COVID-19 IgM Antibody Rapid Test Kit Instructions

PRODUCT NAME

COVID-19 IgM Antibody Rapid Test Kit

MODEL

CMART-A, CMART-B, CMART-C.

PACKAGING

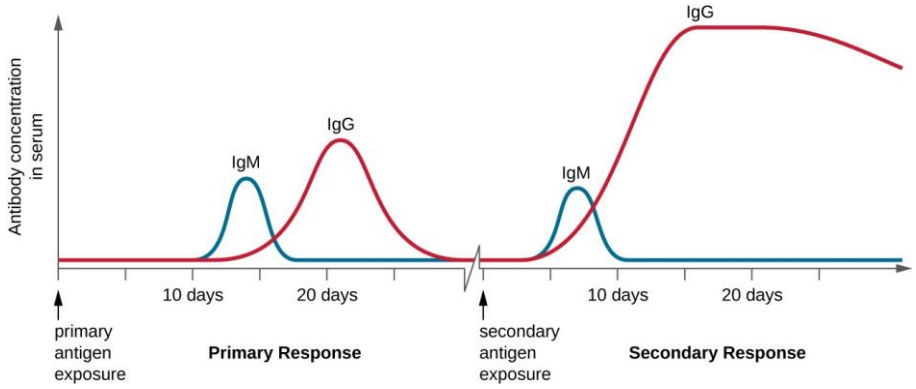
CMART-A: for 1 test per box; CMART-B: for 20 tests per box; CMART-C: for 50 tests per box

INTENDED USE

Hecin COVID-19 IgM Antibody Rapid Test Kit is an immunochromatographic assay for rapid, qualitative detection of SARS-CoV-2 IgM Antibody in human serum and plasma. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by 2019-nCoV. The test only provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

SUMMARY

During 2019 and 2020, a novel virus broke out all over the world. The novel virus, now named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The major clinical symptoms of COVID-19 include fever, fatigue and dry cough, while some patients also showed nasal congestion, runny nose, and diarrhea, etc. Most severe cases have dyspnea a week later. Condition of critical patients could deteriorate rapidly to acute respiratory distress syndrome, septic shock, irreversible metabolic acidosis and blood coagulation dysfunction. It should be noted that severe and critical COVID-19 patients might have no obvious fever throughout the course. Like other respiratory pathogens, IgM is the first antibody produced by the immune system when a person is infected with the novel coronavirus. Generally, IgM level starts to appear 7-10 days after viral exposure. IgM level reaches the peaks 14 days after viral exposure and begin to decline. While IgM level decline, IgG level start to increase until they reach a peak as primary response by human immune system. Therefore, it is very significant parameter for IgM/IgG antibodies to make diagnosis of SARS-CoV-2 infection.



PRINCIPLE

Hecin COVID-19 IgM Antibody Rapid Test Kit is an IgM capture solid-phase immunochromatographic assay and can be used for the detection of SARS-CoV-2 IgM in human serum and plasma. On the test strip the quality control (C) line is pre-coated with anti-rabbit IgG antibody, and the detection (T) line is pre-coated with SARS-CoV-2 antigen. The gold pad is coated with colloidal gold-labeled anti-human IgM and rabbit IgG antibodies. SARS-CoV-2 IgM in serum or plasma will bind to colloidal gold-labeled anti-human IgM and form a gold-labeled antibody-antigen complex. The complex will then move along the strip in the cassette and binds to the pre-coated SARS-CoV-2 antigen on the detection line (T-line) and form the "anti-IgM-IgM-antigen" complex, then a visible pink/purple band will appear at the test line (T). Meanwhile, colloidal gold-labeled rabbit IgG antibody which can be recognized by immobilized anti-rabbit IgG antibody were used as a control, a pink/purple band in the control line (C) should be visualized.

