

Test Report

1. INTRODUCTION

1) Study name

Performance evaluation of rapid diagnostic COVID-19 Ag kit

2) Objective

Test for performance evaluation of GenBody COVID-19 Ag kit

3) Investigational Device

GenBody COVID-19 Ag Test (COVAG025)

4) GCP conformation

This clinical trial will be conducted according to international standards of Good Clinical Practice (GCP) and submitted to a properly constituted Institutional Review Board (IRB), in agreement with local legal prescriptions for formal approval of the trial conduct. (IRB No.: YUMC-2020-06-058)

2. STUDY AMINISTRATIVE STRUCTURE

1) **Institution:** Yeungnam University Medical Center

2) Investigator

-**Name:** Jong Ho Lee

-**Position:** Professor (M.D.)

-**Contact (Email) :** leejongho@ynu.ac.kr

-**Role**

- (1) Plan the protocol of clinical evaluation
- (2) Review the result of clinical evaluation
- (3) Writing the test report of clinical evaluation

3) Operator (2 Persons)

-**Position:** *Laborobory staff*

**They were trained for the instructions for use for the GenBody COVID-19 Ag Test.*

-**Role**

- (1) Patient recruitment, Specimen collection
- (2) Test specimen with investigational device
- (3) Analysing the result of clinical evaluation

3. GENERAL INFORMATION

1) Test Date

June 29, 2020

2) Study method

Tests were performed according to instruction for use of 'GenBody COVID-19 Ag Test' with residual nasopharyngeal swab(NPS)s in VTM (Viral Transport Medium) from 30 positive patients confirmed by real-time PCR method and 100 negative person confirmed by real-time PCR.

- (1) Model name/manufacturer for VTM: ESwap™ 482C (COAPN Diagnostic Inc)
T-SWAB TRANSPORT™ CTM (Noble Bio)
- (2) Real-time PCR: Allplex 2019-nCoV assay(Seegene Inc, EUA approved)
- (3) Storage temperature for the specimens in VTM: stored at -70°C *within 3 months*

3) Specimen information

(1) Inclusion criteria

- i. The specimen is confirmed with real-time PCR

(2) Exclusion criteria

- i. Specimens with unclear PCR results
- ii. Specimen information is unclear.
- iii. Contaminated specimens
- iv. Insufficient specimens to test
- v. eNAT™ (COAPN Diagnostic Inc) medium specimens

4) Acceptance Criteria

Control line should be appeared.

4. RESULT

1) Positive specimen (n=30)

No.	Specimen collection date	Medium	Days after symptom onset	Day of PCR testing	Result of Real-time RT-PCR			GenBody COVID-19 Ag
					E	RdRP	N	Result
1	2020-02-28	CTM	4	2020-02-29	18.18	20.57	21.64	Positive
2	2020-02-28	CTM	2	2020-02-29	20.07	21.50	22.80	Positive
3	2020-02-28	CTM	7	2020-02-29	24.68	26.62	27.48	Positive
4	2020-02-28	CTM	7	2020-02-29	16.04	17.18	17.93	Positive
5	2020-02-28	CTM	2	2020-02-29	16.38	17.28	19.01	Positive
6	2020-02-28	CTM	7	2020-02-29	20.96	21.97	23.59	Positive
7	2020-02-28	CTM	5	2020-02-29	21.93	23.31	24.46	Positive
8	2020-02-29	CTM	No symptom	2020-02-29	31.92	28.95	30.97	Negative
9	2020-02-28	CTM	5	2020-03-01	12.82	15.01	16.60	Positive
10	2020-02-28	CTM	3	2020-03-01	19.57	21.43	23.08	Positive
11	2020-02-29	CTM	7	2020-03-01	25.35	26.46	27.78	Positive
12	2020-02-29	CTM	7	2020-03-01	24.02	25.26	25.86	Positive
13	2020-02-29	CTM	7	2020-03-02	31.04	38.43	33.94	Negative
14	2020-03-01	CTM	8	2020-03-02	11.80	14.69	16.34	Positive
15	2020-03-01	CTM	5	2020-03-03	17.47	20.15	20.24	Positive
16	2020-03-01	CTM	14	2020-03-03	28.49	30.50	31.27	Negative
17	2020-03-02	CTM	5	2020-03-03	23.15	24.44	25.16	Positive
18	2020-03-02	CTM	5	2020-03-03	15.32	16.68	18.89	Positive
19	2020-03-01	CTM	8	2020-03-03	25.61	27.91	28.27	Positive
20	2020-03-02	CTM	No symptom	2020-03-03	24.64	25.07	27.79	Positive
21	2020-03-02	CTM	2	2020-03-03	21.73	23.42	24.55	Positive
22	2020-03-02	CTM	8	2020-03-03	17.29	18.71	20.22	Positive
23	2020-03-02	CTM	11	2020-03-03	21.57	22.79	23.62	Positive
24	2020-03-02	CTM	3	2020-03-04	22.24	24.54	25.17	Positive
25	2020-03-02	CTM	3	2020-03-04	24.37	27.13	26.40	Positive
26	2020-03-02	CTM	9	2020-03-04	22.46	23.80	25.02	Positive
27	2020-03-02	CTM	No symptom	2020-03-04	24.75	26.58	27.93	Positive
28	2020-03-02	CTM	No symptom	2020-03-04	26.88	28.29	29.40	Positive
29	2020-03-03	CTM	1	2020-03-04	26.46	29.34	29.73	Positive
30	2020-03-03	CTM	5	2020-03-04	16.18	17.99	20.34	Positive

