healthy	N/A	-	-
321	Serum	Healthy	N/A	-	-

Comment: - means negative results. + means positive results.

3. Testing results about serum, paired plasma, paired fingerstick blood and venous blood

Item n°	Clinical symptom	PCR testing result	Testing results with COVID-19 IgG/IgM rapid test											
			Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM	Type	IgG	IgM
322	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
323	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
324	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
325	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
326	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
327	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
328	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
329	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
330	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
331	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
332	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
333	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
334	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
335	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
336	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
337	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
338	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
339	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
340	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
341	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
342	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
343	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
344	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
345	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
346	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
347	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
348	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
349	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
350	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
351	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
352	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
353	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
354	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
355	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
356	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
357	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
358	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
359	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
360	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
361	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
362	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
363	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
364	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
365	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
366	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
367	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
368	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
369	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
370	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-
371	Healthy	Negative	Serum	-	-	Plasma	-	-	VWB	-	-	FWB	-	-

Comment: - means negative results. VWB means venous whole blood. FWB means fingerstick whole blood.

➤ Conclusion - Compared with clinical diagnostic results

IgG results

Method		Clinical diagnosis (Confirmed)		Total result
Result		Positive	Negative	
COVID-19 IgG/IgM rapid test for IgG	Positive	75	2	77
	Negative	0	369	369
Total result		75	371	446

Diagnostic Sensitivity: 100.0% (95%CI: 96.1%~100.0%)*

Diagnostic Specificity: 99.5% (95%CI: 98.1%~99.9%)*

Accuracy: 99.6 % (95%CI: 98.4%~99.9%)*

*Confidence Interval

IgM results

Method		Clinical diagnosis (Confirmed)		Total result
Result		Positive	Negative	
COVID-19 IgG/IgM rapid test for IgM	Positive	78	3	81
	Negative	7	368	375
Total result		85	371	456

Diagnostic Sensitivity: 91.8 % (95%CI: 83.8%-96.6%)*

Diagnostic Specificity: 99.2 % (95%CI: 97.7%~99.8%)*

Accuracy: 97.8 % (95%CI: 96.0%~98.9%)*

*Confidence interval

Total Diagnostic Result

Method		Clinical diagnosis (Confirmed)		Total result
Result		Positive	Negative	
COVID-19 IgG/IgM rapid test	Positive	80	3	83
	Negative	5	368	373
Total result		85	371	456

Diagnostic Sensitivity: 94.1 % (95%CI: 86.8%-98.1%)*

Diagnostic Specificity: 99.2 % (95%CI: 97.7%~99.8%)*

Accuracy: 98.2 % (95%CI: 96.6%~99.2%)*

*Confidence interval

Conclusion

Samples from 85 confirmed case and 371 suspected case and healthy population were performed with COVID-19 IgG/IgM Rapid Test. The COVID-19 IgG/IgM Rapid Test products have been compared to clinical symptoms. The results show that the COVID-19 IgG/IgM Rapid Test shows 100.0% Diagnostic sensitivity for IgG test and 91.8% Diagnostic sensitivity for IgM test, 99.5% Diagnostic specificity for IgG test and 99.2% Diagnostic specificity for IgM test. The combined diagnostic sensitivity is 94.1%, combined diagnostic specificity is 99.2% and the accuracy in total is 98.2% for the COVID-19 IgG/IgM Rapid Test.

III. CLINICAL STUDY 3*Hubei Provincial Center for Disease Control and Prevention*

➤ Objective

Evaluate the diagnostic value in SARS-CoV-2 infections (COVID-19) IgG/IgM rapid test.

The study is a retrospective study on testing 70 samples from patients infected SARS-COV-2 (COVID-19) and 10 samples from the excluded cases collected by Hubei Provincial Center for Disease Control and Prevention in February 2020.

➤ Material

COVID-19 IgG/IgM rapid test cassette (colloidal gold)

Product Lot N°: COV2002003-T

➤ Samples

Confirmed cases of COVID-19 (70 cases)

Excluded cases of COVID-19 (10 cases): the confirmed cases and excluded cases were confirmed according to "Diagnosis and Treatment Plan for Pneumonia caused by New Coronavirus Infection (Trial Fifth Edition)" issued by the National Health Commission of P.R. China.

➤ Method

Read the entire manual and bring test and specimens to reach room temperature (15-30°C) before use.

Remove the test cassette from the sealed pouch and use it within one hour, especially temperature above 30°C or at high humidity.

1) Place the test cassette on a clean and level surface. Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 10µL), and transfer the specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µL) to the buffer well (B).

2) Wait for the colored line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

➤ Results

The 70 confirmed cases, including 15 clinical diagnosed cases and 55 definitive diagnosed cases, were confirmed according to "Diagnosis and Treatment Plan for Pneumonia caused by New Coronavirus Infection (Trial Fifth Edition)" issued by the National Health Commission of P.R. China.

➤ Conclusion

80 samples in total were tested, including 70 confirmed cases and 10 excluded cases.

70 confirmed cases were tested with the test. 58 samples were detected as IgG positive and IgM positive. 1 sample was detected as IgG positive and IgM negative. 5 samples were detected as IgM positive and IgG negative. 6 samples were detected as IgG negative and IgM negative.

The clinical sensitivity for IgM test is 90.0% (63/70) and for IgG test is 100.0% (59/59). The clinical sensitivity in total is 91.4% (64/70).

10 excluded cases were tested with the COVID-19 IgG/IgM rapid test. The clinical specificity for IgM test is 100.0% (10/10) and for IgG test is 100.0% (10/10). The clinical specificity in total is 100.0% (10/10).

The accuracy in total is 92.5% (74/80) for the COVID-19 IgG/IgM rapid test .

IV. History (changes)

Revision	Date	Part	Reason/Changes
01	2020-03-25	NA	Creation of the document