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Asan Easy Test® COVID-19 IgG/IgM

ASAN

One step kit for the qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Corona virus in human whole blood, serum or plasma.

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

INTENDED USE

Asan Easy Test® COVID-19 IgG/IgM Kit (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.4 The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after exposure. IgG remains positive, but the antibody level drops overtime.

PRINCIPLE

Asan Easy Test® COVID-19 IgG/IgM kit (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-rabbit IgG (control line C) immobilised on a nitrocellulose strip. The burgundy colored conjugate pad contains colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anti-human IgG) the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS PROVIDED

Asan Easy Test® COVID-19 IgG/IgM contains the following items to perform the assay.

1. Test device in aluminum pouch with a desiccant
2. 10㎕ disposable dropper
3. Assay solution
4. Instruction manual for use

MATERIALS NOT REQUIRED (BUT NOT PROVIDED)

1. Lancet
2. Timer

PRECAUTIONS

1. For *in vitro* diagnostic use only. Do not re-use the product because it is disposable.
2. For professional use only.
3. Only the persons well-trained about the how-to-use of the kit are qualified to perform the test.
4. Do not eat or smoke during handling specimens.
5. Wear protective gloves while handling specimens and wash hands thoroughly after test.
6. During specimens handling, be careful to avoid the powder sample material in liquid form.
7. The contaminated area stained with spilled specimen must be cleaned thoroughly by using a surfactant.
8. Dispose all the samples and devices properly after test, in accordance with GLP.
9. Do not mix with other specimens.
10. Do not hold the pipette in the mouth and use the reagent of the other lots.
11. The device is sensitive to humidity as well as to heat. So, it's very important to take off the device from the sealed pouch when it use.
12. Do not use the kit after the expiration date.
13. The buffer solution contains sodium azide as a preserving agent. Be careful not to contact it in your eyes or onto your skin. if it does, flush it away with plenty of water, and go to see a doctor if necessary.
14. As the possibility of false positive or false negative cannot be completely eliminated due to several factors in this product, final diagnosis shall not be solely based on the result of this product, and the final diagnosis shall be decided by the results of other test methods and the judgement of a medical specialist based on clinical opinions.
15. If the aluminium pouch of a product is damaged before use, or the packing is not well-sealed, the product shall not be used.
16. Do not change the usage of the product or components.

SPECIMEN COLLECTION AND STORAGE

1. Specimen Collection and Storage

1) Serum, plasma or whole blood samples may be used with this test.

2) Whole Blood

[Collection by venipuncture]

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

② If blood specimens are not immediately tested, they should be refrigerated at 2~8℃.

③ When stored at 2~8℃, the blood specimens should be used within 3 days.

[Collection using a lancet]

① Clean the area to be lanced with an alcohol swab.

② Squeeze the end of the fingertip and pierce with a sterile lancet provided.

③ Draw blood into the provided disposable dropper to black line to take 10㎕ of blood.

3) Serum or Plasma

[Serum] 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.

[Plasma] 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.

4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2~8℃ for 3 days. For storage period longer, They can be stored at -20℃ for 12 months. Do not use samples that have been thawed more than once after freezing.

5) Serum or plasma specimens containing a precipitate may yield inconsistent test results.

2. Precaution

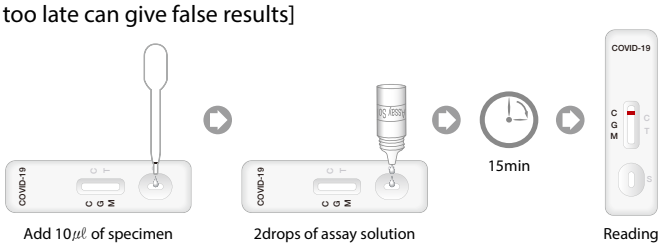
1) Anticogulants such as heparin, EDTA, and citrate do not affect the test result.

2) Use separately disposable dropper or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.

TEST PROCEDURE

1. Place all specimens, test device and allow them to room temperature prior to testing(15~30 min).
2. Please perform the test immediately after removing the device from the foil pouch.

3. [Disposable dropper] Using a disposable dropper, add 10㎕ of serum, plasma or whole blood drawn to black line into the sample well (S).
   [Micropipette use] Add 10㎕ of serum, plasma or whole blood into the sample well (S) directly.
3. Add 2 drop (70-100㎕) of assay solution into the sample well (S).
4. Interpret the test results at 15 minutes.
   [Caution: Do not read the test result after 15 minutes, The reading too late can give false results]



Add 10㎕ of specimen　2drops of assay solution　Reading

STORAGE & EXPIRATION

1. Asan Easy Test® COVID-19 IgG/IgM kit should be stored between 2 to 30℃ (35.6-86℉).
2. Expiration date of this kit is 24 months after its manufacture date.

INTERPRETATION OF RESULTS

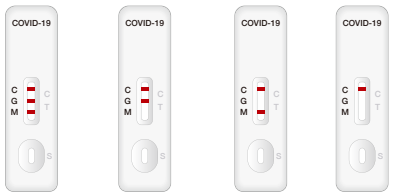
1. NEGATIVE:
The control line is only visible on the test device and the absence of any burgundy color in the both G and M. No anti-Covid antibodies were detected.

2. IgM POSITIVE:
The control line (C) and IgM line (IgM) are visible on the test device. The test indicates for the presence of IgM anti-COVID-19 in the specimen and The result is IgM anti-COVID-19 positive.

3. IgG POSITIVE:
The control line (C) and IgG line (IgG) are visible on the test device. The test indicates for the presence of IgG anti-COVID-19 in the specimen and The result is IgG anti-COVID-19 positive.

4. IgG and IgM POSITIVE:
The control line (C), IgM (IgM) and IgG (IgG) are visible on the test device. The test indicates for the presence of both IgG and IgM anti-COVID-19 in the specimen. The result is IgG and IgM anti-COVID-19 positive.

5. INVALID:
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques may be the reasons for control line failure. Repeat the test using a new test device.



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

PERFORMANCE OF CHARACTERISTIC

1. Cross reactivity
As a result of cross-reactivity testing for diseases that may have symptoms similar to those caused by COVID-19, it was found that the following positive samples did not cause cross-reactivity.

No.	Cross reaction materials	No.	Cross reaction materials
1	Influenza A Positive serum sample	11	HBV Positive serum sample
2	Influenza B Positive serum sample	12	Enterovirus 71 Positive serum sample
3	RSV Positive serum sample	13	Common Coronavirus Positive serum sample
4	Adenovirus Positive serum sample	14	Mycoplasma Positive serum sample
5	Parainfluenza 1~4 Positive serum sample	15	Pneumococco Positive serum sample
6	Measles Positive serum sample	16	Streptococcus Positive serum sample
7	Rubella Positive serum sample	17	Mycobacterium tuberculosis Positive serum sample
8	EB virus Positive serum sample	18	TP Positive serum sample
9	HIV Positive serum sample	19	Chlamydia Positive serum sample
10	HCV Positive serum sample		

2. Interference test
As a result of evaluating the interference of the patient samples below, no interference was observed.

No.	Name of material
1	Triglyceride
2	Bilirubin
3	Rheumatoid factor
4	EDTA
5	Heparin
6	Sodium citrate
7	Hemoglobin

3. Clinical Performace Test
The Asan Easy Test® COVID-19 IgG/IgM have tested with 242 positive specimens and 300 negative specimens and The results are summarized in the following tables.

- Positive coincidence rate: 95% (230/242)

Asan Easy Test® COVID-19 IgG/IgM	1~7 days after onset	8~14 days after onset	15~21 days after onset	1~21 days after onset
Positive	72	126	32	230
Negative	8	2	2	12
Positive coincidence rate	90.0% (72/80)	98.4% (126/128)	94.1% (32/34)	95.0% (230/242)

- Negative coincidence rate: 95.7% (287/300)

LIMITATIONS OF THE TEST

1. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. Humidity and temperature can adversely affect results.
3. The instructions for the use of the test should be followed during testing procedures.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result does not preclude the possibility of an early infection of COVID-19.
5. All specimens should be handled as being potentially infection.
6. Hemolytic samples cannot be used for testing.
7. Some specimens containing unusually high heterophile antibodies or rheumatoid factor may affect expected results.

REFERENCE

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81: 85-164.
2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17: 181-192.

	Do not use if package is damaged		Do not reuse
	Expiry Date	Σ	Tests per Kit
LOT	Lot Number	IVD	*In Vitro* Diagnostic Use
REF	Catalogue number	2℃ 30℃	Store between 2~30℃
	Manufacturer		Refer to Instruction for Use

Manufactured & Sold by
ASAN PHARMACEUTICAL CO., LTD
122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, 17551, Korea
ASAN
Tel: +82-31-656-5991
Fax: +82-31-656-5992
http://www.asanpharm.com

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EC REP MT PROMEDT /Medical Technology Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
Tel/Fax: +49 6894 581020 / +49 6894 581021 / Email: info@mt-procons.com