2) Negative specimens (n=100)

No.	Specimen collection date	Medium	Day of PCR testing	Result of Real-time RT-PCR			GenBody COVID-19 Ag
				E	RdRp	N	Result
1	2020-03-18	CTM	2020-03-18	-	-	-	Negative
2	2020-03-23	CTM	2020-03-23	-	-	-	Negative
3	2020-03-23	CTM	2020-03-23	-	-	-	Negative
4	2020-03-22	CTM	2020-03-22	-	-	-	Negative
5	2020-03-23	CTM	2020-03-23	-	-	-	Negative
6	2020-03-14	CTM	2020-03-14	-	-	-	Negative
7	2020-03-16	CTM	2020-03-16	-	-	-	Negative
8	2020-03-15	CTM	2020-03-15	-	-	-	Negative
9	2020-03-17	CTM	2020-03-17	-	-	-	Negative
10	2020-03-15	CTM	2020-03-15	-	-	-	Negative
11	2020-03-27	CTM	2020-03-27	-	-	-	Negative
12	2020-03-16	CTM	2020-03-16	-	-	-	Negative
13	2020-03-26	CTM	2020-03-26	-	-	-	Negative
14	2020-03-26	CTM	2020-03-26	-	-	-	Negative
15	2020-03-23	CTM	2020-03-23	-	-	-	Negative
16	2020-03-16	CTM	2020-03-16	-	-	-	Negative
17	2020-03-23	CTM	2020-03-23	-	-	-	Negative
18	2020-03-23	CTM	2020-03-23	-	-	-	Negative
19	2020-03-16	CTM	2020-03-16	-	-	-	Negative
20	2020-03-23	CTM	2020-03-23	-	-	-	Negative
21	2020-03-22	CTM	2020-03-22	-	-	-	Negative
22	2020-03-15	CTM	2020-03-15	-	-	-	Negative
23	2020-03-23	CTM	2020-03-23	-	-	-	Negative
24	2020-03-26	CTM	2020-03-26	-	-	-	Negative
25	2020-03-23	CTM	2020-03-23	-	-	-	Negative
26	2020-03-18	CTM	2020-03-18	-	-	-	Negative
27	2020-03-17	CTM	2020-03-17	-	-	-	Negative
28	2020-03-18	CTM	2020-03-18	-	-	-	Negative
29	2020-03-24	CTM	2020-03-24	-	-	-	Negative
30	2020-03-26	CTM	2020-03-26	-	-	-	Negative
31	2020-03-27	CTM	2020-03-27	-	-	-	Negative
32	2020-03-27	CTM	2020-03-27	-	-	-	Negative
33	2020-03-27	CTM	2020-03-27	-	-	-	Negative
34	2020-03-27	CTM	2020-03-27	-	-	-	Negative
35	2020-03-27	CTM	2020-03-27	-	-	-	Negative
36	2020-03-27	CTM	2020-03-27	-	-	-	Negative
37	2020-03-27	CTM	2020-03-27	-	-	-	Negative
38	2020-03-27	CTM	2020-03-27	-	-	-	Negative
39	2020-03-27	CTM	2020-03-27	-	-	-	Negative
40	2020-03-27	CTM	2020-03-27	-	-	-	Negative
41	2020-03-27	CTM	2020-03-27	-	-	-	Negative
42	2020-03-27	CTM	2020-03-27	-	-	-	Negative
43	2020-03-27	CTM	2020-03-27	-	-	-	Negative
44	2020-03-27	CTM	2020-03-27	-	-	-	Negative
45	2020-03-27	CTM	2020-03-27	-	-	-	Negative
46	2020-03-27	CTM	2020-03-27	-	-	-	Negative
47	2020-03-27	CTM	2020-03-27	-	-	-	Negative
48	2020-03-27	CTM	2020-03-27	-	-	-	Negative
49	2020-03-27	CTM	2020-03-27	-	-	-	Negative
50	2020-03-27	CTM	2020-03-27	-	-	-	Negative
51	2020-03-27	CTM	2020-03-27	-	-	-	Negative
52	2020-03-28	CTM	2020-03-28	-	-	-	Negative
53	2020-03-28	CTM	2020-03-28	-	-	-	Negative
54	2020-03-28	ESwab	2020-03-28	-	-	-	Positive

