Hecin Scientific, Inc.

CE Technical Document

Performance Evaluation Summary

(COVID-19 IgM Antibody Rapid Test Kit)

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1. Purpose

We summarize the clinical data of COVID-19 IgM Antibody Rapid Test Kit.

2. Device Information

2.1 Device Name

COVID-19 IgM Antibody Rapid Test Kit

2.2 Device Model

CMART-A, CMART-B, CMART-C

2.3 Packaging:

CMART-A: for 1 test per box;

CMART-B: for 20 tests per box;

CMART-C: for 50 tests per box

2.4 Device structure & composition

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

2.5 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 case samples	Excluded case samples	
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.

3. Summary of clinical data

3.1 Clinical test of COVID-19 IgM Antibody Rapid Test Kit

There were 938 serum and plasma samples collected by three clinical medical institutions, of which 4 were excluded, so the effective samples were 934. The novel coronavirus was diagnosed in 310 cases, 241 cases were excluded, the samples with high suspected and continuously negative nucleic acid detection (including continuous negative cases under nucleic acid detection, clinical diagnosis cases and the cases described in the clinical diagnosis background information with new coronavirus infection pneumonia) have 155 cases, 76 cases of other suspected cases, and 152 cases of repeated detection samples.

Among 310 confirmed samples, 59 cases were early-stage samples and only 48 cases were detected by test reagent, so the sensitivity was 81.36%; 62 cases were middle-stage samples and only 57 cases were detected by test reagent, so the sensitivity was 91.94%; 183 cases were late-stage samples and only 173 cases were detected by test reagent, so the sensitivity was 94.54%; 6 cases were not in the above three stages and only 5 cases were detected by test reagent, so the comprehensive sensitivity was 91.29%; 241 samples were excluded and 237 were negative, so the specificity was 98.34%. The total coincidence rate was 94.37%, the Kappa value was 0.887 > 0.75, and the consistency was good. It can be seen from the detection rate of early, middle and late stage that, with the development of the disease, the detection ability of the test reagent to the samples of middle and late stage is higher than that of early stage. In the early stage of the disease, the IgM antibody titer may not be high and the detection rate is relatively low. In the middle and late stage of the disease, the antibody titer increases and the detection rate of reagents also increases.

A novel coronavirus test showed that the positive coincidence rate was 89.45%, the negative coincidence rate was 66.99%, and the total coincidence rate was 73.73%. Among the 168 samples tested negative for nucleic acid but positive for the test reagent, the confirmed samples were 81, the clinical diagnostic samples were 37, and 30 cases described in the clinical diagnosis background

information with new coronavirus infection pneumonia were highly suspected cases.

3.2 Verification of reference products

Positive / negative detection ability: Three batches of COVID-19 IgM Antibody Rapid Test Kit were used to test the following samples, and each sample was tested only once.

Reference product	Reference product No.	Sample type	Batch: 20200210	Batch: 20200211	Batch: 20200212
Positive reference product	QY01	2019- nCoV IgM Positive plasma	+	+	+
	QY02	2019- nCoV IgM Positive plasma	+	+	+
	QY03	2019- nCoV IgM Positive plasma	+	+	+
	QY04	2019- nCoV IgM Positive plasma	+	+	+
	QY05	2019- nCoV IgM Positive plasma	+	+	+
	QY06	2019- nCoV IgM Positive plasma	+	+	+
Negative reference product	QT01	Coronavirus OC43 IgM Positive serum	-	-	-
	QT02	Coronavirus HKU-1 IgM Positive serum	-	-	-
	QT03	Mycoplasma pneumoniae IgM Positive serum	-	-	-
	QT04	Chlamydia pneumoniae IgM Positive serum	-	-	-
	QT05	Respiratory adenovirus IgM Positive serum	-	-	-
	QT06	2019- nCoV IgM Negative serum	-	-	-
	QT07	2019- nCoV IgM Negative serum	-	-	-
	QT08	2019- nCoV IgM Negative serum	-	-	-

Note: "+" represents the positive result, while "-" represents the negative result.

Conclusion: The test results of this kit for positive reference are all positive, and for negative reference are all negative. Therefore, COVID-19 IgM Antibody Rapid Test Kit can detect 2019n-CoV IgM specifically.