

Neo-nostics (Suzhou) bioengineering Co., Ltd.

Finished product inspection report

Numbering	QMS/D-8.2.6/ZL-02-344	Number of modifications	No.0
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Product name	2019-nCoV IgG/IgM Test Kit		
LOT	8420200309	Specifications	30 tests per box
Inspection item	Standard requirements		Inspection date
			March 10, 2020
physical behavior	Appearance	Randomly take one person's product and observe it visually under natural light. The label shall be complete and the composition shall be complete. The test strip is sealed and stored without damage and pollution.	Test result
	Film strip width	Should not be less than 2.5 mm.	Meet the requirements
	Velocity of liquid migration	Should not be less than 10mm/min.	3.0mm
Coincidence rate of negative reference	IgG	The test with 2019-nCoV-IgG enterprise negative reference or standardized negative reference shall be negative.	100% negative
	IgM	The test with 2019-nCoV-IgM enterprise negative reference or standardized negative reference shall be negative.	100% negative
Detection limit	IgG	Using 2019-nCoV-IgG enterprise minimum detection limit reference test, G1 should be negative, G2 and G3 should be positive.	Meet the requirements
	IgM	Using 2019-nCoV-IgM enterprise minimum detection limit reference test, M1 should be negative, M2 and M3 should be positive.	Meet the requirements
Repeatability	IgG	Using the same 2019-nCoV-IgG enterprise repetitive reference J1 to test 10 products of the same batch number, the results should be consistent, the color development should be uniform, and all are positive.	Meet the requirements
	IgM	The same 2019-nCoV-IgM enterprise repetitive reference J2 was used to detect 10 products of the same batch number. The results should be consistent, the color development should be uniform, and all products should be positive.	Meet the requirements
Conclusion	The product meets the technical requirements of the tested product 2019-nCoV-IgG/IgM Test Kit, and the batch of finished products are judged to be <u>qualified</u>		

Inspector: Sunny
Date: 2020.03.10

Reviewer: Jasmyn
Date: 2020.03.10

Auditor: Green
Date: 2020.03.10