

Test Report

Number: 20200401

PRODUCT NAME	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)		
Lot number	20CG2518X	Sampling method	Random selection
Product specification	One test per bag for one person	Packing specification	20 tests/kit
Test methods	《Standard operating procedure for SARS-CoV-2 Antibody Test (colloidal gold immunochromatography)》		
Sampling date	01/04/2020	Test date	01/04/2020
Sample number	30 boxes	Report date	01/04/2020
Test items	Quality standard	Results	Test conclusion
Appearance	The test card should be clean and integral, no burrs, no damage, no pollution; the material should be firmly attached; the label should be clear and not damaged. The sample dilution should be clear without impurities and flocs.	Meet the requirements	Qualified
Membrane strip width	The membrane strip width of the testing strip should be ≥ 2.5 mm.	4.02mm	Qualified
Liquid migration speed	The liquid migration speed should be no less than 10mm/min.	24.2mm/min	Qualified
Sample dilution volume	The sample dilution volume should be no less than the indicated value.	3.00ml	Qualified
Detection Limit	For the detection of sensitivity reference material, the positive detection rate should be no less than 90%.	100%	Qualified
Negative reference products compliance rate	For the detection of negative reference material, the negative detection rate should be 100%.	100%	Qualified
Positive reference products compliance rate	For the detection of positive reference material, the positive detection rate should be 100%.	100%	Qualified
Precision	For the detection of enterprise reference material P2 and P4, the results should all be positive and the color rendering should be uniform.	P2: + P4: +	Qualified
Conclusion:	Qualified		
Note:			

Inspected by:

检验06

Approved by:

