


Certificate of Analysis

Product Name	2019-nCoV Ag Test (Latex chromatography Assay)		
LOT No.	20211201	Inspection Source	Warehouse
Batch Volume	12020boxes	Packing Size	25T/box
Mfg. Date	2021.12.09	Exp. Date	2023.06.09
Inspected by	Xiaogang Zhao	Date of Inspection	2021.12.31
Inspection Basis	New Coronavirus (2019-nCoV) antigen test kit (latex chromatography) inspection procedures for finished products	Inspection Standard	New Coronavirus (2019-nCoV) antigen test kit (latex chromatography) quality standard for finished products
Test Results			
Items	Acceptance Criteria	Test Result	Conclusion
1. Physical Inspection	The packing box is intact and the foil pouch is well sealed.	Passed	Approved
	The label, package insert and symbols are clear.	Passed	Approved
	The specimen diluent is clear, free of impurities and precipitation.	Passed	Approved
2. Strip Width	Not less than 3.0mm	3.42mm	Approved
3. Liquid Moving Speed	Not less than 10mm/min	17.6mm/min	Approved
4. Performance		Test Result	Conclusion
Positive Reference	The results are all positive for Reference P01-P08	P01-P08 are all positive results.	Approved
Negative Reference	The results are all negative for Reference N01-N10	N01-N10 are all negative results.	Approved
Lowest Detection Limit Reference	L1-L2 results should be positive, L3 results can be positive or negative	L1-L3 were all positive.	Approved
Repeatability Reference CV1	Repeating the test for 5 times, the results should all be positive and the color should be uniform.	All of them were positive and the color was uniform.	Approved
Repeatability Reference CV2	Repeating the test for 5 times, the results should all be positive and the color should be uniform.	All of them were positive and the color was uniform.	Approved
Remark	—		
Inspection Conclusion	 Approved		
Examiner	Xiaogang Zhao.	Inspection date	2021.12.31.
Reviewer	Wenhui Dong	Review date	2021.12.31
Approved by	Fukun Jia	Date of approval	2021.12.31