

Stability Study Report of SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)

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1. Product stability research materials

1.1 Basis for determining the research method

Stability studies are conducted according to the requirements of EN ISO 23640: 2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents, and the performance indicators involved in the kit are tested separately to assess whether they meet the design requirements.

1.2 Test kit and related information

1.2.1 Test kit and related information

The design packaging specification of this product is 25 tests/ box. There are three batches of kits for stability evaluation, 20200301, 20200302, and 20200304. Among them:

Batch numbers of kits used for real-time stability studies: 20200301, 20200302, 20200304

The batch number of the kit used for in use stability study: 20200304

The batch number of the kit for accelerated stability study: 20200304

The batch number of the kit for shipping stability study: 20200304

1.2.2 Reference for the experiment

The batch number of the reference used for the stable performance evaluation is 202001.

Name of reference	Code
Positive reference	Y1-Y10
Repetitive reference	J1、J2
Negative reference	F1-F20
LOD reference	L1-L8

1.2.3 Instruments

Pipette, timer, electronic digital caliper, constant temperature, and humidity box.

1.3 Stability Research Plan

1.3.1 Real-time stability study

1.3.1.1 Test purposes

The assessment is based on the storage conditions specified in the instructions and predicts the storage period during which the kit can maintain normal working performance.

1.3.1.2 Test plan

1) Choose a certain number of three batches of test kits and place them in cold storage at 2~10°C with a dry and cool environment at 10~30°C at room temperature.

2) From the date of production, to 3 months after the expiration date, a total of 15 months, the inspection will be performed every 3 months, namely the 3rd, 6th, 9th, 12th, and 15th month (Due to the severe global new crown virus epidemic, we will synchronize the real-time stability research content with the registration application).

3) During the test, the following performance indicators are mainly observed: packaging appearance, minimum detection limit, intra-batch repeatability, inter-batch repeatability, positive reference product compliance rate, negative reference product compliance rate, and migration speed.

4) Record the test results, and finally summarize the test results.

1.3.2 In use stability study

1.3.2.1 Purposes

Investigate the stability of the kit after being opened in the test process and exposed to a specific environment.

1.3.2.2 Test plan

- 1) Select products from batch number of 20200304 of test kits and equilibrate at room temperature for 30 minutes.
- 2) Tear the sealed aluminum foil bag of the test card, and expose the test reagent card to a specific environment (environmental condition 1: temperature 25°C, humidity 35%; environmental condition 2: temperature 25°C, humidity 85%) to 80 minutes later , Testing once every 20 minutes, namely the 20th minute, the 40th minute, the 60th minute, and the 80th minute.
- 3) During the test, the following performance indicators are mainly observed: minimum detection limit, intra-batch repeatability, positive reference product compliance rate, negative reference product compliance rate, and migration speed.
- 4) Record the test results, and finally summarize the test results.

1.3.3 Accelerated stability study

1.3.3.1 Purposes

High temperature accelerates the degradation rate of product components by chemical or physical changes and predicts the validity period of the real-time stability of the kit.

1.3.3.2 Test plan

- 1) Choose a certain number of 20200304 test kits. According to the accelerated aging life test formula, the room temperature validity period of 12 months is equivalent to 40 days of accelerated aging at 45°C. Therefore, the kit is placed at 45°C for 40 days.
- 2) Test once every 10 days, namely the 10th day, the 20th day, the 30th day, and the 40th day.
- 3) During the test, the following performance indicators are mainly observed: packaging appearance, minimum detection limit, intra-batch repeatability, positive reference product compliance rate, negative reference product compliance rate, and migration speed.
- 4) Record the test results, and finally summarize the test results.

1.3.4 Shipping stability study

1.3.4.1 Purposes

Through actual Shipping tests, investigate the impact of actual Shipping environment changes (such as temperature, bumps, and vibrations during land Shipping) on product performance stability, and formulate product Shipping packaging requirements accordingly.

1.3.4.2 Test plan

- 1) Choose a certain number of 20200304 test kits, put the kits in a carton and seal them, shipping them to other cities in China through logistics, and send them back to the place of departure after arrival.

- 2) Test the returned kits.
- 3) Place the remaining reagents in a cold storage at 2-10°C and a dry and cool environment at 10-30°C at room temperature, and test every 3 months until the product expiration date ends, that is, the third month, the sixth month, and the ninth month. In the 12th month of the month, test the kit.
- 4) During the test, the following performance indicators are mainly observed: packaging appearance, minimum detection limit, intra-batch repeatability, positive reference product compliance rate, negative reference product compliance rate, and migration speed.
- 5) Record the test results, and finally summarize the test results.

