GenBody Inc.
(주)젠바디

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Clinical Study Report

Of

GenBody COVID-19 IgM/IgG RDT

Product:	**GenBody COVID-19 IgM/IgG**
Date:	**2020-03-20**

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Clinical evaluation of GenBody COVID-19 IgM/IgG Rapid Diagnostic Test

1. Introduction

The outbreak of the novel coronavirus (COVID-19) rapidly transmit all over China and lots of countries. Although molecular test (RT-PCR) has become the standard method for diagnosis of this disease, the method have many limitations. In addition, high false negative rates were reported. There is an urgent need for an accurate and rapid testing method that quickly identify large number of infected patients andasymptomatic carriers to prevent virus transmission and assure timely treatment of patients. GenBody COVID-19 IgM/IgG device is a chromatographic immunoassay kit for the rapid and differential detection of immunoglobulin M (IgM) and immunoglobulin G (IgG) against COVID-19 using serum, plasma and whole blood.

The recombinant COVID-19 antigen was coated on the membrane and anti-human IgM and IgG monoclonal antibody was conjugated the gold particles, respectively. When the specimen existing anti-COVID-19 antibodies is loaded into a sample well (S), the antibodies are complexed with anti-human IgM (or IgG) gold conjugate. And this complex migrates and captured by the immobilized recombinant COVID-19 antigens to make a visible band in the test line regions, M and G. The solution continues to migrate to the control line (C) region that binds a control conjugate, thereby producing another red line. GenBody COVID-19 IgM/IgG can detect the antibodies against COVID-19, so that the device is suitable for the diagnosis of COVID-19 infections.

2. Study purpose

To evaluate the clinical performance of GenBody COVID-19 IgM/IgG Rapid Test.

3. Seroconversional study of GenBody IgM/IgG Rapid Test

3.1 Clinical Study of GenBody COVID-19 IgM/IgG with seroconversional specimens

3.2 Study design

1) One lot of device
2) Origin of clinical samples: Dankook University Hospital (Korea, IRB-202003026)
3) One time per sample
4) Instrument: N/A

5) One operator
6) Sample type: serum, plasma, whole blood
7) Study site: Dankook University Hospital (Korea, IRB-202003026)
8) Study period: Feb. 15 2020 ~ Mar. 20, 2020.

3.3. Acceptance criteria & Standards

Positive: +

Negative: -

3.4 Methods of statistical analysis

A. Instrument

N/A

B. Reagent & Material

① Test device: GenBody COVID-19 IgM/IgG

② Reference method: RT-PCR (Seegene Inc.)

C. Sample preparation

Under the approval IRB (Institutional Review Board) in the hospital, we selected two patients who agreed and signed this study. We took their bloods at every day for checking the seroconversional studies of GenBody COVID-19 IgM/IgG.

D. Test procedure

1) All specimens and test devices should be prepared with warm condition, that is, for 15~30 min at room temperature before testing.
2) All testing were followed by the kit manual.

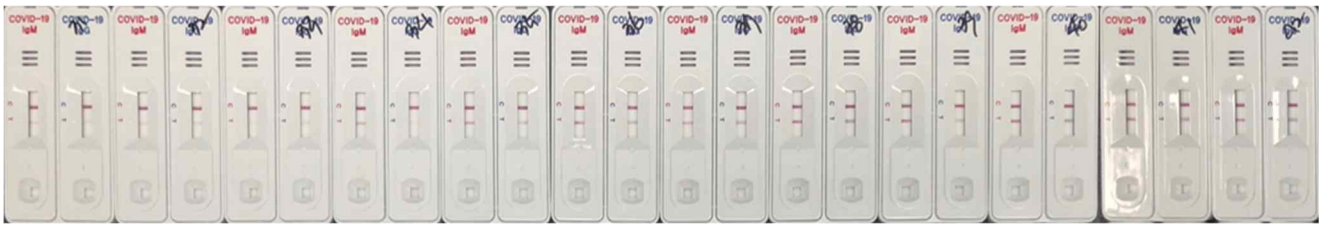
E. Characterization of specimens

Patient	Age	Sex	Infection date	Day from infection	Number of specimen
ID0XXXDK	45	Male	Feb. 27, 2020, from mother's in law	5 days	9 sample (Mar. 03, 04, 06, 07, 08, 10, 11, 13, 14)
ID1XXXDK	38	Female	March 7, 2020, from husband	3 days	12 samples (Mar. 11 (morning/afternoon/night), 12, 13, 14, 15, 16 (before noon/afternoon), 17 (before noon/afternoon), 19

3.5 Results

① Patient I (ID0XXXDK)

