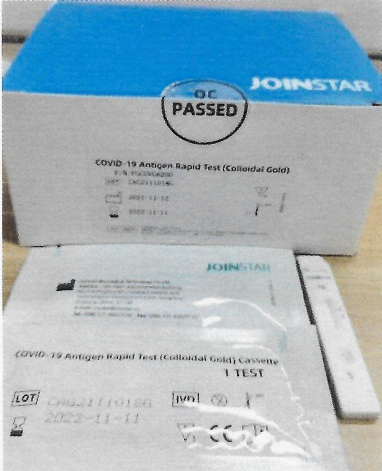




Standard Operating Procedure					
<b>Operation Name</b>	Sensitivity test of Joinstar COVID-19 Antigen Rapid Test (Colloidal Gold) to SARS-CoV-2 Omicron Variants (B.1.1.529)		<b>Document number</b>	nCoV-(R20211227B)	
<b>Drafter</b>	张咪	<b>Proofreader</b>	吴平	<b>Reviewer</b>	范春雷 Prof. Chunlei Fan
<b>Number of pages</b>	6	<b>Implementation department</b>	CELL BIOLOGY	<b>Personnel allocation</b>	2

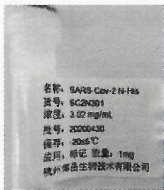

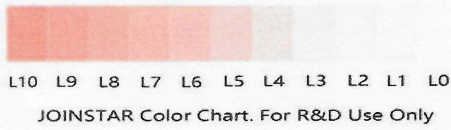
Experiment A	Sample source and grouping design	Experimenter	张咪	Experimental time	2021.12.27
<b>Procedures</b>	<b>Standards</b>		<b>Detection reagent</b>		
<b>Samples</b>	1. SARS-CoV-2 N-Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd. , Cat: SC2N301, Lot#20200430), [Wild Type]  2. 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&amp;D Use Only</p>		
4. Before the experiment, check the pipetting gun (tip) and other consumables are sufficient and sterilized					

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

**Experimental procedure**

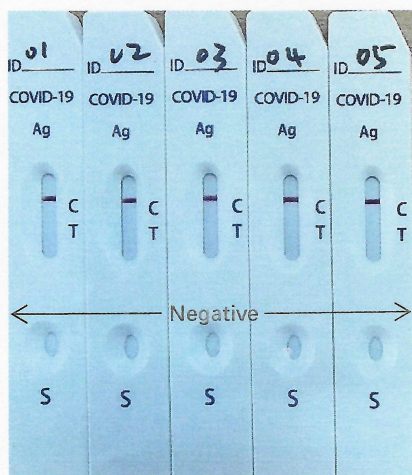
4. In this experiment, the sensitivity of the COVID-19 Antigen Rapid Test (Colloidal Gold) (Lot#: CAG2111018G) produced by Joinstar Biomedical Technology Co.,Ltd was determined by SARS-CoV-2 Nucleocapsid Recombinant Protein (Hangzhou bioeast biotech. Co., Ltd., Cat#: SC2N301, Lot#20200430),[Wild Type];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

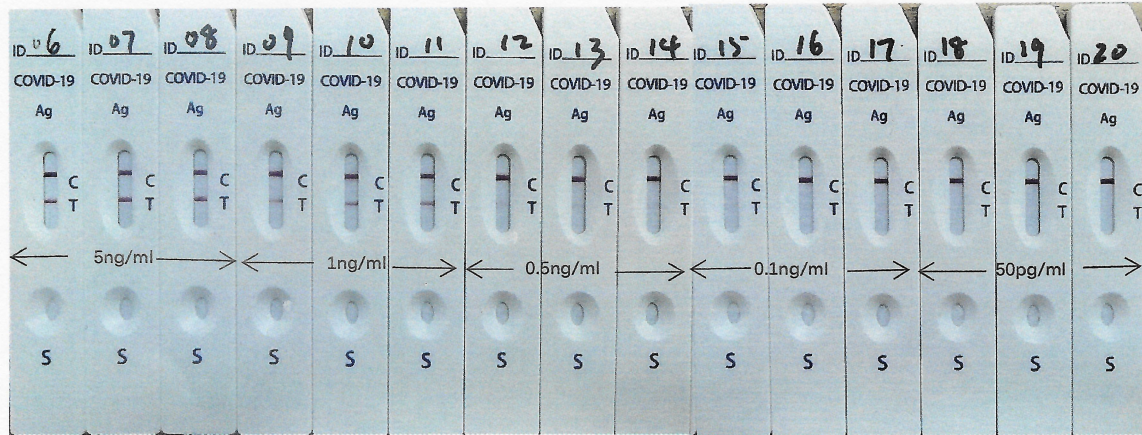
1. Take 35 test strips of Lot#CAG2111018G , grouped and numbered according to the grouping table, and placed flat on the desktop;
2. Add sample according to the contents of the grouping table, 50µl/well;
3. The results were observed and photographed after standing at room temperature for 15-20 minutes.

**Graph data summary**

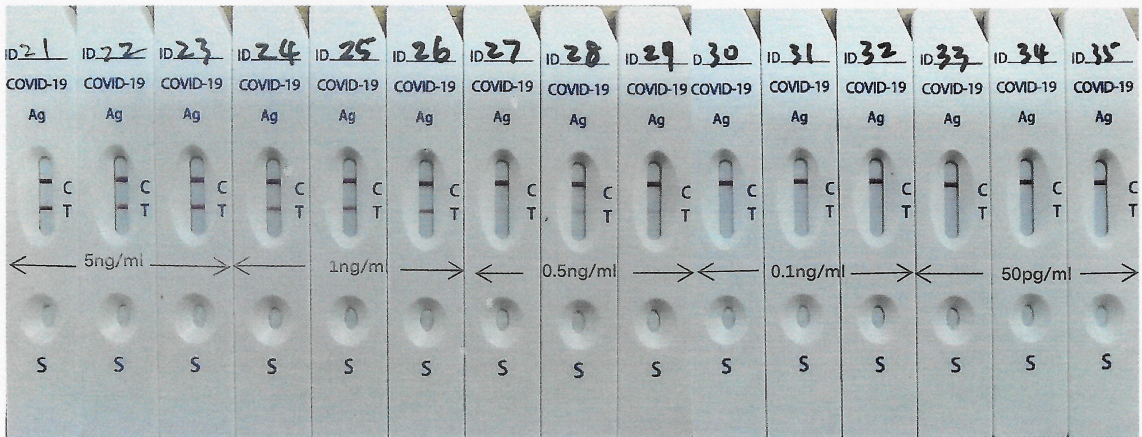
1. Negative control



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.