1.4 Stability performance index requirements and index test plan

Performance index requirements: the real-time stability of the product meets the product stability requirement for 12 months; the product opening stability meets the 60-minute stability requirement after opening; the accelerated stability meets the stability requirement for 40 days at 37°C; the Shippingation stability meets the product stability after Shippingation Claim.

The stability study of this kit uses internal control reference materials as samples.

1.5 Stability research test results and analysis

1.5.1 Real-time stability research test results

Table 1 Real-time stability test results of lot 20200301 kits (Time: 0th month, 25°C)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative

	Y8	Positive			F8	Negative		
	Y9	Positive			F9	Negative		
	Y10	Positive			F10	Negative		
LOD reference	L1	Positive			F11	Negative		
	L2	Positive			F12	Negative		
	L3	Positive			F13	Negative		
	L4	Positive			F14	Negative		
	L5	Positive			F15	Negative		
	L6	Negative			F16	Negative		
	L7	Negative			F17	Negative		
	L8	Negative			F18	Negative		
					F19	Negative		
					F20	Negative		
Repeatability reference	J	Positive	Repeatability reference	J2	Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
Moving speed	Speed	28.95	Speed2	29.31	Speed3	29.7	Acceptance standard	≥10mm/min

Table 2 Real-time stability test results of lot 20200302 kits (Time: 0th month, 25°C)

Appearance inspection			
Acceptance standard	The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.		
	The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.		
	The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.		
Test result	Meet the requirements		
Reference product name	Test result	Reference product name and code	Test result

and code							
Name	Code			Name	Code		
Positive reference	Y1	Positive		Negative reference	F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	
	Y4	Positive			F4	Negative	
	Y5	Positive			F5	Negative	
	Y6	Positive			F6	Negative	
	Y7	Positive			F7	Negative	
	Y8	Positive			F8	Negative	
	Y9	Positive			F9	Negative	
	Y10	Positive			F10	Negative	
LOD reference	L1	Positive			F11	Negative	
	L2	Positive			F12	Negative	
	L3	Positive			F13	Negative	
	L4	Positive			F14	Negative	
	L5	Positive			F15	Negative	
	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
					F19	Negative	
					F20	Negative	
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.8	Speed2	29.4	Speed3	29.6	Acceptance standard $\geq 10\text{mm/min}$

Table 3 Real-time stability test results of lot 20200304 kits (Time: 0th month, 25°C)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative
	L6	Negative		F16	Negative
	L7	Negative		F17	Negative
	L8	Negative		F18	Negative
				F19	Negative
				F20	Negative
Repeatability reference	J	Positive	Repeatability reference	J2	Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive

		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	28.95	Speed2	29.31	Speed3	29.7	Acceptance standard $\geq 10\text{mm/min}$

Table 4 Real-time stability test results of lot 20200301 kits (Time: 3rd month, 25°C)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative

	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
					F19	Negative	
					F20	Negative	
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.4	Speed2	29.4	Speed3	29.6	Acceptance standard $\geq 10\text{mm/min}$

Table 5 Real-time stability test results of lot 20200302 kits (Time: 3rd month, 25°C)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative

	Y7	Positive			F7	Negative	
	Y8	Positive			F8	Negative	
	Y9	Positive			F9	Negative	
	Y10	Positive			F10	Negative	
LOD reference	L1	Positive			F11	Negative	
	L2	Positive			F12	Negative	
	L3	Positive			F13	Negative	
	L4	Positive			F14	Negative	
	L5	Positive			F15	Negative	
	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
					F19	Negative	
					F20	Negative	
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.7	Speed2	29.7	Speed3	29.6	Acceptance standard $\geq 10\text{mm/min}$

Table 6 Real-time stability test results of lot 20200304 kits (Time: 3rd month, 25°C)

Appearance inspection	
Acceptance standard	The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.
	The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.
	The appearance of the sample diluent should be clear and transparent, with no leakage or

		impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative
	L6	Negative		F16	Negative
	L7	Negative		F17	Negative
	L8	Negative		F18	Negative
				F19	Negative
				F20	Negative
Repeatability reference	J	Positive	Repeatability reference	J2	Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive

