

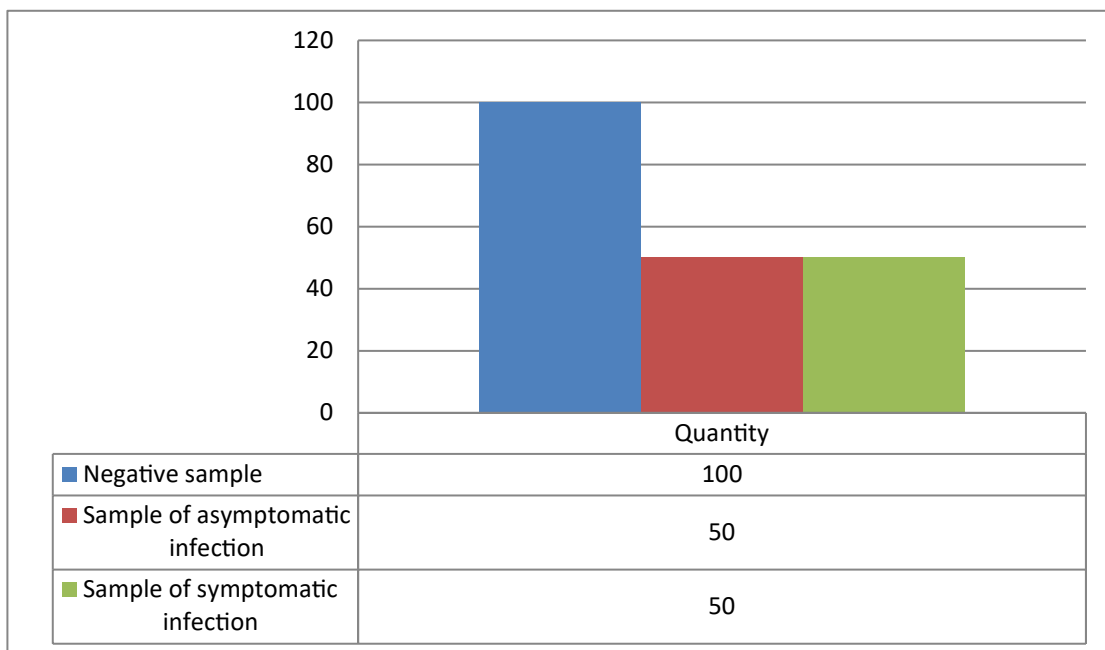
# CLINICAL VERIFICATION REPORT OF COVID-19 ANTIGEN RAPID TEST KIT (COLLOIDAL GOLD)



## 1. Introduction

Multibrands International Ltd conducted clinical trials at Blue Healthcare Clinic from September 21, 2020 to October 05, 2020. The name of the test kit is: Covid-19 Antigen Rapid Test Kit; the batch number is 20200302, and the test sample is saliva.

### Composition of sample disk



### 1.1 Positive samples

The positive samples all from sars-cov-2 patients who have been confirmed by nucleic acid amplification experiments. Among the samples, there are 50 people with asymptomatic infection and 50 people with symptomatic infection.

### 1.2 Negative samples

Negative samples were collected before 2020, before the known sars-cov-2 virus was transmitted.

## 2. Analysis

Covid-19 antigen rapid Test kits produced by Multibrands International Ltd. The test samples all are clinical samples. The sensitivity and specificity estimates in this report can only reflect the performance of the sample tray, and may not reflect the true performance of the kit. The positive background of the sample is



confirmed by nucleic acid, and both asymptomatic infection and symptomatic infection are judged as positive samples

### 3. Important Note

The sensitivity and specificity of the kit tested in this report cannot fully represent the true performance of the new coronavirus antigen test card.

These results are based only on oral saliva oral serum and oral whole blood samples, and may not represent the performance of other sample types in the kit. The number of samples in the test group is the smallest feasible sample size, which can provide a reasonable estimate and confidence interval for the performance of the experiment. The samples used may not represent the antigens detected in other patient groups.

### 4. Description of assessment procedure

4.1 The Covid-19 antigen rapid Test kit is used in strict accordance with the instructions provided by Multibrands International Ltd;

4.2 The Covid-19 antigen rapid Test kit will be tested within the validity period of the product;

4.3 The Covid-19 antigen rapid Test kit has no obvious defects or damage;

4.4 The Covid-19 antigen rapid Test kit is stored in accordance with the conditions marked on the package;

4.5 The test process is completed by 1 inspectors;

4.6 The inspector does not know the background data of the sample;

4.7 The positive and negative controls provided by the test shall be provided by the manufacturer;

4.8 Before the test, the inspector received relevant training on the operation of the kit, and the negative and positive control was confirmed before the test.

