Asan Easy Test® COVID-19 Ag

Clinical Performance Results

Test Date : 2020.09.01~2020.11.26

REVISION HISTORY

Revision No.	Revision Date	A reason of Revisions	Document	Approval
/	/	/	/	/

Division	Prepared	Review		Approval
Position	Researcher	Senior researcher	Director	CEO
Name	Lee, Tae-gyeong	Yu, Sun-hee	Lee, Kyung-chan	Yeom, Jeong-gyu
Signature				
Date	2020.11.26	2020.11.26	2020.11.26	2020.11.26

1. Clinical performance results

1.1 Research purpose

The purpose of this clinical trial is to evaluate positive percent agreement and negative percent agreement of Asan Easy Test® COVID-19 Ag using nasopharyngeal swabs of patients suspected of infection with SARS-CoV-2.

1.2 Research participants

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

1.3 Research sponsor

Role	Name	Belong to	Position
Sponsor	Yeom, Jeong-gyu	ASAN PHARM. CO. LTD	CEO
Monitor	Yu, Sun-hee	ASAN PHARM. CO. LTD	Senior Researcher

1.4, Number of specimens and the basis of calculation for study Targets

(1) Number of specimens

No	Target Specimen Type	Number of test specimens
1	Positive nasopharyngeal swab	150
2	Negative nasopharyngeal swab	350
Total number of specimens		500

(2) Basis for calculation

Based on the reference, the minimum number of specimens required to satisfy statistical representativeness is 30, and in this clinical trial, 150 positive and 350 negative specimens were used.

(3) Reference

https://www.dummies.com/education/math/statistics/the-central-limit-theorem-whats-large-enough/

1.5 Inclusion and exclusion criteria for study target

(1) 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 to be positive or negative for COVID-19 by a real time RT-PCR test

② Specimens that have undergone anonymization process after obtaining IRB approval from Samk wang 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

(2) 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

1.6 Research Method

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. 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 (Emergency Use Anthorized RT-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 selection 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 subinvestigator, and the subinvestigator 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.

1.7 Test results

To evaluate the clinical performance of the Asan Easy Test® COVID-19 Ag, 500 retrospective COVID-19 positive and negative samples (150 specimens from positive nasopharyngeal swabs, 350 specimens from negative nasopharyngeal swabs) were tested. In result, positive percent agreement and negative percent agreement are as follows.

Asan Easy Test® COVID-19 Ag	Emergency Use Authorized RT-PCR Kit results for confirmatory test	
	Positive	Negative
Positive	142	8
Negative	8	342
Total	150	350

- Positive percent agreement: 94.7%(142/150) (95% CI: 89.76% ~ 97.67%)
- Negative percent agreement: 97.7%(342/350) (95% CI: 95.55% ~ 99.01%)

1.8 Conclusion and discussion

To evaluate the positive percent agreement and negative percent agreement of the Asan Easy Test® COVID-19 Ag, a total of 500 samples suitable for the inclusion and exclusion criteria were analyzed. The Positive percent agreement is 94.7% (142/150, 95% CI: 89.76% ~ 97.67%) and Negative percent agreement is 97.7% (342/350, 95% CI: 95.55% ~ 99.01%), 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.