

Certificate Of Analysis

Product name:	SARS-COV-2 Nucleocapsid (N) Antigen Rapid Detection Kit (Colloidal gold method)		
Batch number:	21102701	Validity to:	2023.04.26
Inspection items	Inspection criteria		Inspection results
Appearance	The outer packaging box and aluminum foil packaging of the product are complete and undamaged; the box label and bottle label are clear and complete, and the identification is correct; the product name, batch number and expiration date are clear, the instructions are clear and complete, and the components are complete.		Confirm
Test strip	Appearance: The appearance of the test card should be flat and undamaged, the materials should be firmly attached, and the components should be complete.		Confirm
	Film strip width: The width of the film strip should not be less than 3.5mm.		4.0mm
	Liquid moving speed: not less than 5mm/min.		5.6mm/min
Positive control product compliance rate	The test results of the 5 corporate antigen-positive quality control products should all be positive, and the positive quality control product compliance rate (+/+) should be 5/5.		5/5
Negative control product compliance rate	The test results of 10 corporate antigen-negative (N1-N10) quality control products should all be negative, and the compliance rate (-/-) of negative control products should be 10/10.		10/10
Repeatability	Use corporate repeat nature control products for testing, corporate antigen repeat nature control products for 10 retests, the results should all be positive (+/+) should be 10/10, and the color should be consistent and there is no significant difference.		10/10
Minimum detection limit	Use the lowest detection limit quality control products of the company's antigen antibody for testing. The results should be positive for S1 and S2 tests 3 times, S3 test 3 times can be negative or positive, and the minimum detection limit should not be higher than S2.		Confirm
Conclusion	This batch of products meets the requirements of quality standards, and the product quality is qualified.		

Reporter / Date:

刘阳
2021.10.27

Reviewer / Date:

余韩婷
2021.10.27

Auditor / Date:

