

CERTIFICATE OF ANALYSIS

Name of Product	SARS-CoV-2 Antigen (GICA)		
Lot Number	YF8520003	Batch	/
Specification	25T/box	Number	600 boxes
Manufacture Date	10/27/2020	Expiration Date	04/26/2022
Sampling Date	11/11/2020	Report Date	11/11/2020
Inspection Reference	Finished product inspection standard operating procedures	Sampling Amount	3 boxes
Inspection Items	Quality Standards	Inspection Result	Determination of Result
Physical Examination	Appearance: The appearance should be flat, the logo should be clear. The components should be firmly attached, and the content should be complete.	Coincidence Rate (100%)	<input checked="" type="checkbox"/> Compatible <input type="checkbox"/> Incompatible
	Migration Speed: Liquid migration speed should be not lower than 10mm/min.	Liquid migration speed is (12.14) mm/min	<input checked="" type="checkbox"/> Compatible <input type="checkbox"/> Incompatible
	Width of Membrane: The width of membrane should be wider than 2.5mm.	Width of membrane is (3.95) mm.	<input checked="" type="checkbox"/> Compatible <input type="checkbox"/> Incompatible
Positive Reference Coincidence Rate	Positive Reference Coincidence Rate should be 10/10.	Coincidence Rate is (100%)	<input checked="" type="checkbox"/> Compatible <input type="checkbox"/> Incompatible
Negative Reference Coincidence Rate	Negative Reference Coincidence Rate should be 10/10.	Coincidence Rate is (100%)	<input checked="" type="checkbox"/> Compatible <input type="checkbox"/> Incompatible
Lowest Limit of Detection	Limit of Detection reference L1,L2 should be positive, L3 can be positive or negative, L4and L5 should be negative.	Coincidence Rate is (100%)	<input checked="" type="checkbox"/> Compatible <input type="checkbox"/> Incompatible
Repeatability	Test 2 internal references' repeatability reference (J1~J2), and each repeat for 20 times respectively, the results of J1 should be negative and J2 should be positive.	Coincidence Rate is (100%, 100%)	<input checked="" type="checkbox"/> Compatible <input type="checkbox"/> Incompatible
Conclusion	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Failure	Use Determination	<input checked="" type="checkbox"/> Agree to release <input type="checkbox"/> Disagree to release
Remark			
Quality Inspector/Date	Xin Yang 11/11/2020	Reviewer/Date	Xianpu Gao 11/11/2020
Quality Authorizer/Date of Issue	Mingji. Rei 11/11/2020		