Moving speed	Speed	29.1	Speed2	29.7	Speed3	29.0	Acceptance standard	≥10mm/min
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1.5.2 In use stability research test results

Table 7 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 35%; time: 20 minutes)

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive	Negative reference	F1	Negative		
	Y2	Positive		F2	Negative		
	Y3	Positive		F3	Negative		
	Y4	Positive		F4	Negative		
	Y5	Positive		F5	Negative		
	Y6	Positive		F6	Negative		
	Y7	Positive		F7	Negative		
	Y8	Positive		F8	Negative		
	Y9	Positive		F9	Negative		
	Y10	Positive		F10	Negative		
LOD reference	L1	Positive	F11	Negative			
	L2	Positive	F12	Negative			
	L3	Positive	F13	Negative			
	L4	Positive	F14	Negative			
	L5	Positive	F15	Negative			
	L6	Negative	F16	Negative			
	L7	Negative	F17	Negative			
	L8	Negative	F18	Negative			
			F19	Negative			

						F20	Negative	
Repeatability reference	J	Positive		Repeatability reference	J2	Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
Moving speed	Speed	29.4	Speed2	29.9	Speed3	29.1	Acceptance standard	≥10mm/min

Table 8 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 35%; time: 40 minutes)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative

	Y10	Positive			F10	Negative	
LOD reference	L1	Positive			F11	Negative	
	L2	Positive			F12	Negative	
	L3	Positive			F13	Negative	
	L4	Positive			F14	Negative	
	L5	Positive			F15	Negative	
	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
					F19	Negative	
					F20	Negative	
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.3	Speed2	29.3	Speed3	29.8	Acceptance standard $\geq 10\text{mm/min}$

Table 9 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 35%; time: 60 minutes)

Appearance inspection			
Acceptance standard	The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.		
	The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.		
	The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.		
Test result	Meet the requirements		
Reference product name and code	Test result	Reference product name and code	Test result

Name	Code		Name	Code				
Positive reference	Y1	Positive	Negative reference	F1	Negative			
	Y2	Positive		F2	Negative			
	Y3	Positive		F3	Negative			
	Y4	Positive		F4	Negative			
	Y5	Positive		F5	Negative			
	Y6	Positive		F6	Negative			
	Y7	Positive		F7	Negative			
	Y8	Positive		F8	Negative			
	Y9	Positive		F9	Negative			
	Y10	Positive		F10	Negative			
LOD reference	L1	Positive		F11	Negative			
	L2	Positive		F12	Negative			
	L3	Positive		F13	Negative			
	L4	Positive		F14	Negative			
	L5	Positive		F15	Negative			
	L6	Negative		F16	Negative			
	L7	Negative		F17	Negative			
	L8	Negative		F18	Negative			
				F19	Negative			
				F20	Negative			
Repeatability reference	J	Positive	Repeatability reference	J2	Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
Moving speed	Speed	29.9	Speed2	29.3	Speed3	29.9	Acceptance standard	≥10mm/min

Table 10 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 35%; time: 90 minutes)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative
	L6	Negative		F16	Negative
	L7	Negative		F17	Negative
	L8	Negative		F18	Negative
				F19	Negative
				F20	Negative
Repeatability reference	J	Positive	Repeatability reference	J2	Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive

		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.1	Speed2	29.7	Speed3	29.3	Acceptance standard $\geq 10\text{mm/min}$

Table 11 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 85%; time: 20 minutes)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative

	L5	Positive			F15	Negative	
	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
				F19	Negative		
				F20	Negative		
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.5	Speed2	29.4	Speed3	29.6	Acceptance standard $\geq 10\text{mm/min}$

Table 12 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 85%; time: 20 minutes)

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive		Negative reference	F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	
	Y4	Positive			F4	Negative	

	Y5	Positive			F5	Negative		
	Y6	Positive			F6	Negative		
	Y7	Positive			F7	Negative		
	Y8	Positive			F8	Negative		
	Y9	Positive			F9	Negative		
	Y10	Positive			F10	Negative		
LOD reference	L1	Positive		F11	Negative			
	L2	Positive		F12	Negative			
	L3	Positive		F13	Negative			
	L4	Positive		F14	Negative			
	L5	Positive		F15	Negative			
	L6	Negative		F16	Negative			
	L7	Negative		F17	Negative			
	L8	Negative		F18	Negative			
				F19	Negative			
				F20	Negative			
Repeatability reference	J	Positive		Repeatability reference	J2	Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
Moving speed	Speed	29.7	Speed2	30.0	Speed3	29.3	Acceptance standard	≥10mm/min

