

Certificate of Analysis

Report No: SJCP2022082201

Product name		Monkeypox Virus Antigen Rapid Test Kit Monkeypox Virus Antibody Rapid Test Kit				
Batch number		22082202	Production date	2022.08.22	Expiration date	2024.8.22
Inspection item		Inspection standard			Inspection result	
Physical property	Appearance	The label of the kit is clear and complete, the components are complete; the outer packaging of the product is complete, no damage, and no pollution; the test card should be flat and no damage, the material is firmly attached, and the components are complete.			<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	
	Extraction buffer	The buffer should be clear, free of foreign matter, sediment and floc, the bottle body should be tight, and there should be no leakage.			<input type="checkbox"/> Without buffer <input checked="" type="checkbox"/> With buffer <input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	
	Test strip	The appearance of the test card should be flat without damage, the material should be firmly attached, and the components should be complete. Liquid moving speed: not less than 10mm/min. Test strip width: The width of the film strip should not be less than 2.5mm.			<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	
Compliance rate of positive quality control product		Test the positive quality control product, the results should all be positive.			<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	
Compliance rate of negative quality control product		Test the negative quality control product, the results should all be negative.			<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	
Repeatability		Test the repeatable reference products of the enterprise, it is required that the color rendering is consistent and there is no obvious difference.			<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	
Lowest detection limit		Test the lowest detection limit reference product, the results should all be detected.			<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	
Conclusion		This batch of products meets the requirements of quality standards, and the product quality is qualified.				

Inspector/ Date: 刘丽

2022.08.22

Reviewer/ Date: 张之本

2022.08.22

Reviewer/ Date: 郑静

