National Institutes for Food and Drug Control

Inspection Report

Report Number: RZ202001001

Product Name:COVID-19 IgM Antibody Rapid Test Kit

Manufacturer:Hecin Scientific, Inc.

Inspection Purpose:Registration Test (domestic *in vitro* diagnostic reagents / first registration / quality standard review)

Inspected according to: Product Technical Requirements

Description

1. If the client, producer or sample supplier has any objection to this report, please submit it in writing within 7 days from the date of receipt of the report.
2. The data and conclusions issued in this report are the inspection results of the inspection entries of the sample.
3. This report shall not be altered, added or deleted.
4. The report without the special seal of the inspection report of our hospital is invalid.
5. This report shall not be used for advertising, competingor commercial promotion without the written consent of our hospital.

Address: 2 TiantanXili, Dongcheng District, Beijing (100050)

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National Institutes for Food and Drug Control Inspection Report

Product Name	COVID-19 IgM Antibody Rapid Test Kit	Inspection number	RZ2804202001427
Manufacturer	Hecin Scientific, Inc.	Lot Number	20200210
Sample Supply Organization	Guangzhou Market Supervision Administration	Specification	50T/box
Inspection Purpose	Registration test (domestic in vitro diagnostic reagents / first registration / quality standard review)	Model	IVD
Inspection Entry	All	Pack Size	50T/box
Sample receipt date	2020-02-25	Valid until	2021-08-19
Inspection quantity	3 boxes	Number of seals	/
Inspected according to	Product Technical Requirements		

Inspection Entry	Quality Standard	Inspection Result
【2.1 Physical Properties】		
2.1.1 Appearance	There should be no missing components. The outer packaging of the kit should be clean and contamination-free.The test cassette should be sealed inside the aluminum foil bag. The aluminum foil bags should have no damage or contamination.The sample diluent should be a colorless, clear, homogeneous liquid without impurities or precipitation visible to the naked eye.	Compliance
2.1.2 Membrane Strip Width	The membrane strip width should be no less than 2.5mm.	4.2mm
2.1.3 Liquid Migration Speed	The liquid migration speed should be no less than 10mm/min.	11mm/min
【2.2 Performance Test】		
2.2.1.1 Negative Reference Compliance Rate	The negative reference compliance rate should be no less than 24/25	24/25
2.2.1.2 Positive Reference Compliance Rate	The positive reference compliance rate should be 10/10	10/10
2.2.1.3 Minimum Detection Limit	The test results of reference L1 and L2 should all be positive. The test result of reference L3~L10 could be positive or negative.	L1~L4: positive, L5~L10: negative.

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2.2.1.4 Repeatability (n=10)	All test results should be positive. The colored band observed in 10 replicates should be consistent.	Compliance

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Note：1. The reference product for the test is the national referencefor 2019-nCoV IgM antibody detection reagent (for emergency use) (batch number 370096-202001); 2. According to the product manual, the sample amount of the reference product used in the test was 10uL; results wereobserved after 15 minutes; the result showed after 30 minutes was invalid.

Inspection Conclusion	This product is inspected according to the technical requirements of the product, and the results meet the requirements.		
Authorized signatory		Date of issue	2020-02-25

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National Institutes for Food and Drug Control

Inspection Report

Report Number: RZ202001002

Product Name:COVID-19 IgM Antibody Rapid Test Kit

Manufacturer:Hecin Scientific, Inc.

Inspection Purpose:Registration Test (domestic *in vitro* diagnostic reagents / first registration / quality standard review)

Inspected according to: Product Technical Requirements

Description

1. If the client, producer or sample supplier has any objection to this report, please submit it in writing within 7 days from the date of receipt of the report.
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National Institutes for Food and Drug Control Inspection Report

Product Name	COVID-19 IgM Antibody Rapid Test Kit	Inspection number	RZ2804202001428
Manufacturer	Hecin Scientific, Inc.	Lot Number	20200211
Sample Supply Organization	Guangzhou Market Supervision Administration	Specification	50T/box
Inspection Purpose	Registration test (domestic in vitro diagnostic reagents / first registration / quality standard review)	Model	IVD
Inspection Entry	All	Pack Size	50T/box
Sample receipt date	2020-02-25	Valid until	2021-08-19
Inspection quantity	3 boxes	Number of seals	/
Inspected according to	Product Technical Requirements		