Table 13 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 85%; time: 60 minutes)

Appearance inspection	
Acceptance standard	The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.
	The packaging label should be clearly written, free from wear, and pasted in the correct and

		firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative
	L6	Negative		F16	Negative
	L7	Negative		F17	Negative
	L8	Negative		F18	Negative
				F19	Negative
				F20	Negative
Repeatability reference	J	Positive	Repeatability reference	J2	Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive

		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.6	Speed2	29.4	Speed3	29.3	Acceptance standard $\geq 10\text{mm/min}$

Table 14 In use stability test results of lot 20200304 kits
(Temperature 25°C, humidity 85%; time: 80 minutes)

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive		Negative reference	F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	
	Y4	Positive			F4	Negative	
	Y5	Positive			F5	Negative	
	Y6	Positive			F6	Negative	
	Y7	Positive			F7	Negative	
	Y8	Positive			F8	Negative	
	Y9	Positive			F9	Negative	
	Y10	Positive			F10	Negative	
LOD reference	L1	Positive		F11	Negative		
	L2	Positive		F12	Negative		
	L3	Positive		F13	Negative		
	L4	Positive		F14	Negative		
	L5	Positive		F15	Negative		
	L6	Negative		F16	Negative		
	L7	Negative		F17	Negative		
	L8	Negative		F18	Negative		

						F19	Negative
						F20	Negative
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.4	Speed2	29.9	Speed3	29.7	Acceptance standard $\geq 10\text{mm/min}$

1.5.3 Accelerated stability study test results

Table 15 Accelerated stability test results of the lot 20200304 kits (Time: Day 0, Temperature: 45°C)

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive		Negative reference	F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	
	Y4	Positive			F4	Negative	
	Y5	Positive			F5	Negative	
	Y6	Positive			F6	Negative	
	Y7	Positive			F7	Negative	
	Y8	Positive			F8	Negative	

	Y9	Positive			F9	Negative	
	Y10	Positive			F10	Negative	
LOD reference	L1	Positive			F11	Negative	
	L2	Positive			F12	Negative	
	L3	Positive			F13	Negative	
	L4	Positive			F14	Negative	
	L5	Positive			F15	Negative	
	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
					F19	Negative	
					F20	Negative	
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.4	Speed2	29.5	Speed3	29.3	Acceptance standard $\geq 10\text{mm/min}$

Table 16 Accelerated stability test results of the lot 20200304 kits (Time: Day 10, Temperature: 45 °C)

Appearance inspection			
Acceptance standard	The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.		
	The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.		
	The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.		
Test result	Meet the requirements		
Reference product name and code	Test result	Reference product name and code	Test result

Name	Code		Name	Code				
Positive reference	Y1	Positive	Negative reference	F1	Negative			
	Y2	Positive		F2	Negative			
	Y3	Positive		F3	Negative			
	Y4	Positive		F4	Negative			
	Y5	Positive		F5	Negative			
	Y6	Positive		F6	Negative			
	Y7	Positive		F7	Negative			
	Y8	Positive		F8	Negative			
	Y9	Positive		F9	Negative			
	Y10	Positive		F10	Negative			
LOD reference	L1	Positive		F11	Negative			
	L2	Positive		F12	Negative			
	L3	Positive		F13	Negative			
	L4	Positive		F14	Negative			
	L5	Positive		F15	Negative			
	L6	Negative		F16	Negative			
	L7	Negative		F17	Negative			
	L8	Negative		F18	Negative			
				F19	Negative			
				F20	Negative			
Repeatability reference	J	Positive	Repeatability reference	J2	Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
		Positive			Positive			
Moving speed	Speed	29.9	Speed2	29.9	Speed3	29.5	Acceptance standard	≥10mm/min

Table 17 Accelerated stability test results of the lot 20200304 kits (Time: Day 20, Temperature: 45 °C)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative
	L6	Negative		F16	Negative
	L7	Negative		F17	Negative
	L8	Negative		F18	Negative
				F19	Negative
				F20	Negative
Repeatability reference	J	Positive	Repeatability reference	J2	Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive

		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.3	Speed2	29.1	Speed3	29.5	Acceptance standard $\geq 10\text{mm/min}$

