ASAN-IFU-003 (Rev. 3) CE IVD

Asan Easy Test®
Flu/COVID-19 Ag Combo

※Caution: Please read the precautions and test procedure in this manual before using.

Product name

Product Name	Asan Easy Test® Flu/COVID-19 Ag Combo
Model Name	Asan Easy Test® Flu/COVID-19 Ag Combo
Catalogue Number	AM3493-K (20T) / AM3491-K (25T)

Manufacturing number and expiration date

Refer to the Lot and Exp. Date on the box.

Package unit

For the number of test kits per package, refer to the labeling on the box.

Package unit	Quantity	
	20T	25T
Test device	20ea/Kit	25ea/Kit
Extraction buffer	20ea(0.35mL)/Kit	25ea(0.35mL)/Kit
Dropper filter tip	20ea/Kit	25ea/Kit
Sample collection swab	20ea/Kit	25ea/Kit

Purpose of use

Asan Easy Test® Flu/COVID-19 Ag Combo is an in-vitro diagnostic medical device that diagnoses COVID-19 and Influenza A, B by qualitatively testing SARS-CoV-2 nucleocapsid protein and Influenza virus type A, B nucleocapsid protein antigens in a nasopharyngeal swab by immunochromatographic assay (ICA).

How to use

1) Specimen collection and storage

(1) Specimens: A nasopharyngeal swab is used as the sample. The specimen may have unknown infectious agents, so it must be handled by trained or skilled professionals.
① To collect nasopharyngeal swabs, use the sample collection swab included in the kit.
② For nasopharyngeal swab collection, it is recommended to insert the swab into the nasal cavity where the most secretions are generated, and rotate it once carefully to collect the secretion enough to be visibly wet.

(2) Specimen storage
If the specimen cannot be tested immediately after collection, put the specimen in a Viral Transport Media (or Universal Transport Media) contained in a lidded storage container. The specimens contained in Viral Transport Media (or Universal Transport Media) can be stored for up to 72 hours when refrigerated (2~8℃) or frozen (-20℃).

2) Test preparation

Before testing, place the test device, extraction buffer, and specimen at room temperature, and shake extraction buffer gently before use. The most suitable temperature condition for the test is room temperature (15~25℃). If the reagent is stored at room temperature, it can be opened and used immediately.

3) Test procedure

(1) Place the swab sample in a tube containing the extraction buffer and rub it against the wall of the tube and rotate at least 8 to 10 times to allow sufficient extraction.
(2) The extracted swab is pulled out by turning it along the wall of the tube. During this process, the extract from the swab is squeezed out.
(3) A used swab is classified as infectious waste and should be disposed of safely.
(4) After combining the extraction buffer tube with the dropper filter tip, remove the device from the aluminum pouch and add 4 drops (90~100μl) to the sample well.
(5) If the control line (C) is clearly visible after 15-20 minutes, the result is read.
(6) As the reaction time increases, the intensity of bands of the control line(C) and the test lines (S, A, B) may increase. Therefore, it is possible to obtain more accurate results by determination at a constant time after starting the reaction. When reacting for a long time, non-specific reactions may occur, so results after 30 minutes are not used for determination.

4) Quality control

All test results should have a colored band on the control line (C).

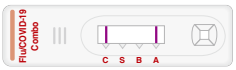
5) Interpretation of results

This product may or may not have color bands on the test lines depending on the presence of SARS-CoV-2, Influenza type A and B virus antigens in the specimen, and the test lines are judged positive and negative according to the presence or absence of the color bands.

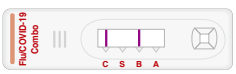
(1) Negative: A color band appears only on the control line (C), and does not appear on the test lines (S, A, B).

(2) Positive
① SARS-CoV-2 positive: When colored bands appear on both the control line (C) and the test line (S).

② Influenza type A virus positive: When color bands appear on both the control line (C) and the test line (A).



③ Influenza type B virus positive: When color bands appear on both the control line (C) and the test line (B).



(3) Invalid or retest: Color band appears on neither the control line (C) nor on the test line (S, A, B), or only one or more color band(s) appear on the test lines (S, A, B) without the control line (C). In this case, the test is invalid and a retest with a new test device is needed.

Storage and stability

The kit can be stored at 1~30℃ for up to 24 months from the manufacturing date.