### 5. Result

Table 1: Summary Results

batch/Lot No. of the kit tested	Parameter evaluated	Amount	Number of Checkouts	The detection rate
	people with asymptomatic infection	50	47	94%
	people with symptomatic infection	50	49	98%
	Negative sample	100	97	97%



Table 2: Summary Statistics

Measure	Estimate Confidence Interval
Combined Sensitivity	96%
Combined Specificity	97%

Table 3: Line Data

Sample Number	PCR Result	Control	Symptom	Type	Result
1	Positive	Pass	Asymptomatic	Saliva	Positive
2	Positive	Pass	Asymptomatic	Saliva	Negative
3	Positive	Pass	Asymptomatic	Saliva	Positive
4	Positive	Pass	Asymptomatic	Saliva	Positive
5	Positive	Pass	Asymptomatic	Saliva	Positive
6	Positive	Pass	Asymptomatic	Saliva	Positive
7	Positive	Pass	Asymptomatic	Saliva	Positive
8	Positive	Pass	Asymptomatic	Saliva	Positive
9	Positive	Pass	Asymptomatic	Saliva	Positive
10	Positive	Pass	Asymptomatic	Saliva	Positive
11	Positive	Pass	Asymptomatic	Saliva	Positive
12	Positive	Pass	Asymptomatic	Saliva	Positive
13	Positive	Pass	Asymptomatic	Saliva	Negative
14	Positive	Pass	Asymptomatic	Saliva	Positive
15	Positive	Pass	Asymptomatic	Saliva	Positive
16	Positive	Pass	Asymptomatic	Saliva	Positive
17	Positive	Pass	Asymptomatic	Saliva	Positive
18	Positive	Pass	Asymptomatic	Saliva	Positive
19	Positive	Pass	Asymptomatic	Saliva	Positive
20	Positive	Pass	Asymptomatic	Saliva	Positive
21	Positive	Pass	Asymptomatic	Saliva	Negative



Sample Number	PCR Result	Control	Symptom	Type	Result
22	Positive	Pass	Asymptomatic	Saliva	Positive
23	Positive	Pass	Asymptomatic	Saliva	Positive
24	Positive	Pass	Asymptomatic	Saliva	Positive
25	Positive	Pass	Asymptomatic	Saliva	Positive
26	Positive	Pass	Asymptomatic	Saliva	Positive
27	Positive	Pass	Asymptomatic	Saliva	Positive
28	Positive	Pass	Asymptomatic	Saliva	Positive
29	Positive	Pass	Asymptomatic	Saliva	Positive
30	Positive	Pass	Asymptomatic	Saliva	Positive
31	Positive	Pass	Asymptomatic	Saliva	Positive
32	Positive	Pass	Asymptomatic	Saliva	Positive
33	Positive	Pass	Asymptomatic	Saliva	Positive
34	Positive	Pass	Asymptomatic	Saliva	Positive
35	Positive	Pass	Asymptomatic	Saliva	Positive
36	Positive	Pass	Asymptomatic	Saliva	Positive
37	Positive	Pass	Asymptomatic	Saliva	Positive
38	Positive	Pass	Asymptomatic	Saliva	Positive
39	Positive	Pass	Asymptomatic	Saliva	Positive
40	Positive	Pass	Asymptomatic	Saliva	Positive
41	Positive	Pass	Asymptomatic	Saliva	Positive
42	Positive	Pass	Asymptomatic	Saliva	Positive
43	Positive	Pass	Asymptomatic	Saliva	Positive
44	Positive	Pass	Asymptomatic	Saliva	Positive
45	Positive	Pass	Asymptomatic	Saliva	Positive
46	Positive	Pass	Asymptomatic	Saliva	Positive
47	Positive	Pass	Asymptomatic	Saliva	Positive
48	Positive	Pass	Asymptomatic	Saliva	Positive
49	Positive	Pass	Asymptomatic	Saliva	Positive
50	Positive	Pass	Asymptomatic	Saliva	Positive
51	Positive	Pass	Symptomatic	Saliva	Positive



Sample Number	PCR Result	Control	Symptom	Type	Result
52	Positive	Pass	Symptomatic	Saliva	Positive
53	Positive	Pass	Symptomatic	Saliva	Positive
54	Positive	Pass	Symptomatic	Saliva	Positive
55	Positive	Pass	Symptomatic	Saliva	Positive
56	Positive	Pass	Symptomatic	Saliva	Positive
57	Positive	Pass	Symptomatic	Saliva	Positive
58	Positive	Pass	Symptomatic	Saliva	Positive
59	Positive	Pass	Symptomatic	Saliva	Positive
60	Positive	Pass	Symptomatic	Saliva	Positive
61	Positive	Pass	Symptomatic	Saliva	Positive
62	Positive	Pass	Symptomatic	Saliva	Positive
63	Positive	Pass	Symptomatic	Saliva	Positive
64	Positive	Pass	Symptomatic	Saliva	Positive
65	Positive	Pass	Symptomatic	Saliva	Positive
66	Positive	Pass	Symptomatic	Saliva	Positive
67	Positive	Pass	Symptomatic	Saliva	Positive
68	Positive	Pass	Symptomatic	Saliva	Positive
69	Positive	Pass	Symptomatic	Saliva	Positive
70	Positive	Pass	Symptomatic	Saliva	Positive
71	Positive	Pass	Symptomatic	Saliva	Positive
72	Positive	Pass	Symptomatic	Saliva	Positive
73	Positive	Pass	Symptomatic	Saliva	Positive
74	Positive	Pass	Symptomatic	Saliva	Positive
75	Positive	Pass	Symptomatic	Saliva	Positive
76	Positive	Pass	Symptomatic	Saliva	Positive
77	Positive	Pass	Symptomatic	Saliva	Positive
78	Positive	Pass	Symptomatic	Saliva	Positive
79	Positive	Pass	Symptomatic	Saliva	Positive
80	Positive	Pass	Symptomatic	Saliva	Positive
81	Positive	Pass	Symptomatic	Saliva	Positive



Sample Number	PCR Result	Control	Symptom	Type	Result
82	Positive	Pass	Symptomatic	Saliva	Positive
83	Positive	Pass	Symptomatic	Saliva	Positive
84	Positive	Pass	Symptomatic	Saliva	Positive
85	Positive	Pass	Symptomatic	Saliva	Positive
86	Positive	Pass	Symptomatic	Saliva	Positive
87	Positive	Pass	Symptomatic	Saliva	Positive
88	Positive	Pass	Symptomatic	Saliva	Positive
89	Positive	Pass	Symptomatic	Saliva	Positive
90	Positive	Pass	Symptomatic	Saliva	Positive
91	Positive	Pass	Symptomatic	Saliva	Positive
92	Positive	Pass	Symptomatic	Saliva	Positive
93	Positive	Pass	Symptomatic	Saliva	Negative
94	Positive	Pass	Symptomatic	Saliva	Positive
95	Positive	Pass	Symptomatic	Saliva	Positive
96	Positive	Pass	Symptomatic	Saliva	Positive
97	Positive	Pass	Symptomatic	Saliva	Positive
98	Positive	Pass	Symptomatic	Saliva	Positive
99	Positive	Pass	Symptomatic	Saliva	Positive
100	Positive	Pass	Symptomatic	Saliva	Positive
101	Negative	Pass	/	Saliva	Negative
102	Negative	Pass	/	Saliva	Negative
103	Negative	Pass	/	Saliva	Negative
104	Negative	Pass	/	Saliva	Negative
105	Negative	Pass	/	Saliva	Negative
106	Negative	Pass	/	Saliva	Negative
107	Negative	Pass	/	Saliva	Negative
108	Negative	Pass	/	Saliva	Negative
109	Negative	Pass	/	Saliva	Negative
110	Negative	Pass	/	Saliva	Negative
111	Negative	Pass	/	Saliva	Negative



