CE IVD

Asan Easy Test® COVID-19 Ag

ASAN

ASAN-IFU-0020 (Rev. 8)

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

Product name

Product Name	Rapid detection kit for SARS-CoV-2 antigens
Model Name	Asan Easy Test® COVID-19 Ag
Catalogue Number	AM3474-K (20T) / AM3476-K (25T)

Manufacturing number and expiration date

Refer to external (packaging box) labeling (Lot, Exp. Date)

Package unit

Self-package unit: Refer to external (package box) labeling

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

The Asan Easy Test® COVID-19 Ag is is a lateral flow immunochromatographic assay intended for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in nasopharyngeal swab specimens from individuals with clinical symptoms of COVID-19 by their healthcare provider.

How to use

1) Specimen preparation and storage

(1) Specimens: nasopharyngeal swabs

① To obtain a nasopharyngeal swab, use the sample collection swab included in the kit.

② For nasopharyngeal swabs 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

It is recommended to use the specimen immediately after collection, if possible. If it cannot be tested immediately after collection, put it in a lidded storage container. Specimens contained in Viral Transport Media can be stored for up to 72 hours when stored refrigerated (2~8℃) or frozen (-20℃).

2) Preparation process before test

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 patient's 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 for 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) Used swab is classified as infectious waste and disposed of safely.

(4) After combining the extraction buffer tube with the dropper filter tip, take out the device from the aluminum pouch and add 4 drops (90~100μl) to the sample well (S).

(5) If the control line (C) is clearly visible after 15-20 minutes, the result is read.

(6) As the reaction time increases, the color band of the control line (C) and the test line (T) may become darker. 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).

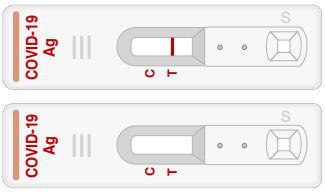
5) Interpretation of results

This product may or may not have a color band on the test line depending on the presence of SARS-CoV-2 antigen in the specimen.

(1) Negative: The color band appears only on the control line (C), and does not appear on the test line (T).

(2) Positive: The color band appears on the control line (C) and the test line (T).

(3) Invalid: The color band appears neither in the control line (C) nor in the test line (T), or the color band appears only in the test line (T). In this case, the test is incorrect or there is a quality issue of the product. Repeat the test with a new test device.



Storage and stability

The kit can be stored at 1~30℃ for up to 24 months from the manufacturing date. The test device must remain in its original sealed pouch until use.

Performance evaluation

1) Analytical sensitivity (Limit of detection, LoD)

When tests were repeated twenty times with diluted inactivated SARS-CoV-2, the lowest concentration at which more than 95% of the total tested number could be judged as positive was determined as the LoD. In result, the LoD of isolate USA-WA1/2020, isolate Italy-INMI1 and isolate Hong Kong/VM20001061/2020 are 5.90×10^2 $TCID_{50}$/mL, 7.46×10^3 $TCID_{50}$/mL and 1.23×10^3 $TCID_{50}$/mL, respectively.

2) Repeatability

For repeatability tests, negative (N), middle positive (M) and low positive (L) samples were tested 1 run a day and 2 times per run for 10 days with 3 lots by one experimenter. The concordance rate between tests, between dates, and between lots is 100%.

Sample	Between-Lot			Concordance rate
	Lot#1	Lot#2	Lot#3	
N	20/20, 100%	20/20, 100%	20/20, 100%	60/60, 100%
M	20/20, 100%	20/20, 100%	20/20, 100%	60/60, 100%
L	20/20, 100%	20/20, 100%	20/20, 100%	60/60, 100%

Sample	Between-Date										Concordance rate
	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	
N	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	60/60, 100%
M	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	60/60, 100%
L	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	6/6, 100%	60/60, 100%

Sample	Between-Test		Concordance rate
	1	2	
N	30/30, 100%	30/30, 100%	60/60, 100%
M	30/30, 100%	30/30, 100%	60/60, 100%
L	30/30, 100%	30/30, 100%	60/60, 100%

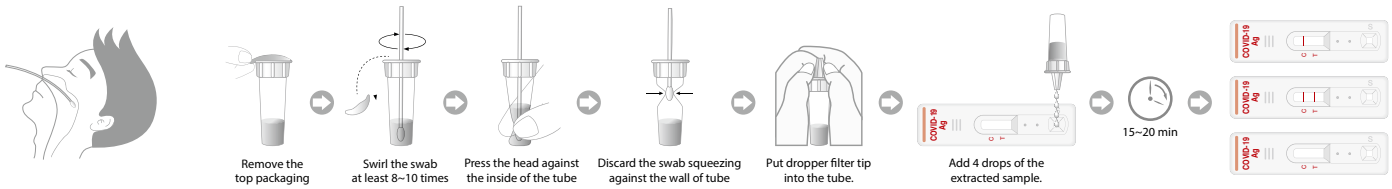
3) Reproducibility

For reproducibility tests, negative (N), middle positive (M) and low positive (L) samples were tested 1 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%.