Performance evaluation

1) Analytical sensitivity (Limit of detection, LoD)

To test the limit of detection, virus isolates of SARS-CoV-2, Influenza virus type A, Influenza virus type B were used. When tests were repeated 10 times with the diluted virus isolates, the lowest concentration at which more than 95% of the total tested number could be judged as positive was determined as the LoD. The LoD of isolates are as follows.

Nr.	Isolierte Viren		LoD
1	COVID-19	SARS-CoV-2 (USA-WA1/2020)	5.90×10^{2} $TCID_{50}$/ml
2		SARS-CoV-2 (Italy-INMI1)	7.46×10^{3} $TCID_{50}$/ml
3		SARS-CoV-2 (Hong Kong/VM20001061/2020)	1.23×10^{3} $TCID_{50}$/ml
4	Influenza A	Influenza A protein New Caledonia(H1N1)	9.76 HA Units/ml
5		Influenza A protein Texas 1/77(H3N2)	20.02 HA Units/ml
6		Influenza B protein Hong Kong 5/72	20 HA Units/ml
7		Influenza Antigen A/Anhui/1/05(H5N1)	0.09ugHA/ml
8		Influenza Antigen A/California/7/2009(H1N1pdm)	4.37ugHA/ml
9		Influenza Antigen A/chick/Hong Kong/G9/1997(H9N2)	0.32ugHA/ml
10		Influenza Antigen A/New Caledonia/20/99(H1N1)	4.06ugHA/ml
11		Influenza A/Singapore/1/57(H2N2)	0.35ugHA/ml
12		Influenza antigen A/Puerto Rico/8/34(H1N1)	0.39ugHA/ml
13		Influenza antigen A/mallard/Netherlands/12/2000(H7N3)	0.22ugHA/ml
14		Influenza antigen A/Victoria/361/2011(H3N2)	1.23ugHA/ml
15		Influenza Antigen A/Anhui/1/2013(H7N9)	0.37ugHA/ml
16	Influenza B	Influenza antigen B/Florida/4/2006	0.08ugHA/ml
17		Influenza antigen B/Brisbane/60/08	5.25ugHA/ml
18		Influenza antigen B/Hong Kong/8/73	0.5ugHA/ml
19		Influenza Antigen B/Malaysia/2506/2004	1.56ugHA/ml
20		Influenza Antigen B/Yamagata/16/88	0.34ugHA/ml
21		Influenza Antigen B/Utah/9/2014	0.01ugHA/ml
22		Influenza Antigen B/Phuket/3073/2013	7.5ugHA/ml
23		Influenza Antigen B/Brisbane/9/2014	1.31ugHA/ml

2) Repeatability

For repeatability tests, negative, COVID-19 (High, Middle, Low), INF A (High, Middle, Low) and INF B (High, Middle, Low) samples were used. The test was performed 2 run a day and 2 times per run for 5 days with 3 lots by one experimenter. The concordance rates between tests, between dates, and between lots are 100%. In conclusion, the Asan Easy Test® Flu/COVID-19 Ag Combo shows the repeatability.

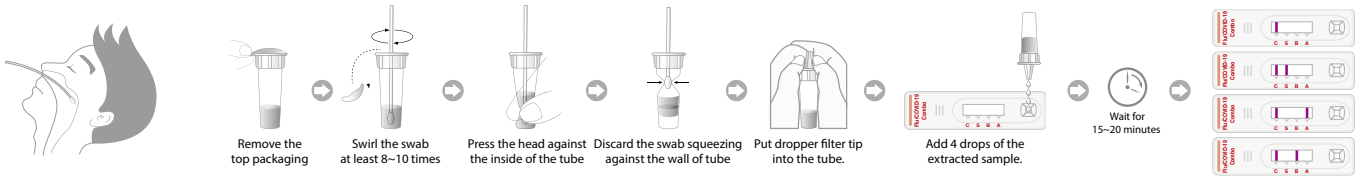
Sample		Between-Lot			Concordance rate
		Lot#1	Lot#2	Lot#3	
N		20/20	20/20	20/20	60/60, 100%
COVID-19	H	20/20	20/20	20/20	60/60, 100%
	M	20/20	20/20	20/20	60/60, 100%
	L	20/20	20/20	20/20	60/60, 100%
INF A	H	20/20	20/20	20/20	60/60, 100%
	M	20/20	20/20	20/20	60/60, 100%
	L	20/20	20/20	20/20	60/60, 100%
INF B	H	20/20	20/20	20/20	60/60, 100%
	M	20/20	20/20	20/20	60/60, 100%
	L	20/20	20/20	20/20	60/60, 100%

