Uncut sheet of COVID-19 antigen detection

Certificate of Analysis

CAT. NO.: 2011K401

Product Name	Uncut sheet of COVID-19 antigen detection Novel coronavirus (SARS-CoV-2) antigen detection kit (colloidal gold immunochromatography)-detection membrane		
Spec.	60mm*300mm	**Lot No.**	2011K401
Production quantity	612 pieces	**Sampling Amount**	8 pieces
Production Date	2020-11-01	**Exp.**	2023-04
Store at	sealed at 2~30℃	**Reported**	2020-11-02

Inspection record

Test items	Acceptance Criteria	Result	Conclusion
Appearance	Clean, no scratches, smooth surface, no damage, no burrs, no stains; Each support of the large board should be firmly pasted.	☑ Meet the requirements ☐ non-compliant	☑ qualified ☐ Unqualified
Length（mm）	300mm±3mm	300mm	☑ qualified ☐ Unqualified
C line, T line position	T line，B position should be 30mm±0.5mm； C line B position should be 34.5mm±0.5mm	T line, B position is：30.0mm C line, B position is：34.5mm	☑ qualified ☐ Unqualified
Liquid moving speed (mm/min)	≥10mm/min	57.5mm/min	☑ qualified ☐ Unqualified
Fading time of film（min）	15~20min	16min	☑ qualified ☐ Unqualified
Positive rate of positive reference	Use the corporate positive reference product P1-P5 to test, The result should meet the requirement as follows: The color intensity of P1 should be C8-C7;	☑ Meet the requirements ☐ non-compliant	☑ qualified ☐ Unqualified

	The color intensity of P2 should be C6~C5; The color intensity of P3 should be C5~C4; The color intensity of P4 should be C8~C7; The color intensity of P5 should be C7~C6.		
Minimum detection limit	Use corporate lowest detection limit reference product L1~L3 for testing, the result should meet the requirement as follows: The color intensity of L1 should be B; The color intensity of L2 should be C9~C7; The color intensity of L3 should be C8~C7.	☑ Meet the requirements ☐ non-compliant	☑ qualified ☐ Unqualified
Precision	Use corporate repeatable reference product R1~R2 to test, and the result should meet the requirement as follows: The color intensity of R1 should be C6~C5; The color intensity of R2 should be C7~C6.	☑ Meet the requirements ☐ non-compliant	☑ qualified ☐ Unqualified
Negative rate of Negative reference	Test corporate negative reference product N1~N7, all color intensity should be B.	☑ Meet the requirements ☐ non-compliant	☑ qualified ☐ Unqualified
Random Clinical Sample	Sampling 100 samples randomly, using the sample extraction solution to elute the sample and test, The test color intensity should be B~C9. Sampling 20 samples randomly in UTM tube with COPAN preserved solution, and test, The test color intensity should be B~C9.	The number of color intensity of B~C9/total number of tests: 120 / 120	☑ qualified ☐ Unqualified
	The total false positive rate should be ≤2%	Total false positive rate: 0	☑ qualified ☐ Unqualified
Remark	/		
Conclusion： ☑ qualified ☐ Unqualified			