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 COVID-19 IgM Antibody in whole blood, serum, plasma and fingertip blood. 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 provides preliminary test results. Negative results don't preclude COVID-19 infection and they cannot be used as the sole basis for treatment or other management decision.

SUMMARY

On December 31, 2019, several cases of pneumonia in Wuhan City, Hubei Province of China were reported to the World Health Organization (WHO). The novel virus, now known as 2019-nCoV (also referred to as SARS-CoV-2), is a member of the beta coronavirus family and has spread across China and to other countries or regions. The WHO has named the disease caused by 2019-nCoV as coronavirus disease 2019 (abbreviated "COVID-19"). 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. Cases infected by symptomatic patients were also reported.

DETECTION 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 COVID-19 specific IgM in whole blood, serum, plasma and fingertip blood. The quality control (C) line is pre-coated with anti-rabbit IgG antibodies, and the detection (T) line is pre-coated with COVID-19 antigen. The gold pad is coated with colloidal gold-labeled anti-human IgM antibodies. COVID-19 specific IgM antibodies in sample will combine with colloidal gold-labeled anti-human IgM antibodies and form a gold-labeled antibody-antigen complex. The complex will then move along the detection card and react with the pre-coated COVID-19 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) after assay. In addition, colloidal gold-labeled rabbit IgG antibodies which can be recognized by immobilized anti-rabbit IgG antibodies were used as a control for proper function of the reagents. 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 use only.
2. This kit is a single-use *in vitro* diagnostic. Do not use it if it is expired.
3. Please read the instructions of the detection kit carefully before the experiment and strictly follow the operation steps.
4. Testing samples must be considered as potentially infectious. Appropriate protective measures should be taken during sample collection, storage, shipment and the testing procedure. 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.
5. Please use the sample diluent provided by this reagent when testing. Test cassettes and sample diluents from different batches should not be mixed.
6. Use fresh specimens for testing. Do not use repeated freeze-thaw samples.
7. It should be at room temperature during operation. Test cassettes stored at low temperature should be restored to room temperature before opening to avoid moisture absorption.
8. Do not use damaged or expired test cassettes.
9. Desiccant is contained in the aluminum foil bag, which cannot be taken orally.
10. Improper sample collection or processing may cause false negative results.
11. If the screening result is positive, please contact your local public health agency.
12. The final diagnosis should be made by the doctor after combining other testing indicators and clinical symptoms.
13. If you have any questions or suggestions during the use of this reagent, please contact us.

MATERIALS

Components	Main Ingredients	Pack Size

		CMART-A	CMART-B	CMART-C
Test cassette	Nitrocellulose membrane, glass fiber, filter paper, PVC board, plastic card case, recombinant COVID-19 protein, anti-human IgM antibody, rabbit IgG polyclonal 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 (for serum/plasma sample); timer; personal protective equipment, such as protective gloves, medical mask, goggles and lab coats; appropriate biohazard waste container and disinfectants.

STORAGE AND STABILITY

1. Stored at 2 ~ 30℃ degree. Valid for 12 months.
2. Test cassettes 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 whole blood, serum, plasma and fingertip blood.
2. Whole blood samples should be tested as soon as possible after collection. If blood samples cannot be tested within 2 hours, they should be stored at 2 ~ 8℃ for no more than 2 days.
3. Serum and plasma samples may be stored for up to 7 days at 2 ~ 8℃ or 3 months at -20℃ prior to testing.
4. Fingertip blood samples should be tested immediately after collection.
5. 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.
6. The collection and transportation of the specimens should be in accordance with "Coronavirus disease (COVID-19) technical guidance: Laboratory testing for COVID-19 in humans", published by WHO, 2020.

