



Standard Operating Procedure					
Operation Name	Sensitivity test of Joinstar COVID-19 Antigen Rapid Test (Colloidal Gold) to SARS-CoV-2 Omicron Variants (B.1.1.529)		Document number	nCoV-(R20211227B)	
Drafter	张咪	Proofreader	吴圣荣	Reviewer	范春雷 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	2021.12.27
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 (P13L, ERS31-33 deletion, R203K, G204R) Protein (His Tag) (Sino Biological , Cat: 40588-V07E34, Lot#ME15DE0701), [Omicron (B.1.1.529)]		COVID-19 Antigen Rapid Test (Colloidal Gold): Joinstar Biomedical Technology Co.,Ltd; Lot#: CAG2111018G 		



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, Δ 31-33, 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 Joinstar		
	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		 <p>L10 L9 L8 L7 L6 L5 L4 L3 L2 L1 L0 JOINSTAR Color Chart. For R&D Use Only</p>		
4. Before the experiment, check the pipetting gun (tip) and other consumables are sufficient and sterilized					

Experiment C	Test report	Experimental time	2021.12.27	Reviewer	范磊 Prof. Chunlei Fan
Experimenter	张咪	Delivery time	2021.12.27	Review time	2021.12.28

Experimental procedure

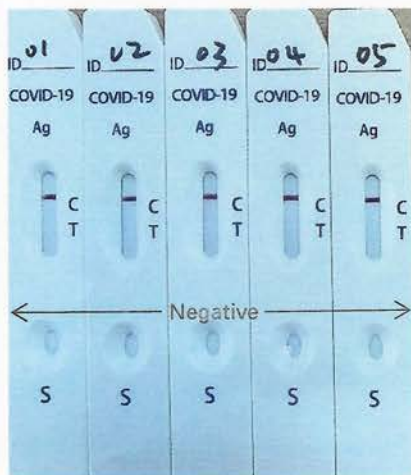
4. In this experiment, the sensitivity of the COVID-19 Antigen Rapid Test (Colloidal Gold) (Lot#: CAG2111018G) produced by Joinstar Biomedical Technology Co.,Ltd was determined by SARS-CoV-2 Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd., Cat#: SC2N301, Lot#20200430), [Wild Type]; 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:

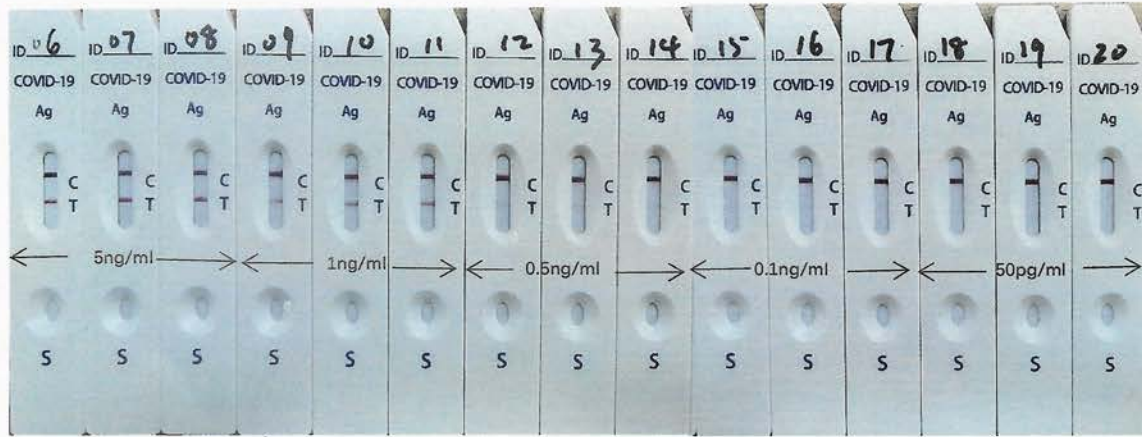
1. Take 35 test strips of Lot#CAG2111018G, grouped and numbered according to the grouping table, and placed flat on the desktop;
2. Add sample according to the contents of the grouping table, 50µl/well;
3. The results were observed and photographed after standing at room temperature for 15-20 minutes.

Graph data summary

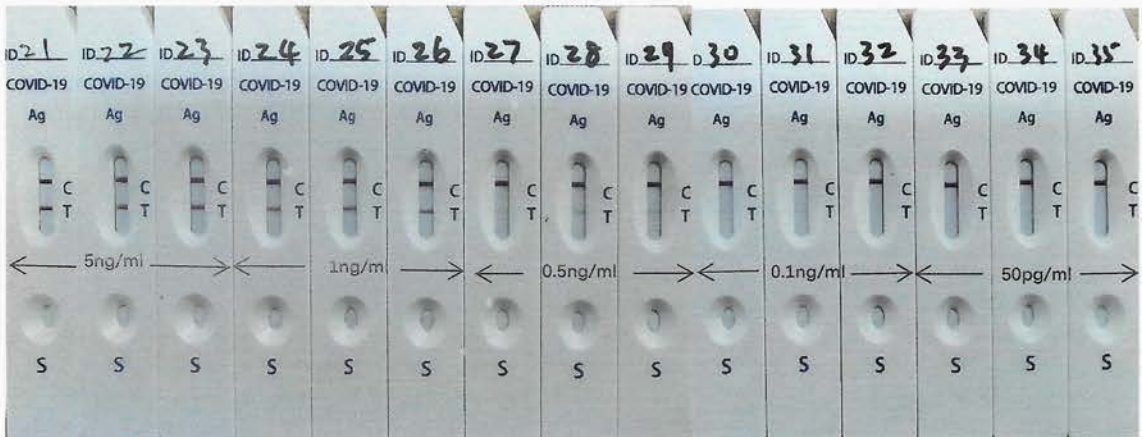
1. Negative control



2. 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)]



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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	10	10	10	8	8	9	6	6	6	4	3	4	2	2	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	10	10	10	8	9	9	6	6	6	3	4	4	2	3	2

Conclusion:

The COVID-19 Antigen Rapid Test (Colloidal Gold) (Lot#: CAG2111018G) produced by Joinstar Biomedical Technology 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 the COVID-19 Antigen Rapid Test (Colloidal Gold) produced by Joinstar Biomedical Technology Co.,Ltd can detect SARS-CoV-2 B.1.1.529 (Omicron) Variant.