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Research Report

Single institution, randomization, single blind and retrospective validation clinical trial to evaluate the clinical positive percent agreement and negative percent agreement of Asan Easy Test COVID-19® Ag using nasopharyngeal swab of patients suspected of having SARS-CoV-2.

September 25, 2020

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1. Research title

Single institution, randomization, single blind and retrospective validation clinical trial to evaluate the clinical positive percent agreement and negative percent agreement of Asan Easy Test® COVID-19 Ag using nasopharyngeal swab of patients suspected of having SARS-CoV-2.

2. Name and Address of the participating site

Samkwang Medical Lab, 57, Baumoe-ro 41-gil, Seocho-gu, Seoul, Republic of Korea

3. Research participants

Role	Name	Major	Position
Principal investigator	Kim, Hyung-nyeon	Diagnostic examination medicine	Diagnostic Examination Medical Specialist
Investigator	Lee, In-seop	Molecular microbiology	Molecular Microbiology Team Leader
Statistics manager	Choi, Sam Kyu	Medical Management	National Project Team Leader
Investigational device manager	Lee, Jong Pil	Clinical pathology	Team Leader

4. Name and Address of the trial sponsor

Asan Pharma. Co., Ltd. 163, Yeongcheon-ro, Hwaseong-si, Gyeonggi-do

5. Purpose

The purpose of this clinical trial is to evaluate positive percent agreement(PPA) and negative percent agreement(NPA) of Asan Easy Test® COVID-19 Ag using retrospective nasopharyngeal swab of patients infected or uninfected with SARS-CoV-2. This study is conducted in accordance with the study protocol approved by the IRB for sufficient review of the ethical and legal requirements of this study.

6. Trial period

September 15~ September 17, 2020

7. Materials

(1) Sample Number

No	Target Specimen Type	Number of test specimens
1	COVID-19 positive nasopharyngeal swab	40
2	COVID-19 negative nasopharyngeal swab	60

Total number of specimens	100

(2) Inclusion criteria

① Residual specimens derived from nasopharyngeal swab from patients who have been tested according to the COVID-19 laboratory diagnostic guidelines regardless of this clinical trial and confirmed confirmed to be positive or negative for COVID-19 by a real time RT-PCR test (PowerChek™2019-nCoV Real-time PCR Kit, EUA approved)

② Specimens that have undergone anonymization process after obtaining IRB approval from Samkwang Medical Foundation

③ Specimens stored in a designated container and stored at –70°C or less for 6 months

④ Specimens with a residual volume of 200μL or more

(3) Exclusion criteria

① Specimens that do not belong to selection criteria

② Specimens contaminated with mold, microorganisms, etc.

③ Specimens stored improperly or whose storage method cannot be determined

8. Methods

This clinical trial was designed as a single institution, randomized, single-blind, retrospective validation study to evaluate the positive percent agreement and negative percent agreement of Asan Easy Test® COVID-19 Ag using residual nasopharyngeal swab specimens.

The specimens have completed a real time RT-PCR test (PowerChek™2019-nCoV Real-time PCR Kit, EUA). Therefore, in this clinical trial, the specmiens were tested with Asan Easy Test® COVID-19 Ag only, and the test results that previously examined by confirmatory test (PowerChek™2019-nCoV Real-time PCR Kit) were used to evaluate clinical performance of Asan Easy Test® COVID-19 Ag.

Specimens of patients identified as positive or negative through confirmatory tests were selected according to the inclusion and exclusion criteria.

The number of random numbers as many as the number of positive and negative specimens required for the clinical trial was maden. A random number was assigned to the anonymized specimen during excluding information on the specimens (positive and negative), and then a subject identification code was given.

The specimens with the subject's identification code were delivered to the investigator, and the investigator measures the specimens with Asan Easy Test® COVID-19 Ag according to the sequence of a random number to determine positive and negative.

If the result of first test is judged invalid, the test is repeated. If the retest result is positive, the test result is judged as positive, and if it is negative, the test result is judged as negative. If invalidity is found in the retest it is considered as invalid and eliminated. The positive percent

agreement and negative percent agreement of Asan Easy Test® COVID-19 Ag were evaluated based on the results of the confirmatory test of the specimens used in the clinical trial.

