




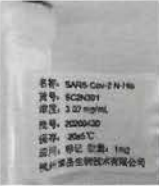

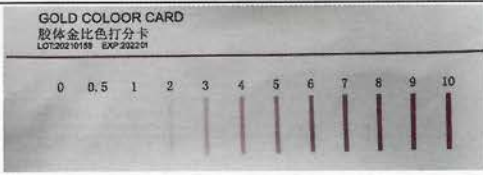
Standard Operating Procedure					
Operation Name	Sensitivity test of Singclean® COVID-19 Test Kit(Colloidal Gold Method) to SARS-CoV-2 Omicron Variants (B.1.1.529)		Document number	nCoV-(R20211228)	
Drafter	张咪	Proofreader	吴王荣	Reviewer	范磊雷 Prof. Chunlei Fan
Number of pages	6	Implementation department	CELL BIOLOGY	Personnel allocation	2

Experiment A	Sample source and grouping design	Experimenter	张咪	Experimental time	2021.12.28
Procedures	Standards		Detection reagent		
Samples	1. SARS-CoV-2 N-Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd. , Cat: SC2N301, Lot#20200430), [Wild Type] 2. SARS-CoV-2 B.1.1.529 (Omicron) Nucleocapsid (PI3L, ERS31-33 deletion, R203K, G204R) Protein (His Tag) (Sino Biological , Cat: 40588-V07E34, Lot#ME15DE0701), [Omicron (B.1.1.529)]		Singclean® COVID-19 Test Kit(Colloidal Gold Method), One Step Coronavirus Antigen Rapid Test Cassette (Nasal Swab): Hangzhou Singclean Medical Products Co.,Ltd; Lot#: P49211211A1A 		



Grouping design:

Group		Results														
Negative control	Standard concentration (ng/ml)	0														
	Test strip number	01			02			03			04			05		
	Chromatic value															
1.SARS-CoV-2 N-Nucleocapsid Protein [Wild Type]	Standard concentration (ng/ml)	5			1			0.5			0.1			0.05		
	Test strip number	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20
	Chromatic value															
2.SARS-CoV-2 Nucleocapsid (P13L, Δ31-33, R203K, G204R,) Protein Recombinant Protein [Omicron(B.1.1.529)]	Standard concentration (ng/ml)	5			1			0.5			0.1			0.05		
	Test strip number	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
	Chromatic value															

Experiment B	Experiment preparation	Experimenter	张咪	Experimental time	2021.12.27
Procedures	Reagents and Instruments		Preparation and matters needing attention		
Experiment preparation	1. Sample diluent		Sample diluent provided by Singclean		
	2. SARS-CoV-2 N-Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd. , Cat: SC2N301, Lot#20200430), [Wild Type] 		The concentration of the original solution was 3.02 mg/mL and diluted with sample diluent to 5ng/ml, 1ng/ml, 0.5ng/ml, 0.1ng/ml, and 50pg/ml respectively.		
	3. SARS-CoV-2 B.1.1.529 (Omicron) Nucleocapsid (P13L, ERS31-33 deletion, R203K, G204R) Protein (His Tag) (Sino Biological , Cat: 40588-V07E34, Lot#ME15DE0701), [Omicron (B.1.1.529)] 		The concentration of the original solution was 0.83µg/µL and diluted with sample diluent to 5ng/ml, 1ng/ml, 0.5ng/ml, 0.1ng/ml, and 50pg/ml respectively.		
	3. Chroma determination color card				
4. Before the experiment, check the pipetting gun (tip) and other consumables are sufficient and sterilized					

Experiment C	Test report	Experimental time	2021.12.28	Reviewer	范磊 Prof. Chunlei Fan
Experimenter	张咪	Delivery time	2021.12.28	Review time	2021.12.29

Experimental procedure

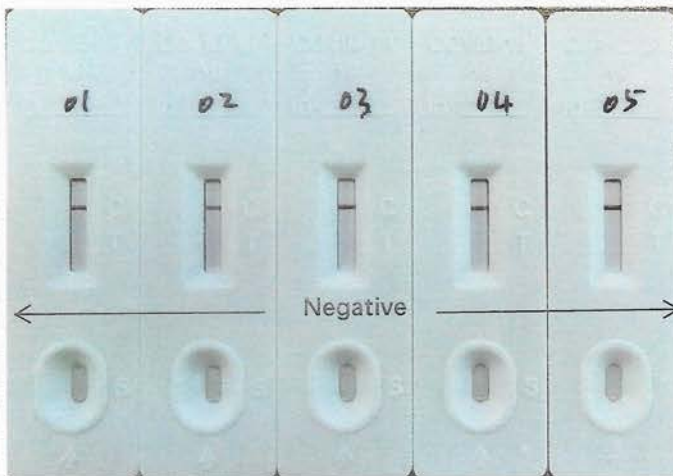
4. In this experiment, the sensitivity of the COVID-19 Test Kit(Colloidal Gold Method), One Step Coronavirus Antigen Rapid Test Cassette (Lot#: P49211211A1A) produced by Hangzhou Singclean Medical Products Co.,Ltd was determined by SARS-CoV-2 Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd., Cat#: SC2N301, Lot#20200430),[Wild Type]; SARS-CoV-2 B.1.1.529 (Omicron) Nucleocapsid (P13L, ERS31-33 deletion, R203K, G204R) Protein (His Tag) (Sino Biological , Cat: 40588-V07E34, Lot#ME15DE0701),[Omicron (B.1.1.529)].