Sample Number	PCR Result	Control	Symptom	Type	Result
112	Negative	Pass	/	Saliva	Negative
113	Negative	Pass	/	Saliva	Negative
114	Negative	Pass	/	Saliva	Negative
115	Negative	Pass	/	Saliva	Negative
116	Negative	Pass	/	Saliva	Negative
117	Negative	Pass	/	Saliva	Negative
118	Negative	Pass	/	Saliva	Negative
119	Negative	Pass	/	Saliva	Negative
120	Negative	Pass	/	Saliva	Negative
121	Negative	Pass	/	Saliva	Negative
122	Negative	Pass	/	Saliva	Negative
123	Negative	Pass	/	Saliva	Negative
124	Negative	Pass	/	Saliva	Negative
125	Negative	Pass	/	Saliva	Negative
126	Negative	Pass	/	Saliva	Negative
127	Negative	Pass	/	Saliva	Negative
128	Negative	Pass	/	Saliva	Negative
129	Negative	Pass	/	Saliva	Negative
130	Negative	Pass	/	Saliva	Negative
131	Negative	Pass	/	Saliva	Negative
132	Negative	Pass	/	Saliva	Negative
133	Negative	Pass	/	Saliva	Negative
134	Negative	Pass	/	Saliva	Negative
135	Negative	Pass	/	Saliva	Negative
136	Negative	Pass	/	Saliva	Negative
137	Negative	Pass	/	Saliva	Negative
138	Negative	Pass	/	Saliva	Negative
139	Negative	Pass	/	Saliva	Negative
140	Negative	Pass	/	Saliva	Positive
141	Negative	Pass	/	Saliva	Negative



Sample Number	PCR Result	Control	Symptom	Type	Result
142	Negative	Pass	/	Saliva	Negative
143	Negative	Pass	/	Saliva	Negative
144	Negative	Pass	/	Saliva	Negative
145	Negative	Pass	/	Saliva	Negative
146	Negative	Pass	/	Saliva	Negative
147	Negative	Pass	/	Saliva	Negative
148	Negative	Pass	/	Saliva	Negative
149	Negative	Pass	/	Saliva	Negative
150	Negative	Pass	/	Saliva	Negative
151	Negative	Pass	/	Saliva	Negative
152	Negative	Pass	/	Saliva	Negative
153	Negative	Pass	/	Saliva	Negative
154	Negative	Pass	/	Saliva	Negative
155	Negative	Pass	/	Saliva	Negative
156	Negative	Pass	/	Saliva	Negative
157	Negative	Pass	/	Saliva	Negative
158	Negative	Pass	/	Saliva	Negative
159	Negative	Pass	/	Saliva	Negative
160	Negative	Pass	/	Saliva	Negative
161	Negative	Pass	/	Saliva	Negative
162	Negative	Pass	/	Saliva	Positive
163	Negative	Pass	/	Saliva	Negative
164	Negative	Pass	/	Saliva	Negative
165	Negative	Pass	/	Saliva	Negative
166	Negative	Pass	/	Saliva	Negative
167	Negative	Pass	/	Saliva	Negative
168	Negative	Pass	/	Saliva	Negative
169	Negative	Pass	/	Saliva	Negative
170	Negative	Pass	/	Saliva	Negative
171	Negative	Pass	/	Saliva	Negative





Sample Number	PCR Result	Control	Symptom	Type	Result
172	Negative	Pass	/	Saliva	Negative
173	Negative	Pass	/	Saliva	Negative
174	Negative	Pass	/	Saliva	Negative
175	Negative	Pass	/	Saliva	Negative
176	Negative	Pass	/	Saliva	Positive
177	Negative	Pass	/	Saliva	Negative
178	Negative	Pass	/	Saliva	Negative
179	Negative	Pass	/	Saliva	Negative
180	Negative	Pass	/	Saliva	Negative
181	Negative	Pass	/	Saliva	Negative
182	Negative	Pass	/	Saliva	Negative
183	Negative	Pass	/	Saliva	Negative
184	Negative	Pass	/	Saliva	Negative
185	Negative	Pass	/	Saliva	Negative
186	Negative	Pass	/	Saliva	Negative
187	Negative	Pass	/	Saliva	Negative
188	Negative	Pass	/	Saliva	Negative
189	Negative	Pass	/	Saliva	Negative
190	Negative	Pass	/	Saliva	Negative
191	Negative	Pass	/	Saliva	Negative
192	Negative	Pass	/	Saliva	Negative
193	Negative	Pass	/	Saliva	Negative
194	Negative	Pass	/	Saliva	Positive
195	Negative	Pass	/	Saliva	Negative
196	Negative	Pass	/	Saliva	Negative
197	Negative	Pass	/	Saliva	Negative
198	Negative	Pass	/	Saliva	Negative
199	Negative	Pass	/	Saliva	Negative
200	Negative	Pass	/	Saliva	Negative