Sample		Between-Test		Concordance rate
		1run	2run	
N		30/30	30/30	60/60, 100%
COVID-19	H	30/30	30/30	60/60, 100%
	M	30/30	30/30	60/60, 100%
	L	30/30	30/30	60/60, 100%
INF A	H	30/30	30/30	60/60, 100%
	M	30/30	30/30	60/60, 100%
	L	30/30	30/30	60/60, 100%
INF B	H	30/30	30/30	60/60, 100%
	M	30/30	30/30	60/60, 100%
	L	30/30	30/30	60/60, 100%

Sample		Between-Date					Concordance rate
		1day	2day	3day	4day	5day	
N		12/12	12/12	12/12	12/12	12/12	60/60, 100%
COVID-19	H	12/12	12/12	12/12	12/12	12/12	60/60, 100%
	M	12/12	12/12	12/12	12/12	12/12	60/60, 100%
	L	12/12	12/12	12/12	12/12	12/12	60/60, 100%
INF A	H	12/12	12/12	12/12	12/12	12/12	60/60, 100%
	M	12/12	12/12	12/12	12/12	12/12	60/60, 100%
	L	12/12	12/12	12/12	12/12	12/12	60/60, 100%
INF B	H	12/12	12/12	12/12	12/12	12/12	60/60, 100%
	M	12/12	12/12	12/12	12/12	12/12	60/60, 100%
	L	12/12	12/12	12/12	12/12	12/12	60/60, 100%

3) Reproducibility

For repeatability tests, negative, COVID-19 (High, Middle, Low), INF A (High, Middle, Low) and INF B (High, Middle, Low) samples were used. The test was performed 2 run a day and 2 times per run for 5 days by 3 different experimenters in 3 different laboratories. The concordance rate between laboratories is 100%. In conclusion, the Asan Easy Test® Flu/COVID-19 Ag Combo shows the reproducibility.



Sample		Between-Laboratory			Concordance rate
		Site A	Site B	Site C	
N		20/20	20/20	20/20	60/60, 100%
COVID-19	H	20/20	20/20	20/20	60/60, 100%
	M	20/20	20/20	20/20	60/60, 100%
	L	20/20	20/20	20/20	60/60, 100%
INF A	H	20/20	20/20	20/20	60/60, 100%
	M	20/20	20/20	20/20	60/60, 100%
	L	20/20	20/20	20/20	60/60, 100%
INF B	H	20/20	20/20	20/20	60/60, 100%
	M	20/20	20/20	20/20	60/60, 100%
	L	20/20	20/20	20/20	60/60, 100%

4) Cross reactivity

The cross-reactivity against various microorganisms and viruses that may exist in the specimens was tested. The Asan Easy Test® Flu/COVID-19 Ag Combo showed positive results on the test line S for SARS-CoV-2 isolates, positive results on the Test line A for influenza virus type A isolates, and positive results on the Test line B for influenza virus type B isolates. Except for these viruses, the Asan Easy Test® Flu/COVID-19 Ag Combo does not show cross reactivity with the pathogens up to the concentrations listed in the table below.

