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SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) Certificate of Analysis

Document NO.: SARS-CoV-2-Ag-210213-01

User Department: QC Dept.

Product Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)		
Lot No.	2021021204	Specification	1Test/box
Manufacture Date	2021.02.09	Expire Date	2023.02.08
Inspection Date	2021.02.13	Report Date	2021.02.13
Inspection Item	Inspection Standard		Result
1.Exterior	The appearance of the kit should be complete without damage; the aluminum foil bag in the kit should be sealed without leaking air; the desiccant package should be complete without spilling; the composition of the buffer should be clear, transparent, and free of impurities such as floc and granular. The test reagents should be flat and flawless, the materials should be firmly attached and the contents should be complete.		pass
2.Membrane strip width	No less than 3mm.		pass
3.Liquid Flow Speed	At least 10mm/min.		pass
4.Negative Reference Product Coincidence Rate	Negative reference sample coincidence rate: 20 negative enterprise reference samples were tested and the results were all negative.		pass
5.Positive Reference Product Coincidence Rate	Positive reference sample coincidence rate: 8 positive enterprise reference samples were tested and the results were all positive.		pass
6.Lower Limit of Detectability	Enterprise reference samples of limited detection were used for testing, S1 and S2 should be positive, S3 should be negative.		pass
7.Sophisticated Detection	Enterprise reference samples of sophisticated detection were used for testing, J1 and J2 should be positive. Test results are consistent, colour intensity of test lines are the same.		pass
Conclusion	According to the Enterprise Internal Standards of SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) <input checked="" type="checkbox"/> PASS <input type="checkbox"/> NOT PASS		
Remark	/		
Checker	Liu Min Juan	Reviewer	Nian Yaxuan
		Person In Charge	Li Hongyan