PRECAUTIONS

1. This kit is for *in vitro* diagnostic use only and for professional person use only.
2. Test cassette is a one-time use. Don't re-use the Test cassette after first use.
3. Do not use it after it is expired.
4. Please read the instructions of the detection kit carefully before testing and strictly follow the user manual.
5. All specimens must be considered as potentially infectious pathogen capable of transmitting diseases. Appropriate precautions should be taken in collection, handling, storage and disposal of specimens. Please wear gloves, masks, protective clothing, etc. All waste including used cotton swabs, test cassettes, droppers and alcohol cotton tablets should be handled as biohazardous items. All process of test and disposal must follow the local law and laboratory regulation.
6. Please use the sample diluent provided by this kit. Test cassettes and sample diluents from different batches should not be mixed use.
7. It should be at room temperature during testing. Test cassette stored at low temperature should be restored to room temperature before opening to avoid moisture.
8. Do not use damaged or expired test cassette.
9. Desiccant is contained in the aluminum foil bag, which cannot be taken orally.
10. Improper specimen collection or processing may cause false negative results.

MATERIALS

Components	Componeents	Pack Size		
		CMART-A	CMART-B	CMART-C
Test cassette	Nitrocellulose membrane, glass fiber, filter paper, PVC board, plastic cassette, recombinant SARS-CoV-2 protein, anti-human IgM antibody, rabbit IgG antibody and anti-rabbit IgG polyclonal antibody	1 pc.	20 pcs.	50 pcs.
Sample diluent	0.01M PBS, etc.	1×0.2ml/tube	1×2ml/bottle	1×5.5ml/bottle

Material Required but Not Provided

Specimen collection containers; centrifuge; timer; personal protective equipment, such as protective gloves, medical mask, goggles and lab coats; appropriate biohazard waste container and disinfectants.

STORAGE AND STABILITY

1. Store at 2~30ºC in the sealed pouch up to the expiration date printed on the package.
2. Test cassette should be used within 1 hour after opening the aluminum foil bag.
3. Sample diluent should be covered immediately after use and stored at 2 ~ 30℃. Please use it within the validity period.
4. Production date and expiration date: See the packaging label for details.

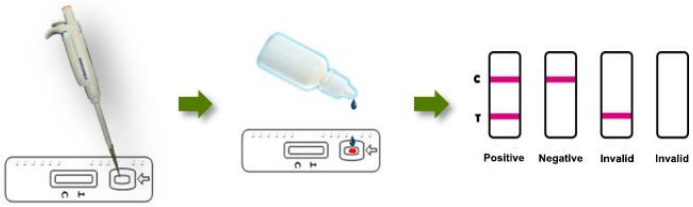
SPECIMEN REQUIREMENTS

1. The test can be performed with serum and plasma.
2. Samples may be stored for up to 7 days at 2 ~ 8℃ or 3 months at -20℃ prior to test.
3. The samples should be restored to room temperature (10 ~ 30℃) before testing. The frozen samples should be completely thawed, rewarmed, and mixed before use. Avoid repeated freeze-thaw cycles.
4. The collection and transportation of the specimens should follow the guideline of "Coronavirus disease (COVID-19) technical guidance: Laboratory testing for SARS-CoV-2 in humans", published by WHO, 2020.

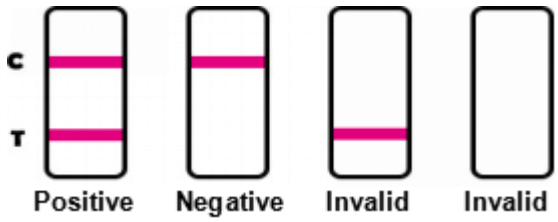
TEST PROCEDURE

Please read the instructions carefully before use.

1. Allow the cassette, diluent and specimen to equilibrate to room temperature (22 ~30℃) prior to testing.
2. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
3. Load 10μL of serum or plasma into the sample well and then add 2 drops (80 μL) of sample diluent to the same well.
4. Wait for 15 minutes and read the results. Do not read results after 30 minutes.



RESULT INTERPRETATION

	**Positive**	Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 IgM antibody in the specimen.
	Negative	Colored band appears at control line (C) only. It indicates that the concentration of the SARS-CoV-2 IgM antibody is zero or below the detection limit of the test.
	Invalid	No visible colored band appears at control line after performing the test. The directions may not have been followed correctly. It is recommended that the specimen be re-tested.