- Sensitivity of GenBody IgM/IgG: 100%

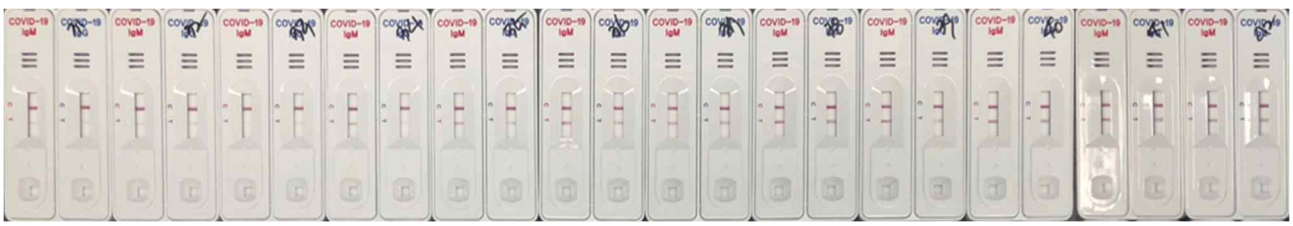


Sample	2020-03-11(1)		2020-03-11(2)		2020-03-11(3)		2020-03-12		2020-03-13		2020-03-14		2020-03-15		2020-03-16(1)		2020-03-16(2)		2020-03-17(1)		2020-03-17(2)		2020-03-19	
result	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Confiscope G20 Raw data	655,366	936,251	759,728	950,036	368,965	246,545	195,441	2,081,137	1,035,130	2,445,731	1,460,743	3,089,387	1,546,842	1,907,032	2,418,757	4,106,909	1,190,445	4,093,522	2,649,952	4,655,336	2,166,324	2,928,624	2,080,084	3,458,473
ELISA (S/CO)	2.18	2.80	2.53	2.86	1.22	0.74	0.64	4.22	2.76	4.24	3.89	4.66	4.13	4.72	5.42	4.62	3.18	4.60	4.69	4.80	4.58	4.70	4.47	4.58

- Serologial spectrum of COVID-19 infected patient

② Patient II (ID1XXXDK)

- Sensitivity of GenBody IgM/IgG: 100%



Sample	2020-03-11(1)		2020-03-11(2)		2020-03-11(3)		2020-03-12		2020-03-13		2020-03-14		2020-03-15		2020-03-16(1)		2020-03-16(2)		2020-03-17(1)		2020-03-17(2)		2020-03-19	
result	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Confiscope G20 Raw data	655,366	936,251	759,728	950,036	368,965	246,545	195,441	2,081,137	1,035,130	2,445,731	1,460,743	3,089,387	1,546,842	1,907,032	2,418,757	4,106,909	1,190,445	4,093,522	2,649,952	4,655,336	2,166,324	2,928,624	2,080,084	3,458,473
ELISA (S/CO)	2.18	2.80	2.53	2.86	1.22	0.74	0.64	4.22	2.76	4.24	3.89	4.66	4.13	4.72	5.42	4.62	3.18	4.60	4.69	4.80	4.58	4.70	4.47	4.58

- Serologial spectrum of COVID-19 infected patient

3.6 Summary of results

We have evaluated two seroconversional blood samples from two patients. The first patient ID0XXXDK was 45-year old man who took the COVID-19 infection at Feb. 27 from his mother's-in-law. After 5 days, he felt the sickness and hospitalized and confirmed by 3 days later as COVID-19. Another patient ID1XXDK was 38-year old women who took the virus infection at Mar. 7 from his husband. After 3 days, she was hospitalized from the symptoms and then confirmed 3 days after. We prepared the seroconversional specimens from them (9 cases from ID0XXDK and 12 cases from ID1XXDK).

Using these two seroconversional specimens (total 9 + 12 = 21 cases), GenBody COVID-19 IgM/IgG Rapid test showed the excellent sensitivity (100%). In especial, the RDT kit showed very good co-relationship with common serological spectrum of viral infection.

It means that, even though there was only two cases, the RDT kit can be useful for the serological test of COVID-19 at 3 or 5 days after its infection.

4. Clinical Evaluation/Diagnostic sensitivity & specificity

4.1. Clinical Study of GenBody COVID-19 IgM/IgG with clinical samples

4.2. Study design

① One lot of device

② Origin of clinical samples: Dankook University Hospital (Korea, IRB-202003026)

③ One time per sample
④ Instrument: N/A
⑤ One operator
⑥ Sample type: serum, plasma, whole blood
⑦ Study site: Dankook University Hospital (Korea, IRB-202003026)
⑧ Study period: Feb. 15 2020 ~ Mar. 20, 2020.

4.3 Acceptance criteria & Standards

Positive: +
Negative: -

4.4. Methods of statistical analysis

A. Instrument

N/A

B. Reagent & Material

① Test device: GenBody COVID-19 IgM/IgG
② Reference method: RT-PCR (Seegene Inc.)

C. Sample preparation

A study was performed by skilled clinicians using total 159 sera (39 positives and 120 negatives) that were collected by Dankook University Hospital (under IRB approval).

D. Test procedure

1) All specimens and test devices should be prepared with warm condition, that is, for 15~30 min at room temperature before testing.
2) All testing were followed by the kit manual.

E. Characterization of specimens

Total 159 blood specimens (Positive: 39, Negative: 120) were collected under the IRB regulation (IRB No. – 202003026) in Dankook University Hospitals. For the recommendation of IRB, all the specimen donors were agreed and signed on the agreement for the clinical testing use.

For the characterization of the samples, we have carried out RT-PCR kit (Allplex COVID-19) purchased from Seegene Inc. (in Korea). Total 39 cases were positive in the molecular test and another 120 cases were collected at 2019 when COVID-19 was not generated in Korea, so that they should be negative for COVID-19. These 159 specimens characterized were used for the clinical evaluation for GenBody COVID-19 IgM/IgG for finding out its diagnostic accuracy.

F. Results

① For IgM

For IgM N= 159		RT-PCR		
		Positive		Negative
		Phase I	Phase II	
GenBody COVID-19 IgM/IgG	Positive	3	25	1
	Negative	6	5	119
Total		9	30	120

- Sensitivity (Phase I/Phase II)= 30% (3/9) / 83% (25/30)
- Specificity= 99% (119/120)

② For IgG

For IgG N= 159		RT-PCR		
		Positive		Negative
		Phase I	Phase II	
GenBody COVID-19 IgM/IgG	Positive	0	30	0
	Negative	9	0	120
Total		9	30	120

- Sensitivity (Phase I/Phase II)= 0% (0/9) / 100% (30/30)
- Specificity= 100% (120/120)

G. Summary of results

GenBody COVID-19 IgM/IgG Rapid test showed the excellent sensitivity and specificity Phase II. Its overal diagnostic performance was the below. However, at the phase I, its diagnostic accuracy was low because there was not enough time

to generate the antibodies after infections (30% of sensitivity and 99.5% of specificity).

1) Phase I (Day 1 ~ 6)

- **Sensitivity= 30% for IgM, 0% for IgG**
- **Specificity= 99% for IgM, 100% for IgG**

2) Phase II (Day 7 ~)

- **Sensitivity= 83% for IgM, 100% for IgG**
- **Specificity= 99% for IgM, 100% for IgG**

3) Overal Diagnostic Accuracy of Phase II (Day 7 ~): combined with IgG and IgM. (IgG + IgM combination) vs (RT-PCR)

- **Sensitivity= 100%**
- **Specificity= 99.5%**

H. Conclusion

The overal sensitivity and specificity of GenBody COVID-19 IgM/IgG was 100% and 99.5%, respectively, comparing with molecular testing (RT-PCR), which are combinated calculation of IgM and IgG.

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[Dataset] Clinical study raw data (Positive: 39, Negative: 120)]

Phase I- Day 1 ~ 6 from symptom, phase II- after Day 7.

(+, Positive; N, Negative)

No	Specimen	Sample collection time	RT-PCR	GenBody COVID-19 IgM/IgG	
				IgM	IgG
1	DK011020	Phase I	+	N	N
2	DK021020	Phase I	+	N	N
3	DK111020	Phase I	+	N	N
4	DK011023	Phase I	+	P	N
5	DK011024	Phase I	+	P	N
6	DK021021	Phase I	+	N	N
7	DK021022	Phase I	+	N	N
8	DB021020	Phase I	+	P	N
9	DB021024	Phase I	+	N	N
10	DK121020	Phase II	+	+	+
11	DK121120	Phase II	+	+	+
12	DK121121	Phase II	+	+	+
13	DK121122	Phase II	+	+	+
14	DK121123	Phase II	+	N	+
15	DK121124	Phase II	+	+	+
16	DK121125	Phase II	+	+	+
17	DK121126	Phase II	+	+	+
18	DK121127	Phase II	+	+	+
19	DK121128	Phase II	+	N	+
20	DK121129	Phase II	+	+	+
21	DK122101	Phase II	+	N	+
22	DK122102	Phase II	+	+	+
23	DK122103	Phase II	+	+	+
24	DK122104	Phase II	+	+	+
25	DK122105	Phase II	+	+	+
26	DK122106	Phase II	+	+	+
27	DK122107	Phase II	+	+	+
28	DB122001	Phase II	+	+	+
29	DB122002	Phase II	+	+	+
30	DB122003	Phase II	+	+	+
31	DB122004	Phase II	+	+	+
32	DB122005	Phase II	+	+	+
33	DB122006	Phase II	+	+	+
34	DB122007	Phase II	+	N	+
35	DB122008	Phase II	+	N	+
36	DB122009	Phase II	+	+	+
37	DB122010	Phase II	+	+	+
38	DB122011	Phase II	+	+	+
39	DB122012	Phase II	+	+	+
40	DK100201	No History	N	N	N
41	DK100202	No History	N	N	N