Sample	Between-Laboratory			Concordance rate
	Site A	Site B	Site C	
N	10/10, 100%	10/10, 100%	10/10, 100%	30/30, 100%
M	10/10, 100%	10/10, 100%	10/10, 100%	30/30, 100%
L	10/10, 100%	10/10, 100%	10/10, 100%	30/30, 100%

4) Cross reactivity

The cross-reactivity against various microorganisms and viruses that may



exist in the specimens was tested. The Asan Easy Test® COVID-19 Ag 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 A H3N2 (Texas)	1×10^{5} $TCID_{50}$/mL
18	Influenza A H3N2 (Wisconsin/67/05)	1.89×10^{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	MERS-Coronavirus (Florida/USA-2_Saudi Arabia_2014)	1×10^{5} $TCID_{50}$/mL
24	Recombinant HCoV-HKU1 nucleoprotein	4 μg/mL
25	Recombinant human SARS coronavirus nucleoprotein	3 pg/mL
26	Rhinovirus A16	$1.25\times10^{5.10}$ U/mL
27	Rhinovirus B42	1.31×10^{5} $TCID_{50}$/mL
28	Enterovirus B111	0.7×10^{4} $TCID_{50}$/mL
29	Enterovirus B8	4.75×10^{5} $TCID_{50}$/mL
30	*Candida albicans*	1×10^{6} cfu/mL
31	*Corynebacterium diphtheria*	1×10^{6} cfu/mL
32	*Enterococcus faecalis*	1×10^{6} cfu/mL
33	*Escherichia coli*	1×10^{6} cfu/mL
34	*Hemophilus influenza*	1×10^{6} cfu/mL
35	*Klebsiella pneumoniae*	1×10^{6} cfu/mL
36	*Neisseria gonorrhoeae*	1×10^{6} cfu/mL
37	*Neisseria sicca*	1×10^{6} cfu/mL
38	*Proreus vulgaris*	1×10^{6} cfu/mL
39	*Pseudomonas aeruginosa*	1×10^{6} cfu/mL
40	*Staphylococcus aureus*	1×10^{6} cfu/mL
41	*Staphylococcus epidermidis*	1×10^{6} cfu/mL
42	*Streptococcus equi*	1×10^{6} cfu/mL
43	*Streptococcus mutans*	1×10^{6} cfu/mL
44	*Streptococcus pneumonia*	1×10^{6} cfu/mL
45	*Streptococcus pyogenes*	1×10^{6} cfu/mL
46	Pooled human nasal wash	N/A

5) Interference

The Asan Easy Test® COVID-19 Ag 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 LoD. The test was performed 3 times repeatedly. In result, the Asan Easy Test® COVID-19 Ag 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® COVID-19 Ag, 450 specimens were tested (150 specimens from positive nasopharyngeal swabs, 300 specimens from negative nasopharyngeal swabs). The positive percent agreement and negative percent agreement are as follows.

Asan Easy Test® COVID-19 Ag	RT-PCR comparator	
	Positive	Negative
Positive	146	1
Negative	4	299
Total	150	300

- Positive percent agreement: 97.3%(146/150) (95% CI: 93.3% ~ 99.3%)
- Negative percent agreement: 99.7%(299/300) (95% CI: 98.2% ~ 100%)

Precautions for use and disposal method

(1) Use this test kit only for in vitro diagnosis (for professionals).
(2) This test kit is disposable and should not be reused.
(3) This test kit must be in a sealed aluminum pouch until use.
(4) When handling this test kit, be careful not to let your hands or other foreign substances directly touch the test line area.
(5) This test kit 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 while 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. Also, 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) If part of the extraction buffer 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) The Asan Easy Test COVID-19 Ag targets the nucleocapsid protein (N-protein) of SARS-CoV-2 as a diagnostic marker, not the spike protein.
(11) This test kit is a diagnostic reagent designed for the detection of SARS-CoV-2 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 antigen in the sample is lower than the limit of detection, or inappropriate collection or storage of the sample, negative results may result.
(12) Samples that are positive for this test kit are retested and the retest result is used as the final result. This reagent 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 finding and the result obtained through other test methods.
(13) When using swab for collecting specimen, DO NOT use Nucleic Acid Preservation & Transport (NAPT) Medium.
(14) Please repeat testing if there is an ongoing suspicion of infection, being a high risk setting or where there is an occupational risk or other requirement.

Exchange and Returns

This product has undergone strict quality control. If the expiration date of the product has passed or 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

ASAN
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