9. Results

To evaluate the clinical performance of the Asan Easy Test® COVID-19 Ag, 100 retrospective COVID-19 positive and negative samples (40 specimens from positive nasopharyngeal swabs, 60 specimens from negative nasopharyngeal swabs) were tested. The results are as follows:

Table 1. Summary of positive percent agreement and negative percent agreement

Asan Easy Test® COVID-19 Ag	PowerChek™2019-nCoV Real-time PCR Kit as confirmatory test	
	Positive	Negative
Positive	37	4
Negative	3	56
Total	40	60

- Positive percent agreement: 92.5%(37/40) (95% CI: 79.61% ~ 98.43%)
- Negative percent agreement: 93.3%(56/60) (95% CI: 83.80% ~ 98.15%)

10. Conclusion

To evaluate the positive percent agreement and negative percent agreement of the Asan Easy Test® COVID-19 Ag, a total of 100 samples suitable for the inclusion and exclusion criteria were analyzed. The Positive percent agreement is 92.5% (37/40, 95% CI: 79.61% ~ 98.43%) and Negative percent agreement is 93.3% (56/60, 95% CI: 83.80% ~ 98.15%), respectively. Considering such clinical performance, the Asan Easy Test® COVID-19 Ag is speculated to be useful to confirm the infection of SARS-CoV-2 in the clinical field.

11. Attachment

Case report form

Case Report Form

Confirmatory test kit	PowerChek™2019-nCoV Real-time PCR Kit
Clinical trial kit	Asan Easy Test® COVID-19 Ag

No.	Identification number	Confirmatory test kit			Clinical trial test kit	Suitability for Inclusion/exclusion criteria
		E gene	RdRP gene	Results		
1	COVID-001	-	-	-	-	■YES □NO
2	COVID-002	-	-	-	-	■YES □NO
3	COVID-003	-	-	-	-	■YES □NO
4	COVID-004	32.90	33.14	+	-	■YES □NO
5	COVID-005	-	-	-	-	■YES □NO
6	COVID-006	-	-	-	-	■YES □NO
7	COVID-007	-	-	-	-	■YES □NO
8	COVID-008	31.51	31.47	+	+	■YES □NO
9	COVID-009	25.08	24.78	+	+	■YES □NO
10	COVID-010	-	-	-	-	■YES □NO
11	COVID-011	17.03	16.47	+	+	■YES □NO
12	COVID-012	-	-	-	-	■YES □NO
13	COVID-013	18.66	18.12	+	+	■YES □NO
14	COVID-014	-	-	-	-	■YES □NO
15	COVID-015	-	-	-	-	■YES □NO
16	COVID-016	16.01	15.86	+	+	■YES □NO
17	COVID-017	-	-	-	-	■YES □NO
18	COVID-018	-	-	-	-	■YES □NO
19	COVID-019	-	-	-	-	■YES □NO
20	COVID-020	-	-	-	-	■YES □NO
21	COVID-021	-	-	-	+	■YES □NO
22	COVID-022	-	-	-	-	■YES □NO
23	COVID-023	23.17	22.70	+	+	■YES □NO
24	COVID-024	-	-	-	+	■YES □NO
25	COVID-025	-	-	-	-	■YES □NO
26	COVID-026	-	-	-	-	■YES □NO
27	COVID-027	-	-	-	+	■YES □NO
28	COVID-028	26.77	26.59	+	+	■YES □NO
29	COVID-029	30.61	30.01	+	+	■YES □NO
30	COVID-030	-	-	-	-	■YES □NO
31	COVID-031	19.31	18.84	+	+	■YES □NO
32	COVID-032	-	-	-	-	■YES □NO
33	COVID-033	-	-	-	-	■YES □NO
34	COVID-034	23.06	23.00	+	+	■YES □NO
35	COVID-035	-	-	-	-	■YES □NO
36	COVID-036	22.27	22.22	+	+	■YES □NO
37	COVID-037	-	-	-	-	■YES □NO