No.	Pathogen	Concentration
1	Coronavirus OC43	1.58×10^{5} $TCID_{50}$/mL
2	Coronavirus NL63	1×10^{5} $TCID_{50}$/mL
3	Coronavirus 229E	1×10^{5} $TCID_{50}$/mL
4	Human metapneumovirus-3 type B1	$1.25\times10^{5.34}$ $TCID_{50}$/mL
5	Parainfluenza virus Type 1	1.14×10^{8} $TCID_{50}$/mL
6	Parainfluenza virus Type 2	1×10^{5} $TCID_{50}$/mL
7	Parainfluenza virus Type 3	3.21×10^{7} $TCID_{50}$/mL
8	Parainfluenza virus Type 4a	$1.25\times10^{5.58}$ $TCID_{50}$/mL
9	Adenovirus Type 1	3.21×10^{7} $TCID_{50}$/mL
10	Adenovirus Type 3	4.75×10^{5} $TCID_{50}$/mL
11	Adenovirus Type 5	$1.25\times10^{6.53}$ $TCID_{50}$/mL
12	Adenovirus Type 7a	1×10^{5} $TCID_{50}$/mL
13	Adenovirus Type 8	1×10^{5} $TCID_{50}$/mL
14	Adenovirus Type 11	$1.25\times10^{6.29}$ $TCID_{50}$/mL
15	Influenza A H1N1 (New Caledonia)	3.59×10^{5} $TCID_{50}$/mL
16	Influenza A H1N1 pdm (New California/07/09)	1.31×10^{5} $TCID_{50}$/mL
17	Influenza virus A H3N2 (Wisconsin/67/05)	1.89×10^{5} $TCID_{50}$/mL
18	Influenza A H3N2 (Texas)	1×10^{5} $TCID_{50}$/mL
19	Influenza B (Florida)	1×10^{5} $TCID_{50}$/mL
20	Influenza B (Lee/40)	1×10^{5} $TCID_{50}$/mL
21	Respiratory syncytial virus type A	1×10^{5} $TCID_{50}$/mL
22	Respiratory syncytial virus type B	1×10^{5} $TCID_{50}$/mL
23	*Hemophilus influenza*	1×10^{6} cfu/mL
24	*Streptococcus pneumonia*	1×10^{6} cfu/mL
25	*Streptococcus pyogenes*	1×10^{6} cfu/mL
26	*Candida albicans*	1×10^{6} cfu/mL
27	MERS-Coronavirus (Florida/USA-2_Saudi Arabia_2014)	1×10^{5} TCID50/mL
28	SARS-CoV-2(USA-WA1/2020)	1.51×10^{6} TCID50/ml
29	SARS-CoV-2(Italy-INMI1)	9.55×10^{6} TCID50/m
30	SARS-CoV-2 (Hong Kong/VM20001061/2020)	3.16×10^{6} TCID50/ml
31	Recombinant HCoV-HKU1 nucleoprotein	4 μg/mL
32	Recombinant human SARS coronavirus nucleoprotein	3 pg/mL
33	Rhinovirus A16	$1.25\times10^{5.10}$ U/mL
34	Rhinovirus B42	1.31×10^{5} $TCID_{50}$/mL
35	Enterovirus B111	0.7×10^{4} $TCID_{50}$/mL
36	Enterovirus B8	4.75×10^{5} $TCID_{50}$/mL
37	*Corynebacterium diphtheria*	1×10^{6} cfu/mL
38	*Enterococcus faecalis*	1×10^{6} cfu/mL
39	*Escherichia coli*	1×10^{6} cfu/mL
40	*Klebsiella pneumoniae*	1×10^{6} cfu/mL
41	*Neisseria gonorrhoeae*	1×10^{6} cfu/mL
42	*Neisseria sicca*	1×10^{6} cfu/mL
43	*Proreus vulgaris*	1×10^{6} cfu/mL
44	*Pseudomonas aeruginosa*	1×10^{6} cfu/mL
45	*Staphylococcus aureus*	1×10^{6} cfu/mL
46	*Staphylococcus epidermidis*	1×10^{6} cfu/mL
47	*Streptococcus equi*	1×10^{6} cfu/mL
48	*Streptococcus mutans*	1×10^{6} cfu/mL
49	*Pooled human nasal wash*	N/A

5) Interference

The Asan Easy Test® Flu/COVID-19 Ag Combo was evaluated for potential interference response by substances that may be present in specimens. Each substance was spiked into negative and low positive samples with concentration of 1×LoD. The test was performed 3 times repeatedly. In result, the Asan Easy Test® Flu/COVID-19 Ag Combo is not interfered with at the concentrations of the substances listed in the table below.