Inspection Entry	Quality Standard	Inspection Result
【2.1 Physical Properties】		
2.1.1 Appearance	There should be no missing components. The outer packaging of the kit should be clean and contamination-free.The test cassette should be sealed inside the aluminum foil bag. The aluminum foil bags should have no damage or contamination.The sample diluent should be a colorless, clear, homogeneous liquid without impurities or precipitation visible to the naked eye.	Compliance
2.1.2 Membrane Strip Width	The membrane strip width should be no less than 2.5mm.	4.3mm
2.1.3 Liquid Migration Speed	The liquid migration speed should be no less than 10mm/min.	14mm/min
【2.2 Performance Test】		
2.2.1.1 Negative Reference Compliance Rate	The negative reference compliance rate should be no less than 24/25	24/25
2.2.1.2 Positive Reference Compliance Rate	The positive reference compliance rate should be 10/10	10/10
2.2.1.3 Minimum Detection Limit	The test results of reference L1 and L2 should all be positive. The test result of reference L3~L10 could be positive or negative.	L1~L3: positive, L4~L10: negative.

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2.2.1.4 Repeatability (n=10)	All test results should be positive. The colored band observed in 10 replicates should be consistent.	Compliance

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Note：1. The reference product for the test is the national referencefor 2019-nCoV IgM antibody detection reagent (for emergency use) (batch number 370096-202001); 2. According to the product manual, the sample amount of the reference product used in the test was 10uL; results wereobserved after 15 minutes; the result showed after 30 minutes was invalid.

Inspection Conclusion	This product is inspected according to the technical requirements of the product, and the results meet the requirements.		
Authorized signatory		Date of issue	2020-02-25

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National Institutes for Food and Drug Control

Inspection Report

Report Number: RZ202001003

Product Name:COVID-19 IgM Antibody Rapid Test Kit

Manufacturer:Hecin Scientific, Inc.

Inspection Purpose:Registration Test (domestic *in vitro* diagnostic reagents / first registration / quality standard review)

Inspected according to: Product Technical Requirements

Description

1. If the client, producer or sample supplier has any objection to this report, please submit it in writing within 7 days from the date of receipt of the report.
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National Institutes for Food and Drug Control Inspection Report

Product Name	COVID-19 IgM Antibody Rapid Test Kit	Inspection number	RZ2804202001429
Manufacturer	Hecin Scientific, Inc.	Lot Number	20200212
Sample Supply Organization	Guangzhou Market Supervision Administration	Specification	50T/box
Inspection Purpose	Registration test (domestic in vitro diagnostic reagents / first registration / quality standard review)	Model	IVD
Inspection Entry	All	Pack Size	50T/box
Sample receipt date	2020-02-25	Valid until	2021-08-19
Inspection quantity	3 boxes	Number of seals	/
Inspected according to	Product Technical Requirements		

Inspection Entry	Quality Standard	Inspection Result
【2.1 Physical Properties】		
2.1.1 Appearance	There should be no missing components. The outer packaging of the kit should be clean and contamination-free.The test cassette should be sealed inside the aluminum foil bag. The aluminum foil bags should have no damage or contamination.The sample diluent should be a colorless, clear, homogeneous liquid without impurities or precipitation visible to the naked eye.	Compliance
2.1.2 Membrane Strip Width	The membrane strip width should be no less than 2.5mm.	4.2mm
2.1.3 Liquid Migration Speed	The liquid migration speed should be no less than 10mm/min.	11mm/min
【2.2 Performance Test】		
2.2.1.1 Negative Reference Compliance Rate	The negative reference compliance rate should be no less than 24/25	24/25
2.2.1.2 Positive Reference Compliance Rate	The positive reference compliance rate should be 10/10	10/10
2.2.1.3 Minimum Detection Limit	The test results of reference L1 and L2 should all be positive. The test result of reference L3~L10 could be positive or negative.	L1~L4: positive, L5~L10: negative.

National Institutes for Food and Drug Control Inspection Report

2.2.1.4 Repeatability (n=10)	All test results should be positive. The colored band observed in 10 replicates should be consistent.	Compliance

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Note：1. The reference product for the test is the national referencefor 2019-nCoV IgM antibody detection reagent (for emergency use) (batch number 370096-202001); 2. According to the product manual, the sample amount of the reference product used in the test was 10uL; results wereobserved after 15 minutes; the result showed after 30 minutes was invalid.

Inspection Conclusion	This product is inspected according to the technical requirements of the product, and the results meet the requirements.		
Authorized signatory		Date of issue	2020-02-25