CE IVD

Asan Easy Test® COVID-19 IgG/IgM (N)

ASAN

ASAN-IFU-004 (Rev. 2)

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

Product name

Product Name	Rapid detection kit of IgG and IgM antibodies to SARS-CoV-2
Model Name	Asan Easy Test® COVID-19 IgG/IgM (N)
Catalogue Number	AM3486-K (20T) / AM3485-K (25T)

Manufacturing number and expiration date

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

Package unit

Refer to the external box labeling

Package unit	Quantity per Kit	
	20T	**25T**
Test device	20ea	25ea
Buffer solution	1ea (5mL)	1ea (5mL)
Disposable dropper	20ea	25ea
Instruction manual for use	1ea	1ea

Purpose of use

Asan Easy Test® IgG/IgM (N) is an in-vitro diagnostic medical device that confirms the production of SARS-CoV-2 antibodies by qualitatively testing IgG and IgM antibodies against SARS-CoV-2 in human serum, plasma (sodium citrate, EDTA, heparin) and whole blood (sodium citrate, EDTA, heparin) by immunochromatographic assay (ICA).

How to use

1) Specimen collection and storage

(1) Whole Blood

① Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture.

② If blood specimen is not immediately tested, it must be refrigerated at 2 ~ 8℃ and must be used within 2 days.

(2) Serum

① Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen or supernatant.

② If serum specimen is not tested immediately, it should be refrigerated at 2~8℃ but not longer than for 3 days.

③ Do not use specimen that have been thawed more than once after freezing. Serum specimen containing a precipitate may yield inconsistent test results.

(3) Plasma

① Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.

② If Plasma specimen is not tested immediately, it should be refrigerated at 2~8℃ for 3 days.

③ Do not use specimen that have been thawed more than once after freezing. Plasma specimen containing a precipitate may yield inconsistent test results.

2) Test preparation

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

3) Test procedure

(1) Remove the test device from the aluminum pouch and place it on a flat surface.

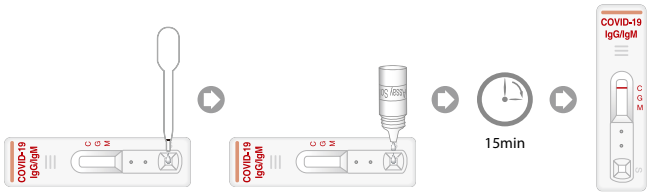
(2) [Disposable dropper] Using a disposable dropper, collect 10㎕ of serum, plasma, or 20㎕ of whole blood up to the marked black line and add it into the sample well.
[When using Micropipette] Using a micropipette, add 10㎕ of serum, plasma or 20㎕ of whole blood directly into the sample well.

(3) Used disposable droppers of micropipette tips are classified as infectious waste and should be disposed of safely.

(4) Add 2~3 drops (70-100㎕) of assay solution into the sample well.

(5) If the control line (C) is clearly visible after 15 minutes, interpret the test results.

(6) As the reaction time increases, the intensity of bands of the control line (C) and the test lines 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 15 minutes are not used for determination.



Add 10㎕ of specimen 2~3 drops of assay solution

4) Quality control

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

5) Interpretation of results

There may or may not be color band(s) on the IgG and/or IgM lines depending on the presence of IgG or IgM antibodies to SARS-CoV-2 in the specimen. The test is interpreted as positive or negative according to the presence or absence of the color band(s) on the IgG and IgM line.

(1) Negative: A color band appears only on the control line (C), and not on the IgG or IgM lines. No IgG or IgM antibodies to SARS-CoV-2 were detected in the specimen.

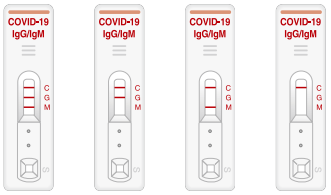
(2) Positive

① IgM positive: A color band appear on the control line (C) and the IgM line (M). The test result indicates the presence of IgM antibodies to SARS-CoV-2 in the specimen.

② IgG positive: A color band appear on the control line (C) and the IgG line (G). The test result indicates the presence of IgG antibodies to SARS-CoV-2 in the specimen.

③ IgM and IgG positive: A color band appear on the control line (C), the IgM line (M) and IgG line (G). The test result indicates the presence of IgM and IgG antibodies to SARS-CoV-2 in the specimenn.