Experimental procedure:

1. Take 35 test strips of Lot# P49211211A1A , grouped and numbered according to the grouping table, and placed flat on the desktop;
2. Add sample according to the contents of the grouping table, 100μl/well;
3. The results were observed and photographed after standing at room temperature for 15-20 minutes.

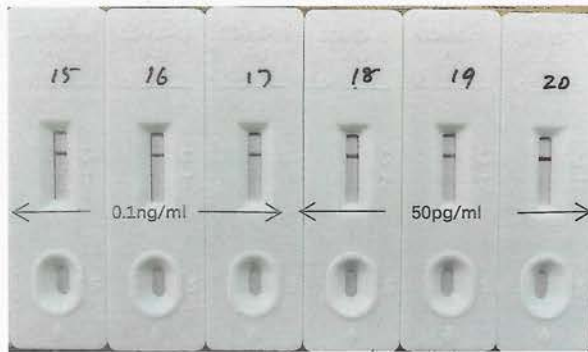
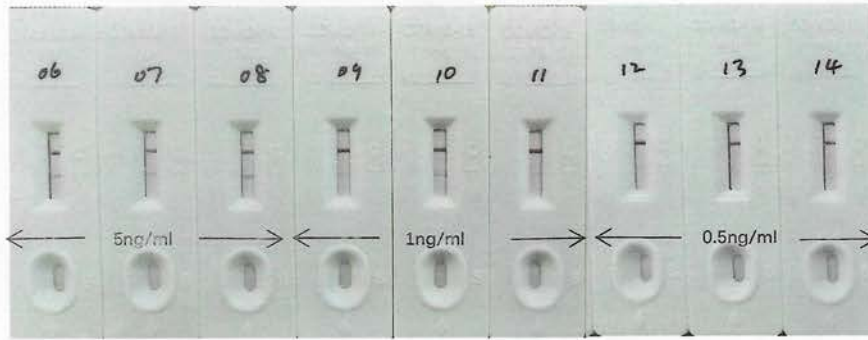
Graph data summary

1. Negative control

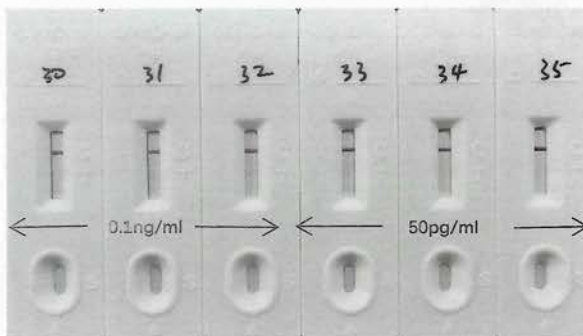


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2. SARS-CoV-2 Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd., Cat#: SC2N301, Lot#20200430), [Wild Type]



3. SARS-CoV-2 B.1.1.529 (Omicron) Nucleocapsid (P13L, ERS31-33 deletion, R203K, G204R) Protein (His Tag) (Sino Biological , Cat: 40588-V07E34, Lot#ME15DE0701), [Omicron (B.1.1.529)]



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Group		Results																			
Negative control	Standard concentration (ng/ml)	0																			
	Test strip number	01				02				03				04				05			
	Chromatic value	0				0				0				0				0			
1.SARS-CoV-2 N-Nucleocapsid Protein [Wild Type]	Standard concentration (ng/ml)	5				1				0.5				0.1				0.05			
	Test strip number	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20					
	Chromatic value	9	8	10	8	9	8	5	4	5	4	5	3	2	3	2					
2. SARS-CoV-2 Nucleocapsid (P13L, ERS31-33 deletion, R203K, G204R) Protein [Omicron (B.1.1.529)]	Standard concentration (ng/ml)	5				1				0.5				0.1				0.05			
	Test strip number	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35					
	Chromatic value	8	9	10	9	9	8	4	5	4	4	5	5	3	2	3					

Conclusion:

The Singclean® COVID-19 Test Kit(Colloidal Gold Method), One Step Coronavirus Antigen Rapid Test Cassette (Nasal Swab) (Lot#: P49210430A1A) produced by Hangzhou Singclean Medical Products Co.,Ltd was sensitive to SARS-CoV-2 Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd., Cat#: SC2N301, Lot#20200430),[Wild Type]; SARS-CoV-2 B.1.1.529 (Omicron) Nucleocapsid (P13L, ERS31-33 deletion, R203K, G204R) Protein (His Tag) (Sino Biological , Cat : 40588-V07E34, Lot#ME15DE0701),[Omicron (B.1.1.529)], with a sensitivity of 50pg/ml.

Experiments prove that product of Singclean COVID-19 Test Kit (Colloidal Gold Method), One Step Coronavirus Antigen Rapid Test Cassette (Nasal Swab) can detect SARS-CoV-2 B.1.1.529 (Omicron) Variant.

