

# Clinical Performance Evaluation Report of COVID-19 Antigen Rapid Test

## 1. Objective

The CLUNGENE<sup>®</sup> COVID-19 Antigen Rapid Test (hereinafter referred to as the CLUNGENE Device) manufactured by Hangzhou Clongene Biotech Co., Ltd. is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.

This study is intended to evaluate the clinical performance, between the CLUNGENE Device and the comparator RT-PCR assay.

## 2. Method

A study of 285 direct nasopharyngeal swabs was performed. The specimens were collected from symptomatic patients suspected of COVID-19 at 3 locations and tested at a single central laboratory.

Two nasopharyngeal swabs were collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. At all locations, one nasopharyngeal swab was immediately frozen at -70°C for later testing, and the other swab was eluted in 3 mL viral transport media and tested with RT-PCR assay for detection of SARS-CoV-2. A total of 285 retrospective nasopharyngeal swab specimens within a pre-specified date range were selected and then tested by the CLUNGENE Device in a blinded fashion. The operators were blinded to the RT-PCR test results. The PPA, NPA and the 95% confidence interval (CI) were calculated.

## 3. Enrollment criteria (inclusion/exclusion criteria)

### 3.1 Inclusion criteria

- Individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

### 3.2 Exclusion criteria

- Unable to obtain samples of information needed for the experiment
- Samples that have been contaminated or contaminated during sample storage
- Samples with inappropriate storage conditions

## 4. Product information

Evaluation reagent	COVID-19 Antigen Rapid Test		
Batch No.	2020050130	Storage condition	4~30°C
Valid until	2022-04	Manufacturer	Hangzhou Clongene Biotech Co., Ltd.

RT-PCR reagent	Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2		
NMPA Registration No.	国械注准 20203400065		
Manufacturer	BGI Genomics Co. Ltd.	Storage condition	lower than -18°C

## 5. Result

The results are summarized in the following table.

COVID-19 Antigen		RT-PCR		Total
		Positive	Negative	
CLUNGENE <sup>®</sup> Device	Positive	64	0	64
	Negative	6*	215	221
Total		70	215	285

Positive Percent Agreement (PPA)= True Positive / (True Positive + False Negative)

PPA: 91.4% (64/70), (95%CI: 82.5%~96.0%)

Negative Percent Agreement (NPA) = True Negative / (True Negative + False Positive)

NPA: 100% (215/215), (95%CI: 98.2%~100%)

\* The 6 discordant specimens (CLUNGENE Device Negative/ Comparator RT-PCR assay Positive) had Ct Values of 34, 36, 35.5, 34, 35 and 33.

The PPA is 98.5% (64/65) (95%CI: 91.8%~99.7%) with specimens of a Ct count  $\leq 33$ .

## 6. Conclusion

Taken together, the CLUNGENE Antigen Rapid Test had a positive percent agreement (sensitivity) of 91.4% (95% CI: 82.5%~96.0%) and negative percent agreement (specificity) of 100% (95% CI: 98.2%~100%). The PPA is 98.5% (64/65) (95%CI: 91.8%~99.7%) with specimens of a Ct count  $\leq 33$ .

Evaluation organization (seal):