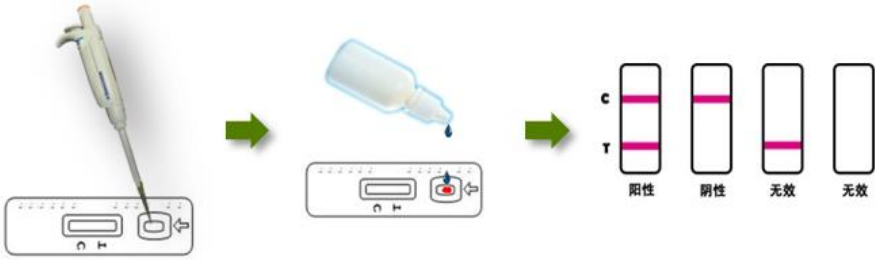
TEST PROCEDURE

Please read the instructions carefully before use.

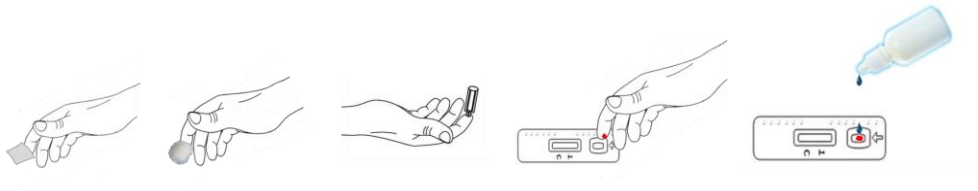
1. Allow the device, diluent and specimen to equilibrate to room temperature (22 ~30℃) prior to testing.
2. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
3. Please apply different sample adding methods for different sample types as following:
   A. For serum, plasma and whole blood specimens: Transfer 10μL of serum or plasma specimen, or 20μL of whole blood to the sample well and then add 2 drops (80 μL) of sample diluent to the same well.
   B. For fingertip blood specimens: Disinfect the fingers according to the operating standard, then use a disposable tip blood collection needle to take the fingertip blood. Discard the first drop of blood, then squeeze out a volume of about 20μL (one drop) of blood bead. Approach the finger to the sample well to transfer the blood bead into the well. Use a medical cotton ball to press the fingertips to stop bleeding.

   Note: Adding too much of whole blood or fingertip blood could cause false positive results. Where conditions permit, it is recommended to accurately add samples using a micro-pipette or pipette.
4. Wait for 15 minutes and read the results. Do not read results after 30 minutes.

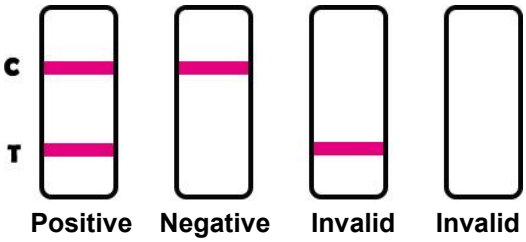
   Method A:



Method B:



RESULT INTERPRETATION



Positive	Colored bands appear at both test line (T) and control line (C). It indicates a positive result for the COVID-19 IgM antibodies in the specimen.
Negative	Colored band appears at control line (C) only. It indicates that the concentration of the COVID-19 IgM antibodies 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 PROCEDURE

1. The test results are for clinical reference only. A confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated. Sample collection and sample processing have a greater impact on pathogen detection.
2. Negative test results do not rule out the possibility of viral infection.
3. Limited by the method of antibody detection reagents, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation for negative test results.
4. Possible causes of false negative results:

①Some unknown components shielded the viral IgM antibodies determinants from binding to labeled antibodies.

②Improper storage of samples leads to the degradation of IgM antibodies.

③In the early stage of infection, the absence or low titers of pathogen-specific IgM antibodies can lead to negative results Early IgM antibodies have not been produced.

5. Adding too much sample will lead to false positive results.

PERFORMANCE CHARACTERISTICS

A. Sensitivity and Specificity

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 enterprise reference products, all positive reference products are positive, consistent with known results of reference products; all negative reference products are negative.

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.

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Hecin Scientific, Inc.
4F, Building A, #1 Ruifa Rd, Luogang District
Guangzhou, P. R. China 510530 (86)020-82512529

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany