

Test Report

(2020) class ZC No. 0054

Product Name Novel coronavirus (2019-nCoV) IgG/IgM antibody combined
detection kit (colloidal gold method)

Specifications 50 Persons/Box

Test Category Registration inspection

Entrusting Unit Nanjing Nuoweizan Medical Technology Co., Ltd.

Jiangsu Testing and Inspection Institute for Medical Devices

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Product Name	Novel coronavirus (2019-nCoV) IgG/IgM antibody combined detection kit (colloidal gold method)		Product number	SLZC2002016
	Send sample ()	Sampling (√)		
Trademark	/		Specifications	50 Persons/Box
Entrusting Unit	Nanjing Nuoweizan Medical Technology Co., Ltd.		Kind of inspection	Registered supplementary inspection
Entrusting Unit address	Floor 1-3, East Section, Building C2, Hongfeng Science Park, Kechuang Road, Nanjing Economic and Technological Development Zone		Product number/batch number	P5020010152
				P5020010252
				P5020010352
Production Unit	Nanjing Nuoweizan Medical Technology Co., Ltd.		Sample number	/
Inspected Unit	Nanjing Nuoweizan Medical Technology Co., Ltd.		Date of production	January 28, 2020
				January 29, 2020
				January 30, 2020
Sample Unit	Nanjing Procuratorial Branch of Jiangsu Provincial Drug Administration		Number of samples	6 box/batch, total of three batches
Sampling site	Nanjing Nuoweizan Medical Technology Co., Ltd.		Sampling basic number	/
Sampling Date	February 7, 2020		Place of survey	Laboratory of this inspection center
Date received	February 10, 2020		Date of survey	February 10, 2020~ February 11, 2020
Inspection item	Full performance			
Inspection standard	Nanjing Nuoweizan Medical Technology Co., Ltd. "New coronavirus (2019-nCoV) IgG/IgM antibody combined detection kit (colloidal gold method)" product technical requirements			
Inspection conclusion	The tested samples conform to the technical requirements of the Novel coronavirus (2019-nCoV) IgG/IgM antibody combined detection kit (colloidal gold method) of Nanjing Nuoweizan Medical Technology Co., Ltd.			
	(Special seal for inspection report or official seal of inspection unit)			
	Date of issue: February 11, 2020			
Remarks	(1) "-" in the report indicates that this item is not applicable, and "/" in the report indicates that this item is blank. (2) The reference materials used in this test were provided by Nanjing Nuoweizan Medical Technology Co., Ltd. with the batch number of 20562101			

Approver: 

Position: Authorized signatory

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Serial No.	Inspection item	Clause	Requirements	Product No./batch No.	Inspection result	Single conclusion	Remarks
1	Appearance	2.1.1	All components of the kit shall be complete and complete; the packaging bag shall be well sealed without damage; the material shall be firmly attached and the membrane strip shall be closely assembled with the cartridge.	P5020010152	Meet the requirements	Accord with	/
				P5020010252			
				P5020010352			
2	Film strip width	2.1.2	The width of the film strip shall not be less than 2.5mm	P5020010152	3.54mm	Accord with	/
				P5020010252	3.60mm		
				P5020010352	3.55mm		
3	Velocity of liquid migration	2.1.3	The liquid migration speed shall not be less than 10mm/min.	P5020010152	47.1mm/min	Accord with	/
				P5020010252	45.5mm/min		
				P5020010352	40.2mm/min		
4	Sensitivity	2.2	The detection results of enterprise sensitivity reference materials S1 to S3 should be: 1)S1: Novel coronavirus IgG/IgM antibody detection results are all positive; 2)S2: The detection results of Novel coronavirus IgG/IgM antibody are all positive; 3)S3: Novel coronavirus IgG/IgM antibody detection results are positive or negative;	P5020010152	S1: Positive S2: Positive S3: Positive	Accord with	/
				P5020010252	S1: Positive S2: Positive S3: Positive		
				P5020010352	S1: Positive S2: Positive S3: Positive		
5	Positive reference compliance rate	2.3	The results of detection with positive reference materials from enterprises are as follows: 1) The detection results of novel coronavirus IgG antibodies from PC01 to PC05 are all positive, and the detection results of IgM antibodies are all negative, with a coincidence rate of 100%; 2) The detection results of IgG antibody in 2)PC06-PC10 novel coronavirus are all negative, and the detection results of IgM antibody are all positive, with a coincidence rate of 100%. 3) The detection results of novel coronavirus IgG/IgM antibodies of 3)PC11-PC15 are all positive with a coincidence rate of 100%.	P5020010152	Coincidence rate: 100%	Accord with	/
				P5020010252			
				P5020010352			
6	Negative reference compliance rate	2.4	When tested with the negative reference substance of the enterprise, NCO1-NCO6 novel coronavirus IgG/IgM are all negative, and the coincidence rate is 100%.	P5020010152	Coincidence rate: 100%	Accord with	/
				P5020010252			
				P5020010352			

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Serial No.	Inspection item	Clause	Requirements	Product No./batch No.	Inspection result	Single conclusion	Remarks
7	Repeatability	2.5	The results of CV1 and CV2 tests showed that IgG/IgM antibody was positive with uniform color development.	P5020010152	Meet the requirements	Accord with	/
				P5020010252			
				P5020010352			
8	Between-run precision	2.6	Take three batches of kits and test the repeated reference products of the enterprise. The results of the kits of the three batches are all positive and the color development is uniform.	P5020010152	3.54mm	Accord with	/
				P5020010252	3.60mm		
				P5020010352	3.55mm		
				P5020010252			
				P5020010352			
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Surveyor: Guo Jingjing

Reviewer: Zhang Xiaoyan

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Plates and Explanations



Product description

Model specifications or other instructions

Product model specification is 50 persons/box