Date: September 10, 2020



**Clinic Data of Positive Specimens:**

No.	Age	Gender	Swab Specimen Collection Data	Days After Symptom Onset	RT-PCR		CLUNGENE Device Test Result
					Ct Value	Result	
1	32	Male	2020-02-21	2	24.13	Positive	Positive
2	63	Female	2020-02-21	5	27.96	Positive	Positive
3	40	Male	2020-02-25	6	30.27	Positive	Positive
4	26	Female	2020-02-26	4	22.31	Positive	Positive
5	50	Female	2020-02-28	3	21.16	Positive	Positive
6	53	Male	2020-02-29	6	30.20	Positive	Positive
7	41	Female	2020-02-29	7	29.48	Positive	Positive
8	34	Male	2020-03-01	5	27.23	Positive	Positive
9	63	Male	2020-03-05	1	22.36	Positive	Positive
10	52	Male	2020-03-06	6	34.18	Positive	Negative
11	64	Female	2020-03-10	3	20.54	Positive	Positive
12	64	Female	2020-03-20	1	21.72	Positive	Positive
13	25	Male	2020-03-20	6	33.14	Positive	Positive
14	15	Male	2020-03-22	4	23.03	Positive	Positive
15	19	Female	2020-03-24	2	24.82	Positive	Positive
16	67	Female	2020-03-24	7	32.26	Positive	Positive
17	35	Male	2020-03-26	7	36.14	Positive	Negative
18	70	Male	2020-03-28	3	20.47	Positive	Positive
19	45	Female	2020-03-31	5	25.94	Positive	Positive
20	20	Female	2020-03-31	1	22.57	Positive	Positive
21	33	Male	2020-04-02	4	21.55	Positive	Positive
22	21	Male	2020-04-03	3	23.46	Positive	Positive
23	54	Male	2020-04-04	5	26.51	Positive	Positive
24	63	Female	2020-04-06	5	27.48	Positive	Positive
25	59	Female	2020-04-08	3	23.88	Positive	Positive
26	64	Male	2020-04-12	4	24.96	Positive	Positive
27	71	Male	2020-04-17	4	24.05	Positive	Positive
28	25	Female	2020-04-17	5	28.16	Positive	Positive
29	13	Male	2020-04-19	5	24.15	Positive	Positive
30	62	Female	2020-04-21	5	25.53	Positive	Positive
31	23	Male	2020-04-21	3	25.06	Positive	Positive
32	29	Female	2020-04-29	6	30.22	Positive	Positive
33	46	Female	2020-07-23	6	29.36	Positive	Positive
34	51	Male	2020-07-27	5	28.50	Positive	Positive
35	30	Male	2020-07-27	5	26.08	Positive	Positive
36	47	Female	2020-08-04	5	31.17	Positive	Positive
37	32	Female	2020-08-05	1	20.93	Positive	Positive
38	46	Male	2020-08-11	4	23.52	Positive	Positive
39	25	Male	2020-08-11	6	30.89	Positive	Positive
40	44	Female	2020-08-17	7	32.10	Positive	Positive
41	49	Female	2020-08-17	7	35.53	Positive	Negative

42	23	Male	2020-08-17	7	29.46	Positive	Positive
43	50	Male	2020-08-18	2	24.35	Positive	Positive
44	36	Male	2020-08-18	4	21.29	Positive	Positive
45	38	Female	2020-08-18	6	34.11	Positive	Negative
46	63	Female	2020-08-19	7	28.45	Positive	Positive
47	55	Male	2020-08-24	3	22.01	Positive	Positive
48	28	Male	2020-08-24	2	20.72	Positive	Positive
49	25	Female	2020-08-24	6	28.41	Positive	Positive
50	30	Female	2020-08-24	5	27.37	Positive	Positive
51	42	Male	2020-08-24	7	28.12	Positive	Positive
52	25	Male	2020-08-25	6	31.08	Positive	Positive
53	48	Male	2020-08-25	7	30.24	Positive	Positive
54	40	Female	2020-08-25	6	28.63	Positive	Positive
55	51	Female	2020-08-25	4	23.17	Positive	Positive
56	62	Male	2020-08-25	4	23.95	Positive	Positive
57	58	Female	2020-08-25	2	24.35	Positive	Positive
58	47	Female	2020-08-26	6	27.22	Positive	Positive
59	57	Male	2020-08-26	3	21.65	Positive	Positive
60	43	Male	2020-08-27	3	20.34	Positive	Positive
61	54	Female	2020-08-27	7	35.02	Positive	Negative
62	58	Male	2020-08-27	4	25.27	Positive	Positive
63	62	Female	2020-08-27	6	32.98	Positive	Negative
64	60	Male	2020-08-27	2	23.35	Positive	Positive
65	39	Female	2020-08-27	1	23.76	Positive	Positive
66	47	Female	2020-08-27	3	25.43	Positive	Positive
67	55	Male	2020-08-28	2	23.69	Positive	Positive
68	28	Male	2020-08-28	7	32.77	Positive	Positive
69	35	Female	2020-08-28	2	24.81	Positive	Positive
70	40	Male	2020-08-28	4	26.45	Positive	Positive

Remark: A specimen is positive for SARS-CoV-2 if the Ct value of ORF1ab gene is not higher than 37.