(3) Invalid or retest: If a color band on the control line does not appear, it may be due to an incorrect test procedure. Repeat the test using a new test device.



IgG Positive IgM Positive IgG Positive IgM Negative IgG Negative IgM Positive Negative

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)

Serially diluted SARS-CoV-2 antibody positive specimens were used to determine the limit of detection. When tests were repeated 20 times with the diluted SARS-CoV-2 antibody positive specimens, 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 was confirmed using a commercial ELISA kit. The LoD of the Asan Easy Test® COVID-19 IgG/IgM (N) are as follows.

Specimen	Used commercial ELISA kit	Limit of Detection (Calculated value)
SARS-CoV-2 IgG serum	Anti-SARS-CoV-2 IgG ELISA	1.26
SARS-CoV-2 IgM serum	Anti-SARS-CoV-2 IgM ELISA	1.2

2) Repeatability

For repeatability tests, negative, SARS-CoV-2 IgG positive (High, Middle, Low) and SARS-CoV-2 IgM positive (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® COVID-19 IgG/IgM (N) shows the repeatability.

Sample	Between-Lot			Concordance rate
	Lot 1	Lot 2	Lot 3	
SARS-CoV-2 IgG Negative	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM Negative	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgG High Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgG Medium Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgG Low Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM High Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM Medium Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM Low Positive	20/20	20/20	20/20	60/60, 100%

Sample	Between-Test		Concordance rate
	Run 1	Run 2	
SARS-CoV-2 IgG Negative	30/30	30/30	60/60, 100%
SARS-CoV-2 IgM Negative	30/30	30/30	60/60, 100%
SARS-CoV-2 IgG High Positive	30/30	30/30	60/60, 100%
SARS-CoV-2 IgG Medium Positive	30/30	30/30	60/60, 100%
SARS-CoV-2 IgG Low Positive	30/30	30/30	60/60, 100%

SARS-CoV-2 IgM High Positive	30/30	30/30	60/60, 100%
SARS-CoV-2 IgM Medium Positive	30/30	30/30	60/60, 100%
SARS-CoV-2 IgM Low Positive	30/30	30/30	60/60, 100%

Sample	Between-Date					Concordance rate
	Day 1	Day 2	Day 3	Day 4	Day 5	
SARS-CoV-2 IgG Negative	12/12	12/12	12/12	12/12	12/12	60/60, 100%
SARS-CoV-2 IgM Negative	12/12	12/12	12/12	12/12	12/12	60/60, 100%
SARS-CoV-2 IgG High Positive	12/12	12/12	12/12	12/12	12/12	60/60, 100%
SARS-CoV-2 IgG Medium Positive	12/12	12/12	12/12	12/12	12/12	60/60, 100%
SARS-CoV-2 IgG Low Positive	12/12	12/12	12/12	12/12	12/12	60/60, 100%
SARS-CoV-2 IgM High Positive	12/12	12/12	12/12	12/12	12/12	60/60, 100%
SARS-CoV-2 IgM Medium Positive	12/12	12/12	12/12	12/12	12/12	60/60, 100%
SARS-CoV-2 IgM Low Positive	12/12	12/12	12/12	12/12	12/12	60/60, 100%

3) Reproducibility

For repeatability tests, negative, SARS-CoV-2 IgG positive (High, Middle, Low) and SARS-CoV-2 IgM positive (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® COVID-19 IgG/IgM (N) shows the reproducibility.

Sample	Between-Laboratory			Concordance rate
	Site A	Site B	Site C	
SARS-CoV-2 IgG Negative	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM Negative	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgG High Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgG Medium Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgG Low Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM High Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM Medium Positive	20/20	20/20	20/20	60/60, 100%
SARS-CoV-2 IgM Low Positive	20/20	20/20	20/20	60/60, 100%

4) Cross reactivity

The cross-reactivity against various antibodies to common bacteria and viruses, including respiratory diseases that may exist in the specimens was tested. The Asan Easy Test® COVID-19 IgG/IgM (N) does not show cross reactivity with the positive specimens listed in the table below.