No.	Interfering substance	Analytical concentration
1	Mucin	1mg/mL
2	Human whole blood	1%
3	Zanamivir	1mg/mL
4	Beclomethasone	1mg/mL
5	Sulfur	1%
6	Histamine Dihydrochloride	1%
7	Tamiflu(Oseltamivir phosphate)	5mg/mL
8	Hemoglobin	80g/L
9	Mentol	1mg/mL
10	Conjugated Bilirubin	0.2g/L
11	Mupirocin	1mg/mL
12	Tobramycin	1mg/mL
13	Rheumatoid factor	20IU/mL
14	Phenylephrine	50mg/mL

6) Clinical evaluation

To evaluate the clinical performance of the Asan Easy Test® Flu/COVID-19 Ag Combo, nasopharyngeal swabs which were confirmed with RT-PCR were tested. 500 specimens(150 positive nasopharyngeal swabs, 350 negative nasopharyngeal swabs) for COVID-19, 150 specimens (50 specimens positive nasopharyngeal swabs, 100 specimens negative nasopharyngeal swabs) for Influenza type A, 150 specimens(30 specimens positive nasopharyngeal swabs, 120 specimens negative nasopharyngeal swabs) for Influenza type B were tested. The positive percent agreement and negative percent agreement are as follows.

(1) SARS-CoV-2

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

- Positive percent agreement: 94.7% (142/150) (95% CI: 89.8% ~ 97.7%)
- Negative percent agreement: 98.6% (345/350) (95% CI: 96.7% ~ 99.5%)

(2) Influenza virus A

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

- Positive percent agreement: 98.0%(49/50) (95% CI: 89.4% ~ 100.0%)
- Negative percent agreement: 100.0%(100/100) (95% CI: 96.4% ~ 100.0%)

(3) Influenza virus B

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

- Positive percent agreement: 90.0%(27/30) (95% CI: 73.5% ~ 97.9%)
- Negative percent agreement: 100.0%(120/120) (95% CI: 97.0% ~ 100.0%)

Precautions for use and disposal method

1) Use this test only for in vitro diagnosis (for professionals).
2) This test is disposable and should not be reused.
3) This test must remain in a sealed aluminum pouch until use.
4) When handling the test, be careful not to let your hands or other foreign substances directly come into contact with the test line area.
5) This test is very sensitive to moisture, so pay attention to performance degradation due to moisture. In particular, be careful as the moisture content of the device increases due to condensation when the container is opened if the temperature of the device is lower than room temperature.
6) When handling specimens, use disposable surgical gloves and be careful as there may be infections due to unknown microorganisms or viruses. Wash your hands thoroughly after handling.
7) Do not use the product if the aluminum pouch is damaged or does not seal well, or the product is past the expiration date.
8) Medical waste used in the test is autoclaved at 121℃ for 1 hour or more and then discarded.
9) The extraction buffer contains sodium azide and Triton X-100 as an extractant. If part of this solution gets into your eyes or mouth, or comes into contact with your skin, rinse thoroughly with running water and seek medical attention if necessary.
10) This test is a diagnostic test designed for the detection of SARS-CoV-2, Influenza type A and B virus antigen. The result can be obtained by a simple and quick method, but the sensitivity may differ from the test method designed with a more accurate principle. In addition, if the concentration of SARS-CoV-2, Influenza type A and B virus antigen in the sample is lower than the limit of detection, or inappropriate collection or storage of the sample occurs, negative results may occur.
11) This test only checks the presence of SARS-CoV-2, Influenza A and B virus antigens, and the intensity of the test line and the concentration of SARS-CoV-2, influenza A and B virus antigens are not correlated.
12) Samples that are positive for this test are retested and the retest result is considered to be the final result. This test cannot completely rule out the possibility of false-positive and false-negative results due to various factors. Therefore, the final diagnosis should be made according to the judgment of a specialist based on clinical findings and results obtained through other test methods.
13) When using a swab for collecting specimen, DO NOT use Nucleic Acid Preservation & Transport (NAPT) Medium.

Exchange and Returns

This product has undergone strict quality control. If the expiration date of the product has passed when purchased or if it has been deteriorated, damaged, or contaminated, it will be exchanged.

Symbols for IVD components and reagents

Symbol	Explanation	Symbol	Explanation
CE	CE mark		Temperature limit
IVD	In-vitro diagnostics Medical devices		Manufacturer
LOT	Lot number	REF	Catalog number
	Use by date	EC REP	Authorized representative in the European community
	Sufficient for <n> tests		Do not reuse
	Consult instructions for use		Do not use if package is damaged and consult instructions for use

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