38	COVID-038	-	-	-	-	■YES ☐NO
39	COVID-039	-	-	-	-	■YES ☐NO
40	COVID-040	-	-	-	-	■YES ☐NO
41	COVID-041	19.14	18.83	+	+	■YES ☐NO
42	COVID-042	-	-	-	-	■YES ☐NO
43	COVID-043	18.71	18.54	+	+	■YES ☐NO
44	COVID-044	-	-	-	-	■YES ☐NO
45	COVID-045	-	-	-	-	■YES ☐NO
46	COVID-046	-	-	-	-	■YES ☐NO
47	COVID-047	-	-	-	-	■YES ☐NO
48	COVID-048	24.81	24.52	+	+	■YES ☐NO
49	COVID-049	19.39	19.14	+	+	■YES ☐NO
50	COVID-050	28.96	28.59	+	+	■YES ☐NO
51	COVID-051	-	-	-	-	■YES ☐NO
52	COVID-052	28.69	28.34	+	+	■YES ☐NO
53	COVID-053	17.21	17.08	+	+	■YES ☐NO
54	COVID-054	-	-	-	-	■YES ☐NO
55	COVID-055	-	-	-	-	■YES ☐NO
56	COVID-056	17.21	17.08	+	+	■YES ☐NO
57	COVID-057	-	-	-	-	■YES ☐NO
58	COVID-058	13.47	13.62	+	+	■YES ☐NO
59	COVID-059	-	-	-	-	■YES ☐NO
60	COVID-060	30.39	30.25	+	+	■YES ☐NO
61	COVID-061	27.20	26.72	+	+	■YES ☐NO
62	COVID-062	17.21	17.04	+	+	■YES ☐NO
63	COVID-063	21.46	21.16	+	+	■YES ☐NO
64	COVID-064	-	-	-	-	■YES ☐NO
65	COVID-065	24.21	24.05	+	+	■YES ☐NO
66	COVID-066	29.65	29.23	+	+	■YES ☐NO
67	COVID-067	-	-	-	-	■YES ☐NO
68	COVID-068	-	-	-	-	■YES ☐NO
69	COVID-069	-	-	-	-	■YES ☐NO
70	COVID-070	27.46	27.12	+	+	■YES ☐NO
71	COVID-071	-	-	-	-	■YES ☐NO
72	COVID-072	-	-	-	+	■YES ☐NO
73	COVID-073	-	-	-	-	■YES ☐NO
74	COVID-074	33.48	34.69	+	-	■YES ☐NO
75	COVID-075	30.02	29.29	+	+	■YES ☐NO
76	COVID-076	-	-	-	-	■YES ☐NO
77	COVID-077	-	-	-	-	■YES ☐NO
78	COVID-078	22.50	22.38	+	+	■YES ☐NO
79	COVID-079	24.44	24.27	+	+	■YES ☐NO
80	COVID-080	28.61	28.15	+	+	■YES ☐NO
81	COVID-081	-	-	-	-	■YES ☐NO
82	COVID-082	-	-	-	-	■YES ☐NO
83	COVID-083	-	-	-	-	■YES ☐NO

84	COVID-084	-	-	-	-	■YES ☐NO
85	COVID-085	-	-	-	-	■YES ☐NO
86	COVID-086	27.68	27.47	+	+	■YES ☐NO
87	COVID-087	-	-	-	-	■YES ☐NO
88	COVID-088	-	-	-	-	■YES ☐NO
89	COVID-089	34.03	33.33	+	-	■YES ☐NO
90	COVID-090	-	-	-	-	■YES ☐NO
91	COVID-091	-	-	-	-	■YES ☐NO
92	COVID-092	28.60	28.23	+	+	■YES ☐NO
93	COVID-093	-	-	-	-	■YES ☐NO
94	COVID-094	-	-	-	-	■YES ☐NO
95	COVID-095	29.75	29.42	+	+	■YES ☐NO
96	COVID-096	-	-	-	-	■YES ☐NO
97	COVID-097	16.15	16.08	+	+	■YES ☐NO
98	COVID-098	20.11	19.77	+	+	■YES ☐NO
99	COVID-099	19.78	19.36	+	+	■YES ☐NO
100	COVID-100	22.86	22.34	+	+	■YES ☐NO

*** Results determination method of Samkwang Medical Lab(Kogenebiotech PowerChek™2019-nCoV Real-time PCR Kit)**
: If the Ct value of each sample is ≤35, it is determined as positive, and if it is >35, it is determined as negative.