Operator/ Date:  2020.09.10       2020.09.10

**Clinic Data of Negative Specimens:**

No.	Age	Gender	Swab Specimen Collection Data	RT-PCR		CLUNGENE Device Test Result
				Ct Value	Result	
1	60	Male	2020-06-10	0	Negative	Negative
2	52	Male	2020-06-10	0	Negative	Negative
3	21	Female	2020-06-10	0	Negative	Negative
4	54	Female	2020-06-10	0	Negative	Negative
5	58	Male	2020-06-10	0	Negative	Negative
6	27	Female	2020-06-10	0	Negative	Negative
7	61	Male	2020-06-10	0	Negative	Negative
8	58	Male	2020-06-10	0	Negative	Negative
9	35	Male	2020-06-10	0	Negative	Negative
10	26	Female	2020-06-10	0	Negative	Negative
11	17	Male	2020-06-10	0	Negative	Negative
12	30	Female	2020-06-10	0	Negative	Negative
13	52	Female	2020-06-10	0	Negative	Negative
14	58	Female	2020-06-10	0	Negative	Negative
15	42	Male	2020-06-10	0	Negative	Negative
16	45	Female	2020-06-10	0	Negative	Negative
17	26	Female	2020-06-10	0	Negative	Negative
18	65	Female	2020-06-10	0	Negative	Negative
19	20	Female	2020-06-10	0	Negative	Negative
20	23	Female	2020-06-10	0	Negative	Negative
21	40	Male	2020-06-10	0	Negative	Negative
22	48	Female	2020-06-10	0	Negative	Negative
23	49	Female	2020-06-11	0	Negative	Negative
24	28	Female	2020-06-11	0	Negative	Negative
25	58	Female	2020-06-11	0	Negative	Negative
26	46	Female	2020-06-11	0	Negative	Negative
27	33	Male	2020-06-11	0	Negative	Negative
28	64	Male	2020-06-11	0	Negative	Negative
29	48	Female	2020-06-11	0	Negative	Negative
30	18	Male	2020-06-11	0	Negative	Negative
31	49	Female	2020-06-11	0	Negative	Negative
32	25	Male	2020-06-11	0	Negative	Negative
33	56	Male	2020-06-11	0	Negative	Negative
34	53	Male	2020-06-11	0	Negative	Negative
35	59	Male	2020-06-11	0	Negative	Negative
36	6	Male	2020-06-11	0	Negative	Negative
37	48	Male	2020-06-11	0	Negative	Negative
38	37	Male	2020-06-11	0	Negative	Negative
39	47	Female	2020-06-11	0	Negative	Negative
40	29	Female	2020-06-15	0	Negative	Negative
41	18	Female	2020-06-15	0	Negative	Negative

42	56	Male	2020-06-15	0	Negative	Negative
43	22	Female	2020-06-15	0	Negative	Negative
44	59	Male	2020-06-15	0	Negative	Negative
45	12	Male	2020-06-15	0	Negative	Negative
46	63	Female	2020-06-15	0	Negative	Negative
47	47	Male	2020-06-15	0	Negative	Negative
48	33	Male	2020-06-15	0	Negative	Negative
49	48	Female	2020-06-15	0	Negative	Negative
50	48	Female	2020-06-15	0	Negative	Negative
51	43	Female	2020-06-15	0	Negative	Negative
52	58	Female	2020-06-15	0	Negative	Negative
53	49	Female	2020-06-15	0	Negative	Negative
54	63	Male	2020-06-15	0	Negative	Negative
55	37	Male	2020-06-15	0	Negative	Negative
56	24	Female	2020-06-15	0	Negative	Negative
57	45	Female	2020-06-15	0	Negative	Negative
58	30	Female	2020-06-15	0	Negative	Negative
59	52	Male	2020-06-15	0	Negative	Negative
60	19	Male	2020-06-15	0	Negative	Negative
61	30	Female	2020-06-15	0	Negative	Negative
62	27	Female	2020-06-15	0	Negative	Negative
63	36	Female	2020-06-15	0	Negative	Negative
64	48	Male	2020-06-15	0	Negative	Negative
65	45	Male	2020-06-15	0	Negative	Negative
66	47	Male	2020-06-15	0	Negative	Negative
67	59	Female	2020-06-15	0	Negative	Negative
68	42	Male	2020-06-15	0	Negative	Negative
69	44	Male	2020-06-15	38.16	Negative	Negative
70	57	Female	2020-06-15	0	Negative	Negative
71	25	Female	2020-06-15	0	Negative	Negative
72	50	Female	2020-06-15	0	Negative	Negative
73	47	Male	2020-06-15	0	Negative	Negative
74	62	Male	2020-06-15	0	Negative	Negative
75	34	Male	2020-06-15	0	Negative	Negative
76	37	Male	2020-06-16	0	Negative	Negative
77	39	Male	2020-06-16	0	Negative	Negative
78	18	Female	2020-06-16	0	Negative	Negative
79	63	Female	2020-06-16	0	Negative	Negative
80	36	Male	2020-06-16	0	Negative	Negative
81	21	Female	2020-06-16	0	Negative	Negative
82	32	Female	2020-06-16	0	Negative	Negative
83	59	Female	2020-06-16	0	Negative	Negative
84	34	Male	2020-06-16	0	Negative	Negative
85	22	Male	2020-06-16	0	Negative	Negative
86	26	Male	2020-06-16	0	Negative	Negative

87	55	Female	2020-06-16	0	Negative	Negative
88	53	Male	2020-06-16	0	Negative	Negative
89	24	Female	2020-06-17	0	Negative	Negative
90	63	Male	2020-06-17	0	Negative	Negative
91	72	Male	2020-06-17	0	Negative	Negative
92	24	Female	2020-06-17	0	Negative	Negative
93	19	Male	2020-06-17	0	Negative	Negative
94	33	Female	2020-06-17	0	Negative	Negative
95	59	Male	2020-06-17	0	Negative	Negative
96	36	Male	2020-06-18	0	Negative	Negative
97	53	Male	2020-06-18	0	Negative	Negative
98	20	Female	2020-06-18	0	Negative	Negative
99	53	Male	2020-06-18	0	Negative	Negative
100	44	Female	2020-06-18	0	Negative	Negative
101	20	Female	2020-06-18	0	Negative	Negative
102	65	Female	2020-06-18	0	Negative	Negative
103	37	Female	2020-06-18	0	Negative	Negative
104	25	Male	2020-06-18	0	Negative	Negative
105	57	Male	2020-06-18	0	Negative	Negative
106	65	Male	2020-06-18	0	Negative	Negative
107	23	Male	2020-06-18	0	Negative	Negative
108	53	Male	2020-06-18	0	Negative	Negative
109	35	Male	2020-06-18	0	Negative	Negative
110	50	Female	2020-06-18	0	Negative	Negative
111	60	Female	2020-06-18	0	Negative	Negative
112	21	Male	2020-06-19	0	Negative	Negative
113	63	Female	2020-06-19	0	Negative	Negative
114	49	Female	2020-06-19	0	Negative	Negative
115	49	Female	2020-06-19	0	Negative	Negative
116	18	Male	2020-06-19	0	Negative	Negative
117	20	Male	2020-06-19	0	Negative	Negative
118	44	Male	2020-06-19	0	Negative	Negative
119	25	Female	2020-06-19	0	Negative	Negative
120	19	Male	2020-06-19	0	Negative	Negative
121	55	Female	2020-06-19	0	Negative	Negative
122	30	Male	2020-06-19	0	Negative	Negative
123	18	Male	2020-06-19	0	Negative	Negative
124	59	Female	2020-06-20	0	Negative	Negative
125	41	Male	2020-06-20	0	Negative	Negative
126	54	Female	2020-06-20	0	Negative	Negative
127	11	Male	2020-06-20	0	Negative	Negative
128	34	Male	2020-06-20	0	Negative	Negative
129	21	Male	2020-06-20	0	Negative	Negative
130	36	Female	2020-06-20	0	Negative	Negative
131	44	Male	2020-08-05	0	Negative	Negative

132	27	Male	2020-08-05	0	Negative	Negative
133	10	Female	2020-08-05	0	Negative	Negative
134	54	Female	2020-08-11	0	Negative	Negative
135	25	Male	2020-08-11	0	Negative	Negative
136	58	Male	2020-08-11	0	Negative	Negative
137	33	Male	2020-08-11	0	Negative	Negative
138	69	Female	2020-08-11	0	Negative	Negative
139	25	Female	2020-08-18	0	Negative	Negative
140	57	Male	2020-08-18	0	Negative	Negative
141	51	Female	2020-08-18	0	Negative	Negative
142	9	Female	2020-08-18	0	Negative	Negative
143	17	Male	2020-08-18	0	Negative	Negative
144	40	Male	2020-08-18	0	Negative	Negative
145	68	Female	2020-08-19	0	Negative	Negative
146	32	Male	2020-08-19	39.31	Negative	Negative
147	46	Female	2020-08-24	0	Negative	Negative
148	50	Male	2020-08-24	0	Negative	Negative
149	32	Female	2020-08-24	0	Negative	Negative
150	39	Female	2020-08-24	0	Negative	Negative
151	34	Male	2020-08-25	0	Negative	Negative
152	54	Male	2020-08-25	0	Negative	Negative
153	42	Female	2020-08-25	0	Negative	Negative
154	26	Male	2020-08-25	0	Negative	Negative
155	38	Male	2020-08-25	0	Negative	Negative
156	29	Female	2020-08-25	0	Negative	Negative
157	48	Male	2020-08-25	0	Negative	Negative
158	30	Male	2020-08-25	0	Negative	Negative
159	48	Male	2020-08-25	0	Negative	Negative
160	55	Female	2020-08-25	0	Negative	Negative
161	58	Male	2020-08-25	0	Negative	Negative
162	48	Female	2020-08-25	0	Negative	Negative
163	17	Female	2020-08-25	0	Negative	Negative
164	62	Female	2020-08-25	0	Negative	Negative
165	45	Male	2020-08-25	0	Negative	Negative
166	20	Female	2020-08-25	0	Negative	Negative
167	59	Female	2020-08-25	0	Negative	Negative
168	70	Female	2020-08-25	0	Negative	Negative
169	60	Female	2020-08-25	0	Negative	Negative
170	30	Female	2020-08-25	0	Negative	Negative
171	56	Male	2020-08-25	0	Negative	Negative
172	27	Female	2020-08-25	0	Negative	Negative
173	40	Female	2020-08-25	0	Negative	Negative
174	46	Female	2020-08-25	0	Negative	Negative
175	69	Female	2020-08-25	0	Negative	Negative
176	23	Female	2020-08-25	0	Negative	Negative



177	35	Male	2020-08-25	0	Negative	Negative
178	42	Male	2020-08-25	0	Negative	Negative
179	46	Female	2020-08-25	0	Negative	Negative
180	43	Male	2020-08-25	0	Negative	Negative
181	27	Female	2020-08-25	0	Negative	Negative
182	26	Male	2020-08-25	0	Negative	Negative
183	28	Male	2020-08-25	0	Negative	Negative
184	44	Male	2020-08-26	0	Negative	Negative
185	31	Male	2020-08-26	0	Negative	Negative
186	65	Male	2020-08-26	0	Negative	Negative
187	29	Male	2020-08-26	0	Negative	Negative
188	8	Male	2020-08-26	0	Negative	Negative
189	63	Female	2020-08-26	0	Negative	Negative
190	49	Female	2020-08-26	0	Negative	Negative
191	56	Female	2020-08-26	0	Negative	Negative
192	64	Male	2020-08-26	0	Negative	Negative
193	49	Female	2020-08-26	0	Negative	Negative
194	34	Male	2020-08-26	0	Negative	Negative
195	70	Male	2020-08-26	0	Negative	Negative
196	63	Female	2020-08-26	0	Negative	Negative
197	42	Male	2020-08-26	0	Negative	Negative
198	66	Male	2020-08-27	0	Negative	Negative
199	37	Female	2020-08-27	0	Negative	Negative
200	30	Female	2020-08-27	0	Negative	Negative
201	24	Female	2020-08-27	0	Negative	Negative
202	33	Female	2020-08-27	0	Negative	Negative
203	21	Female	2020-08-27	0	Negative	Negative
204	59	Male	2020-08-27	0	Negative	Negative
205	37	Male	2020-08-27	0	Negative	Negative
206	49	Female	2020-08-27	0	Negative	Negative
207	42	Female	2020-08-27	0	Negative	Negative
208	26	Female	2020-08-27	0	Negative	Negative
209	50	Male	2020-08-27	0	Negative	Negative
210	31	Male	2020-08-27	0	Negative	Negative
211	44	Female	2020-08-28	0	Negative	Negative
212	58	Female	2020-08-28	0	Negative	Negative
213	35	Female	2020-08-28	0	Negative	Negative
214	22	Male	2020-08-28	0	Negative	Negative
215	70	Male	2020-08-28	0	Negative	Negative

Operator/ Date: *PP/KC 2020.09.10*

*陈本新 2020.09.10*