LIMITATIONS OF THE TEST

1. The test results are for clinical reference only. A final diagnostic result should only be determined by physician after all clinical and laboratory findings have been evaluated.
2. Negative test results do not rule out the possibility of viral infection.
3. Limited by the method of antibody detection, it is recommended to use nucleic acid detection or virus culture identification methods for result determination.
4. In early stage of viral exposure, IgM test may be negative due to low IgM level. It is suggested to retest after 7-14 days to see if IgM level increase.
5. Possible causes of false negative results:
   a. Some unknown components shielded the viral IgM antibody determinants from binding to labeled antibody.
   b. Improper storage of samples leads to the degradation of IgM antibody.
   c. In the early stage of infection, the IgM antibody have not been produced. The absence or low titers of pathogen-specific IgM antibody in blood could lead to negative results.
6. Blood with some unnormal immune factors may lead to false positive result. Loading too much sample in the well of test strip may lead to false positive result.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity

Total 551 clinical case samples which include 310 confirmed case samples and 241 confirmed excluded case samples, were obtained for testing. Test results between Hecin COVID-19 IgM Antibody Rapid Test Kit and the confirmed case samples were compared. The results of sensitivity and specificity between the two method are show below.

Reagents	Clinical cases		Total
	Confirmed	Excluded	
Positive	283	4	287
Negative	27	237	264
Total	310	241	551

Sensitivity: 91.29% (95%CI: 87.58%~94.18%); Specificity: 98.34% (95%CI: 95.81%-99.55%)
Total consistent: 94.37% (95%CI: 92.11%-96.15%)

B. Cross-reactivity

Specimens which tested positive with following various agents were investigated with Hecin COVID-19 IgM Antibody Rapid Test Kit. The results showed no cross reactivity:

Coronavirus OC43 IgM antibody	Coronavirus HKu-1 IgM antibody
Influenza A virus IgM antibody	Influenza B virus IgM antibody
Respiratory Syncytial Virus IgM antibody	Adenovirus IgM antibody
Enterovirus EV71 IgM antibody	Coxsackie Virus A16 IgM antibody
Measles virus IgM antibody	Parainfluenza virus IgM antibody
human Cytomegalovirus IgM antibody	Mumps Virus IgM antibody
Varicella-Zoster Virus IgM antibody	EB Virus Capsid Antigen IgM antibody
Mycoplasma pneumoniae IgM antibody	Chlamydia pneumoniae IgM antibody
2019-nCoV IgG antibody	

C. Interferences

Substances at the concentration showed in the following table will not interfere the test results of Hecin COVID-19 IgM Antibody Rapid Test Kit:

Endogenous interference

Hemoglobin	≤2 g / L	Triglyceride	≤37 mmol / L
Bilirubin	≤342 μmol / L	Rheumatoid Factor	≤100 IU / mL
HAMA	≤200 ng / mL	Antinuclear antibody	≤150 RU / mL
Antimitochondrial antibody		≤80 U / mL	
Total IgM	≤2 mg / mL	Total IgG	≤30 mg / mL

Drug interference

Interferon alpha	750 U / L	Zanamivir	0.015 mg / mL
Ribavirin	0.3375 mg / mL	Oseltamivir	0.1125 mg / mL
Paramivir	0.675 mg / mL	Lopinavir	0.6 mg / mL
Ritonavir	0.15 mg / mL	Abidol	0.45 mg / mL
Levofloxacin	0.45 mg / mL	Azithromycin	1.125 mg / mL
Ceftriaxone	3 mg / mL	Meropenem	4.5 mg / mL
Tobramycin	0.3 mg / mL		

Anticoagulant

EDTA	Commonly used concentration

D. Precision

Testing SARS-NoV-19 antibody reference panel from authority. Passed the reference panel test.

INDEX OF SYMBOL

	Keep away from Light		*In Vitro* Diagnostic Use
	Keep Dry		Biohazard
	Do not reuse		Refer to the Instructions

BIBLIOGRAPHY

1. World Health Organization. Coronavirus disease (COVID-19) technical guidance: Laboratory testing for COVID-19 in humans. Jan. 17, 2020.
2. Jianfeng He. *Prevention and Control of the Infection of COVID-19*. Guangzhou: Guangdong Technology Press, 2020, pp.1-51.
3. B Lymphocytes and Humoral Immunity. https://courses.lumenlearning.com/microbiology/ chapter/ b-lymphocytes and humoral immunity/

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