



检 验 报 告

Test Report

(2020) QW 类第 0506 号

样 品 名 称 2019 新型冠状病毒 IgM/IgG 抗体二合一
Product Name 检测试剂盒(胶体金法)

规 格 型 号 25 人份/盒
Specifications

检 验 类 别 委托检验
Test Category

委 托 单 位 基蛋生物科技股份有限公司
Entrusting Unit



江 苏 省 医 疗 器 械 检 验 所

Jiangsu Testing and Inspection Institute for Medical Devices

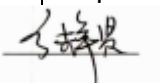
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Test item description	One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)		Sample No.	SLQW2002121
	Send sample(v)	Draw sample()		
Trade Mark	/		Model/Type reference	25 Tests
Applicant's name	Getein Biotech, Inc.		Test category	Entrusted test
Address	No. 9 Bofu Road, Luhe District, Nanjing 211505, China; No.6 Kefeng Road, Jiangbei new district, Nanjing 211500, China		Product serial number	6XGM20001 6XGM20002 6XGM20003
Manufacturer	Getein Biotech, Inc.		Sample drawing No.	/
Inspected company	Getein Biotech, Inc.		Date of manufacture	February 4 th , 2020 February 5 th , 2020 February 6 th , 2020
Sample drawing organization	/		Sample quantity	30 boxes per batch, 3 batched in total
Sample drawing place	/		Sampling basic number	/
Sample drawing date	/		Test place	Jiangsu Province Institute for Medical Device Testing
send Sample date	February 21 th , 2020		Test date	From February 21 th , 2020 to February 22 th , 2020
Test items	All			
Standard	Product registration standard of Getein Biotech, Inc. for One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)			
Conclusion	The sample meet the product registration standard of Getein Biotech, Inc. for One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold).			
Note	1) In report, "—" represent not Applicable, "/" represent blank content. 2) These test items, 'Lower Limit of Detection', 'Conformity rate of positive reference', 'Conformity rate of negative reference', use the enterprise reference provided by the Getein Biotech, Inc. and the production date is February 15th, 2020. These test items, 'Repeatability', 'Within-run Precision', use the quality controls provided by the Getein Biotech, Inc. and the batch no. of IgM and IgG are XGM20001Z and XGG20001Z, respectively.			

Signature:



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No.	Test Item	Clause	Requirment	Product serial number	result	conclusion	Remarks
1	Appearance	2.1	Package box and aluminum foil bag are intact and undamaged	6XGM20001	Meet requirement	Pass	/
				6XGM20002	Meet requirement		
				6XGM20003	Meet requirement		
2	Whole blood buffer	2.2.1	Appearance: Clear and transparent, no suspended matter, sealed bottle, no leakage	6XGM20001	Meet requirement	Pass	/
				6XGM20002	Meet requirement		
				6XGM20003	Meet requirement		
		2.2.2	Quantity: 1.5mL Net Content: ≥ 1.5g	6XGM20001	2.00g	Pass	/
				6XGM20002	1.89g		
				6XGM20003	2.03g		
		2.2.3	pH: 7.2±0.5	6XGM20001	6.96	Pass	/
				6XGM20002	6.99		
				6XGM20003	7.02		
3	Strip	2.3.1	Appearance: Neat and flat, free of burrs, No damage and pollution, Materials are firmly attached.	6XGM20001	Meet requirement	Pass	/
				6XGM20002	Meet requirement		
				6XGM20003	Meet requirement		
		2.3.2	Width of Strip: 4.00mm±0.20mm	6XGM20001	4.15mm	Pass	/
				6XGM20002	4.11mm		
				6XGM20003	4.12mm		
		2.3.3	Capillary Flow Rate: no less than 10 mm/min	6XGM20001	14.4mm/min	Pass	/
				6XGM20002	12.3mm/min		
				6XGM20003	17.1mm/min		

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No.	Test Item	Clause	Requirment	Product serial number	result	conclusion	Remarks
4	Lower Limit of Detection	2.4	Novel Coronavirus(2019-nCoV) IgM antibody: L1 and L2 were positive, L3 was positive or negative, L4 was negative	6XGM20001	L1: positive L2: positive L3: negative L4: negative	Pass	/
				6XGM20002	L1: positive L2: positive L3: negative L4: negative		
				6XGM20003	L1: positive L2: positive L3: negative L4: negative		
			Novel Coronavirus(2019-nCoV) IgG antibody: L1 and L2 were positive, L3 was positive or negative, L4 was negative	6XGM20001	L1: positive L2: positive L3: negative L4: negative	Pass	/
				6XGM20002	L1: positive L2: positive L3: negative L4: negative		
				6XGM20003	L1: positive L2: positive L3: negative L4: negative		
5	Conformity rate of positive reference	2.5	Novel Coronavirus(2019-nCoV) IgM antibody: All positive, and the conformity rate was 100%.	6XGM20001	Conformity rate: 100%	Pass	/
				6XGM20002	Conformity rate: 100%		
				6XGM20003	Conformity rate: 100%		
			Novel Coronavirus(2019-nCoV) IgG antibody: All positive, and the conformity rate was 100%.	6XGM20001	Conformity rate: 100%	Pass	/
				6XGM20002	Conformity rate: 100%		
				6XGM20003	Conformity rate: 100%		

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No.	Test Item	Clause	Requirment	Product serial number	result	conclusion	Remarks
6	Conformity rate of negative reference	2.6	Novel Coronavirus(2019-nCoV) IgM antibody: All negative, and the conformity rate was 100%.	6XGM20001	Conformity rate: 100%	Pass	/
				6XGM20002	Conformity rate: 100%		
				6XGM20003	Conformity rate: 100%		
			Novel Coronavirus(2019-nCoV) IgG antibody: All negative, and the conformity rate was 100%.	6XGM20001	Conformity rate: 100%	Pass	/
				6XGM20002	Conformity rate: 100%		
				6XGM20003	Conformity rate: 100%		
7	Repeatability	2.7	The results of the same batch should be consistent. The color rendering degree should be consistent.	6XGM20001	IgM, IgG: positive; The color rendering degree: Consistent	Pass	/
				6XGM20002	IgM, IgG: positive; The color rendering degree: Consistent		
				6XGM20003	IgM, IgG: positive; The color rendering degree: Consistent		
8	Within-run Precision	2.8	The results of all three batches should be consistent. The color rendering degree should be consistent.	6XGM20001 6XGM20002 6XGM20003	IgM, IgG: positive; The color rendering degree: Consistent	Pass	/

Tester: 孙小燕

Verifier: 刘芳

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Photo and Instruction



Model/Type or Others

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