No.	Specimen collection date	Medium	Day of PCR testing	Result of Real-time RT-PCR			GenBody COVID-19 Ag
				E	RdRp	N	Result
55	2020-03-28	ESwab	2020-03-28	-	-	-	Negative
56	2020-03-28	ESwab	2020-03-28	-	-	-	Negative
57	2020-03-28	ESwab	2020-03-28	-	-	-	Negative
58	2020-03-28	ESwab	2020-03-28	-	-	-	Negative
59	2020-03-28	ESwab	2020-03-28	-	-	-	Negative
60	2020-03-28	ESwab	2020-03-28	-	-	-	Negative
61	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
62	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
63	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
64	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
65	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
66	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
67	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
68	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
69	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
70	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
71	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
72	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
73	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
74	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
75	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
76	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
77	2020-04-01	ESwab	2020-04-01	-	-	-	Positive
78	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
79	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
80	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
81	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
82	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
83	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
84	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
85	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
86	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
87	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
88	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
89	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
90	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
91	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
92	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
93	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
94	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
95	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
96	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
97	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
98	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
99	2020-04-01	ESwab	2020-04-01	-	-	-	Negative
100	2020-04-01	ESwab	2020-04-01	-	-	-	Negative

5. DATA ANALYSIS

		Real-time RT-PCR		Total
		+	-	
GenBody COVID-19 Ag Test	+	27	2	29
	-	3	98	101
Total		30	100	130

- **Sensitivity:** 90.00% (27/30), 95% CI 73.47% to 97.89%
- **Specificity:** 98.00% (98/100), 95% CI 92.96% to 99.76%

6. CONCLUSION

The clinical evaluation for the GenBody COVID-19 Ag Test for rapid detection of SARS-CoV-2 antigen was conducted at the Yeungnam University Medical Center in Korea, 130 residual and selected specimens in VTM from persons, who were hospitalized or visited, were tested with comparing to commercialized molecular assays.

The GenBody COVID-19 Ag Test showed 90% of sensitivity and 98% of specificity. Among the positive specimens confirmed by real-time PCR, COVID-19 Ag was not detected when the Ct values of each genes in the real-time PCR results were high(weak positive). It is expected that better results were obtained from fresh specimens than from residual specimens.

The limitation of our study was a small number of specimens (positive specimens;30, negative specimens; 100).

Hereby, I confirm that the above is true.

June 30, 2020

Principal Investigator

Jong Ho Lee

Signature