42	DK100203	No History	N	N	N
43	DK100204	No History	N	N	N
44	DK100205	No History	N	N	N
45	DK100206	No History	N	N	N
46	DK100207	No History	N	N	N
47	DK100208	No History	N	N	N
48	DK100209	No History	N	N	N
49	DK100210	No History	N	N	N
50	DK100211	No History	N	N	N
51	DK100212	No History	N	N	N
52	DK100213	No History	N	N	N
53	DK100214	No History	N	N	N
54	DK100215	No History	N	N	N
55	DK100216	No History	N	N	N
56	DK100217	No History	N	N	N
57	DK100218	No History	N	N	N
58	DK100219	No History	N	N	N
59	DK100220	No History	N	N	N
60	DK100221	No History	N	N	N
61	DK100222	No History	N	N	N
62	DK100223	No History	N	+	N
63	DK100224	No History	N	N	N
64	DK100225	No History	N	N	N
65	DK100226	No History	N	N	N
66	DK100227	No History	N	N	N
67	DK100228	No History	N	N	N
68	DK100229	No History	N	N	N
69	DK100230	No History	N	N	N
70	DK100231	No History	N	N	N
71	DK100232	No History	N	N	N
72	DK100233	No History	N	N	N
73	DK100234	No History	N	N	N
74	DK100235	No History	N	N	N
75	DK100236	No History	N	N	N
76	DK100237	No History	N	N	N
77	DK100238	No History	N	N	N
78	DK100239	No History	N	N	N
79	DK100240	No History	N	N	N
80	DK100241	No History	N	N	N
81	DK100242	No History	N	N	N
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83	DK100244	No History	N	N	N
84	DK100245	No History	N	N	N
85	DK100246	No History	N	N	N
86	DK100247	No History	N	N	N
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88	DK100249	No History	N	N	N
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91	DK100252	No History	N	N	N

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97	DK100258	No History	N	N	N
98	DK100259	No History	N	N	N
99	DK100260	No History	N	N	N
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101	DK100262	No History	N	N	N
102	DK100263	No History	N	N	N
103	DK100264	No History	N	N	N
104	DK100265	No History	N	N	N
105	DK100266	No History	N	N	N
106	DK100267	No History	N	N	N
107	DK100268	No History	N	N	N
108	DK100269	No History	N	N	N
109	DK100270	No History	N	N	N
110	DK100271	No History	N	N	N
111	DK100272	No History	N	N	N
112	DK100273	No History	N	N	N
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114	DK100275	No History	N	N	N
115	DK100276	No History	N	N	N
116	DK100277	No History	N	N	N
117	DK100278	No History	N	N	N
118	DK100279	No History	N	N	N
119	DK100280	No History	N	N	N
120	DK100281	No History	N	N	N
121	DK100282	No History	N	N	N
122	DK100283	No History	N	N	N
123	DK100284	No History	N	N	N
124	DK100285	No History	N	N	N
125	DK100286	No History	N	N	N
126	DK100287	No History	N	N	N
127	DK100288	No History	N	N	N
128	DK100289	No History	N	N	N
129	DK100290	No History	N	N	N
130	DK100291	No History	N	N	N
131	DK100292	No History	N	N	N
132	DK100293	No History	N	N	N
133	DK100294	No History	N	N	N
134	DK100295	No History	N	N	N
135	DK100296	No History	N	N	N
136	DK100297	No History	N	N	N
137	DK100298	No History	N	N	N
138	DK100299	No History	N	N	N
139	DK100300	No History	N	N	N
140	DK100301	No History	N	N	N
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142	DK100303	No History	N	N	N
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147	DK100308	No History	N	N	N
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152	DK100313	No History	N	N	N
153	DK100314	No History	N	N	N
154	DK100315	No History	N	N	N
155	DK100316	No History	N	N	N
156	DK100317	No History	N	N	N
157	DK100318	No History	N	N	N
158	DK100319	No History	N	N	N
159	DK100320	No History	N	N	N

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