NO.	Cross-reactive specimen	NO.	Cross-reactive specimen
1	HIV positive sample	15	RSV positive sample
2	HCV positive sample	16	Adenovirus positive sample
3	HAV positive sample	17	Parainfluenza 1/2/3 IgG positive sample
4	Zika positive sample	18	Mycoplasma pneumoniae positive sample
5	Dengue positive sample	19	Enerovirus positive sample
6	WNV positive sample	20	Borrelia burgdorferi positive sample
7	CHIK positive sample	21	Legionella pneumophilia IgG positive sample
8	Parvo B19 IgG positive sample	22	Measles IgG positive sample
9	TBE positive sample	23	Measles IgM positive sample
10	EBV vaccine positive sample	24	Human coronavirus 229E positive sample
11	VZV posive sample	25	Human coronavirus OC43 positive sample
12	Leptospira positive sample	26	Human coronavirus HKU1 positive sample
13	Inflenza A IgG positive sample	27	Human coronavirus NL63 positive sample
14	Inflenza B IgG positive sample		

5) Interference

The Asan Easy Test® COVID-19 IgG/IgM (N) 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® COVID-19 IgG/IgM (N) is not interfered with at the concentrations of the substances listed in the table below.

NO.	Interfering substance	Analytical concentration
1	Triglyceride	10g/L
2	Bilirubin	0.2g/L
3	Hemoglobin	80g/L
4	RF	20IU/ml
5	Heparin	75unit/ml
6	EDTA	5mg/ml
7	Sodium citrate	10mg/ml
8	Cholesterol	100μg/mL
9	Biotin	308μM
10	Caffeine	308μM
11	Ibuprofen	2.5mM
12	Acetaminophen	200μM
13	Acetylsalicylic acid	3.7mM
14	Quinine	150μM

6) Clinical evaluation

A total of 120 specimens derived from SARS-CoV-2 positive and negative patients confirmed by EUA-authorized SARS-CoV-2 RT-PCR kit were tested to evaluate the clinical performance of Asan Easy Test® COVID-19 IgG/IgM (N). The positive percent agreement and negative percent agreement are as follows.

(1) Summary of Positive Percent Agreement

Positive Percent Agreement (PPA)		Asan Easy Test COVID-19 IgG/IgM (N)		
		IgM	IgG	IgM/IgG
Days from onset of symptoms	1 ~ 7	71.4% (5/7) (95% CI: 29.0-96.3)	71.4% (5/7) (95% CI: 29.0-96.3)	85.7% (6/7) (95% CI: 42.1-99.6)
	8 ~ 14	66.7% (2/3) (95% CI: 9.4-99.2)	66.7% (2/3) (95% CI: 9.4-99.2)	66.7% (2/3) (95% CI: 9.4-99.2)
	≥15	80.0% (28/35) (95% CI: 63.0-91.6)	97.1% (34/35) (95% CI: 85.1-99.9)	100% (35/35) (95% CI: 90.0-100.0)
	Total	77.8% (35/45) (95% CI: 62.9-88.8)	91.1% (41/45) (95% CI: 78.8-97.5)	95.6% (43/45) (95% CI: 84.9-99.5)

(2) Summary of Negative Percent Agreement

Negative Percent Agreement (NPA)	Asan Easy Test COVID-19 IgG/IgM (N)		
	IgM	IgG	IgM/IgG
	98.7% (74/75) (95% CI: 92.8-100.0)	98.7% (74/75) (95% CI: 92.8-100.0)	97.3% (73/75) (95% CI: 90.7-99.7)

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 be in a sealed aluminum pouch until use.
4) When handling this test, be careful not to let your hands or other foreign substances directly touch 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 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 infectious 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) The extraction buffer contains Tween-20 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 IgG and IgM antibodies to SARS-CoV-2. 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 anti-SARS-CoV-2 antibodies in the sample is lower than the limit of detection, or inappropriate collection or storage of the sample, negative results may result.
11) This product only checks the presence of anti-SARS-CoV-2 antibodies, and cannot be used for the sole SARS-CoV-2 infection diagnosis.
12) This product only checks for specific antibodies to SARS-CoV-2, and there is no correlation between the strength of the test line and the titer of the SARS-CoV-2 specific antibody.
13) If there is a mutation in the site to which the antibody contained in this product binds, it may be evaluated as negative.
14) The results of this product cannot be used to finally determine the SARS-CoV-2 infection status (initial, recovery, etc.).
15) Samples that are positive for this test can be retested and the retest result is considered as a 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 finding and the results obtained through other test methods.

Exchange and Returns

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