EC Declaration of Conformity

In accordance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

WE HEREWITH DECLARE EXCLUSIVELY UNDER SOLE RESPONSIBILITY THAT THE BELOW MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product name:	Rapid detection kit for influenza virus A, B and SARS-CoV-2 antigens
Model Name:	Asan Easy Test® Flu/COVID-19 Ag Combo
Catalogue Number:	AM3493-K (20T)/AM3491-K (25T)

Applied Directive : 98/79/EC

Classification : other IVD according to Annex III of the IVD Directive 98/79/EC

Conformity Assessment Route : Annex III of the Directive 98/79/EC
(No Annex II, List A or B product, no self-testing product)

Manufacturer : **ASAN PHARMACEUTICAL CO., LTD.**

Address : 122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, 17551, Korea

EC Representative : **MT Promedt Consulting GmbH**

Address : Altenhofstrasse 80, 66386 St. Ingbert, Germany

EDMA code : 15 70 90 90 00 Other Other Virology Rapid Tests
15 04 80 04 00 Influenza & Para Influenza

Date : 2020.11.23

Place of Issue : Anseong-si

Yoom, Joong Gyu

CEO of ASAN PHARMACEUTICAL CO., LTD.

Annex I. Applied standards

EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Symbols for use in the labelling of medical devices
EN ISO 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
EN 13612: 2002 / AC: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366:2008/A1:2015	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007/A1:2014)

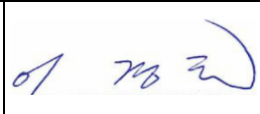
Asan Easy Test®

Flu/COVID-19 Ag Combo

Clinical Performance Results

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	2020.09.25	2020.09.25	2020.09.25	2020.09.25

1 COVID-19

1.1 Research purpose

The purpose of this clinical trial is to evaluate positive percent agreement and negative percent agreement of Asan Easy Test® Flu/COVID-19 Ag Combo 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	Oh, Rae Won	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 and 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 200uL 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® Flu/COVID-19 Ag Combo 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® Flu/COVID-19 Ag Combo 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® Flu/COVID-19 Ag Combo.

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® Flu/COVID-19 Ag Combo 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® Flu/COVID-19 Ag Combo 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® Flu/COVID-19 Ag Combo, 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® Flu/COVID-19 Ag Combo	Emergency Use Authorized RT-PCR Kit results for confirmatory test	
	Positive	Negative
Positive	142	5
Negative	8	345
Total	150	350

- Positive percent agreement: 94.7% (142/150) (95% CI: 86.76% ~ 97.67%)
- Negative percent agreement: 98.6% (345/350) (95% CI: 96.70% ~ 99.53%)

1.8 Conclusion and discussion

To evaluate the positive percent agreement and negative percent agreement of the Asan Easy Test® Flu/COVID-19 Ag Combo, 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: 86.76% ~ 97.67%) and negative percent agreement is 98.6% (345/350, 95% CI: 96.70% ~ 99.53%), respectively. Considering such clinical performance, the Asan Easy Test® Flu/COVID-19 Ag Combo is speculated to be useful to confirm the infection of SARS-CoV-2 in the clinical field.

2 Influenza A, B

2.1 Research purpose

The purpose of this clinical trial is to evaluate positive percent agreement and negative percent agreement of Asan Easy Test® Flu/COVID-19 Ag Combo using nasopharyngeal swabs of patients suspected of infection with Influenza A, B virus.

2.2 Research participants

Role	Name	Belong to	Position
Principal investigator	Song, Min-jeong	Jangwon Medical Lab.	Center Director
Investigator 1	Moon, Jeong-seon	Jangwon Medical Lab.	Reseacher
Investigator 2	Yuk, Ji-hye	Jangwon Medical Lab.	Reseacher
Investigational device manager	Joo, Yeon-ju	Jangwon Medical Lab.	Reseacher

2.3 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

2.4. 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 Influenza A nasopharyngeal swab	50
2	Positive Influenza B nasopharyngeal swab	30
3	Negative nasopharyngeal swab	70
Total number of specimens		150

2) Basis for calculation

The number of samples was calculated by considering the Clinical and Laboratory Standards Institute (CLSI) guidelines and prevalence in Korea.

2.5 Inclusion and exclusion criteria for study target

1) Inclusion criteria

(1) Residual specimens derived from nasopharyngeal swab from patients who were participated in the test by Jangwon Medical Lab regardless of this clinical trial and confirmed to be positive or negative for Influenza and by a real time RT-PCR test (Real-Q Flu A, B Detection Kit, BioSewoom Inc. Korea)

(2) Specimens that have undergone anonymization process after obtaining IRB approval from Jangwon 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 200uL 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

2.6 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® Flu/COVID-19 Ag Combo using residual nasopharyngeal swab specimens.

The specimens have completed a real time RT-PCR test (Real-Q Flu A, B Detection Kit in this clinical trial, the specmiens were tested with Asan Easy Test® Flu/COVID-19 Ag Combo only, and the test results that previously examined by confirmatory test used to evaluate clinical performance of Asan Easy Test® Flu/COVID-19 Ag Combo.

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 made. 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® Flu/COVID-19 Ag Combo 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® Flu/COVID-19 Ag Combo were evaluated based on the results of the confirmatory test of the specimens used in the clinical trial.

2.7 Test results

To evaluate the clinical performance of the Asan Easy Test® Flu/COVID-19 Ag Combo, 150 retrospective Influenza A, B positive and negative samples (80 specimens from positive nasopharyngeal swabs; 50 for Influenza A, 30 for Influenza B, 70 specimens from negative nasopharyngeal swabs) were tested. In result, positive percent agreement and negative percent agreement are as follows.

1) Influenza A

Asan Easy Test® Flu/COVID-19 Ag Combo	Real-Q Flu A, B Detection Kit for confirmatory test	
	Positive	Negative
Positive	49	0
Negative	1	100
Total	50	100

- Positive percent agreement: 98.0%(49/50) (95% CI: 88.0% ~ 99.9%)
- Negative percent agreement: 100.0%(100/100) (95% CI: 95.4% ~ 100.0%)

2) Influneza B

Asan Easy Test® Flu/COVID-19 Ag Combo	Real-Q Flu A, B Detection Kit for confirmatory test	
	Positive	Negative
Positive	27	0
Negative	3	120
Total	30	120

- Positive percent agreement: 90.0%(37/40) (95% CI: 72.3% ~ 97.4%)
- Negative percent agreement: 100.0%(120/1200) (95% CI: 96.1% ~ 100.0%)

2.8 Conclusion and discussion

To evaluate the positive percent agreement and negative percent agreement of the Asan Easy Test® Flu/COVID-19 Ag Combo, a total of 100 samples suitable for the inclusion and exclusion criteria were analyzed. In case of Influenza A the Positive percent agreement is 98.0% (49/50, 95% CI: 88.0% ~ 99.9%) and Negative percent agreement is 100.0% (100/100, 95% CI: 95.4% ~ 100.0%), respectively. In case of Influenza B the Positive percent agreement is 90.0% (27/30, 95% CI: 72.3% ~ 97.4%) and Negative percent agreement is 100.0% (100/100, 95% CI: 96.1% ~ 100.0%), respectively. Considering such clinical performance, the Asan Easy Test® Flu/COVID-19 Ag Combo is speculated to be useful to confirm the infection of Influenza A, B virus in the clinical field.