

Clinical Trials Study Report of COVID-19 IgG/IgM

Rapid Test Cassette

1. Purpose:

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

2. Material:

2.1 COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/ Serum/ Plasma)

Lot No.: COV2002003-S

2.2 Sample information:

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 5th)

3. Method:

The BIOTEST's COVID-19 IgG/IgM Rapid Test Cassette (Whole blood/ Serum/ Plasma) was parallel compared with Clinical Diagnostic Result and PCR Testing Result.

4. 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.

5. Results:

5.1. Perform the confirmed samples with the BIOTEST's test.

Item No.	Type of Sample	Clinical Symptom	PCR testing Result	Testing Result with BIOTEST's 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	+	+
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	+	+

5.2. Perform the suspected samples and negative sample with the BIOTEST's test.

Item No.	Type of Sample	Clinical Symptom	PCR testing Result	Testing Result with BIOTEST's 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	-	-

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

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

Item No.	Clinical Symptom	PCR testing Result	Testing Result with BIOTEST's 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	-	-
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	-	-
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.

6. Conclusion:

6.1 Compared with clinical diagnostic result:

Method		Clinical Diagnostic Result		Total Result
COVID-19 IgG/IgM Rapid Test Cassette 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%)*

IgM Results:

Method		Clinical Diagnostic Result		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgM	Results	Confirmed Case	Suspected Case and Healthy Case	
	Positive	33	2	35
	Negative	5	171	176
Total Results		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

6.2 Compared with Commercial PCR Test:

IgG Results:

Method		PCR		Total Results
COVID-19 IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	37	1	38
	Negative	1	172	173
Total Results		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 Results
COVID-19 IgG/IgM	Results	Positive	Negative	

Rapid Test Cassette for IgM	Positive	33	2	35
	Negative	5	171	176
Total Results		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

7. Conclusion:

Samples from 38 confirmed case and 173 suspected case and healthy population were performed with BIOTEST's COVID-19 IgG/IgM Rapid Test Cassette. The COVID-19 IgG/IgM Rapid Test Cassette 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 Cassette shows 97.4% relative sensitivity and 99.4% relative specificity for IgG and 86.8% relative sensitivity and 98.8% relative specificity for IgM.

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