Table 18 Accelerated stability test results of the lot 20200304 kits (Time: Day 30, Temperature: 45°C)

Appearance inspection					
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.			
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.			
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative

	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
					F19	Negative	
					F20	Negative	
Repeatability reference	J	Positive		Repeatability reference	J2	Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
		Positive				Positive	
Moving speed	Speed	29.3	Speed2	29.6	Speed3	29.7	Acceptance standard $\geq 10\text{mm/min}$

Table 19 Accelerated stability test results of the lot 20200304 kits (Time: Day 40, Temperature: 45°C)

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive		Negative reference	F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	
	Y4	Positive			F4	Negative	
	Y5	Positive			F5	Negative	
	Y6	Positive			F6	Negative	

	Y7	Positive			F7	Negative		
	Y8	Positive			F8	Negative		
	Y9	Positive			F9	Negative		
	Y10	Positive			F10	Negative		
LOD reference	L1	Positive			F11	Negative		
	L2	Positive			F12	Negative		
	L3	Positive			F13	Negative		
	L4	Positive			F14	Negative		
	L5	Positive			F15	Negative		
	L6	Negative			F16	Negative		
	L7	Negative			F17	Negative		
	L8	Negative			F18	Negative		
					F19	Negative		
					F20	Negative		
Repeatability reference	J	Positive			Repeatability reference	J2	Positive	
		Positive					Positive	
		Positive					Positive	
		Positive					Positive	
		Positive					Positive	
		Positive					Positive	
		Positive		Positive				
		Positive		Positive				
		Positive		Positive				
		Positive		Positive				
Moving speed	Speed	29.7	Speed2	29.2	Speed3	29.1	Acceptance standard $\geq 10\text{mm/min}$	

1.5.4 Shipping stability test

The test results of the returned lot 20200304 kits continue to be stored at 2-10°C on day 0

Table 20 Shipping stability test results of lot 20180102 kits (shipped to Zhengzhou)

Appearance inspection	
Acceptance standard	The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.
	The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.
	The appearance of the sample diluent should be clear and transparent, with no leakage or

		impurities.			
Test result		Meet the requirements			
Reference product name and code		Test result	Reference product name and code		Test result
Name	Code		Name	Code	
Positive reference	Y1	Positive	Negative reference	F1	Negative
	Y2	Positive		F2	Negative
	Y3	Positive		F3	Negative
	Y4	Positive		F4	Negative
	Y5	Positive		F5	Negative
	Y6	Positive		F6	Negative
	Y7	Positive		F7	Negative
	Y8	Positive		F8	Negative
	Y9	Positive		F9	Negative
	Y10	Positive		F10	Negative
LOD reference	L1	Positive		F11	Negative
	L2	Positive		F12	Negative
	L3	Positive		F13	Negative
	L4	Positive		F14	Negative
	L5	Positive		F15	Negative
	L6	Negative		F16	Negative
	L7	Negative		F17	Negative
	L8	Negative		F18	Negative
				F19	Negative
				F20	Negative
Repeatability reference	J	Positive	Repeatability reference	J2	Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive
		Positive			Positive

Moving speed	Speed	29.2	Speed2	29.1	Speed3	29.5	Acceptance standard	≥10mm/min
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Table 21 The test results of the returned lot 20200304 kits continue to be stored at 10-30°C on day 0

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive	Negative reference		F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	
	Y4	Positive			F4	Negative	
	Y5	Positive			F5	Negative	
	Y6	Positive			F6	Negative	
	Y7	Positive			F7	Negative	
	Y8	Positive			F8	Negative	
	Y9	Positive			F9	Negative	
	Y10	Positive			F10	Negative	
LOD reference	L1	Positive			F11	Negative	
	L2	Positive			F12	Negative	
	L3	Positive			F13	Negative	
	L4	Positive			F14	Negative	
	L5	Positive			F15	Negative	
	L6	Negative			F16	Negative	
	L7	Negative			F17	Negative	
	L8	Negative			F18	Negative	
					F19	Negative	
					F20	Negative	
Repeatability	J	Positive	Repeatability	J2	Positive		

reference		Positive		reference		Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
Moving speed	Speed	29.7	Speed2	29.5	Speed3	29.9	Acceptance standard	≥10mm/min

Table 22 The test results of the returned batch number 20200304 kit continue to be stored at 2-10°C on the 90th day

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive		Negative reference	F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	
	Y4	Positive			F4	Negative	
	Y5	Positive			F5	Negative	
	Y6	Positive			F6	Negative	
	Y7	Positive			F7	Negative	
	Y8	Positive			F8	Negative	
	Y9	Positive			F9	Negative	
	Y10	Positive			F10	Negative	
LOD reference	L1	Positive		F11	Negative		
	L2	Positive		F12	Negative		

	L3	Positive			F13	Negative		
	L4	Positive			F14	Negative		
	L5	Positive			F15	Negative		
	L6	Negative			F16	Negative		
	L7	Negative			F17	Negative		
	L8	Negative			F18	Negative		
					F19	Negative		
					F20	Negative		
Repeatability reference	J	Positive		Repeatability reference	J2	Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
Moving speed	Speed	29.8	Speed2	29.1	Speed3	29.3	Acceptance standard	≥10mm/min

Table 22 The test results of the returned batch number 20200304 kit continue to be stored at 10-30°C on the 90th day

Appearance inspection							
Acceptance standard		The appearance of the test card should be flat, free of burrs, damage, and pollution, the material should be firmly attached, and the card should be tightly fixed.					
		The packaging label should be clearly written, free from wear, and pasted in the correct and firm position.					
		The appearance of the sample diluent should be clear and transparent, with no leakage or impurities.					
Test result		Meet the requirements					
Reference product name and code		Test result		Reference product name and code		Test result	
Name	Code			Name	Code		
Positive reference	Y1	Positive		Negative reference	F1	Negative	
	Y2	Positive			F2	Negative	
	Y3	Positive			F3	Negative	

	Y4	Positive			F4	Negative		
	Y5	Positive			F5	Negative		
	Y6	Positive			F6	Negative		
	Y7	Positive			F7	Negative		
	Y8	Positive			F8	Negative		
	Y9	Positive			F9	Negative		
	Y10	Positive			F10	Negative		
	LOD reference	L1	Positive		F11	Negative		
		L2	Positive		F12	Negative		
		L3	Positive		F13	Negative		
L4		Positive		F14	Negative			
L5		Positive		F15	Negative			
L6		Negative		F16	Negative			
L7		Negative		F17	Negative			
L8		Negative		F18	Negative			
				F19	Negative			
				F20	Negative			
Repeatability reference	J	Positive		Repeatability reference	J2	Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
		Positive				Positive		
Moving speed	Speed	29.3	Speed2	29.6	Speed3	30.0	Acceptance standard $\geq 10\text{mm/min}$	

1.6 Summary and conclusions of stability study results

The stability study results and conclusions are summarized in Table 23.

Table 23 Summary and conclusions of the stability study results

Summary of research results	Conclusion
① Real-time stability research results As the real-time stability research experiment is not over yet, no summary	No conclusion

<p>② Accelerated stability research results</p> <p>After the kit is stored at 37°C for 10 days, 20 days, 30 days, and 40 days, it is tested according to the requirements of the accelerated stability study protocol, and all Test results meet the requirements.</p>	<p>This kit is placed at 37°C for 40 days and will not affect the performance of this kit.</p>
<p>③ Results of shipping stability research</p> <p>One batch of kits is transported, exported to other cities in China, and sent back to the place of departure again upon arrival. Test according to the requirements of the transportation stability research program, and various Test result Meet the requirements.</p> <p>As the transportation stability research experiment has not yet ended, no summary will be made temporarily.</p>	<p>No conclusion</p>
<p>④ Results of in use stability study</p> <p>One batch of kits equilibrated at room temperature for 30 minutes. Tear off the sealed aluminum foil bag of the test card, and expose the test reagent card to a specific environment (after temperature 25, humidity 35%, temperature 25 degrees, humidity 85%) to 60 minutes, according to the requirements of the stability study program after opening Testing, various Test result Meet the requirements.</p>	<p>After the test reagent card is opened, it is effective within 60 minutes when exposed to a temperature of 25°C and a humidity of 35-85%.</p>

In summary, although the real-time stability and transportation stability research experiments have not yet been completed, according to the results of accelerated stability experiments, the SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay) developed by us has good stability. Can achieve the desired design goals. Therefore, we tentatively set the validity period of this kit at 2-30°C as 12 months; research tests on the stability of opening, thermal acceleration, and transportation conditions can also ensure that the research kit is safe and effective when transported to the customer.