

**SARS-CoV-2 IgM/IgG antibody test kit  
(Colloidal Gold Method)**

**stability evaluation**

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## 1 Transportation stability study

**The initiation and conclusion dates:** 2020.03.08-2020.04.20.

### 1.1 Purpose

To study the transportation stability of SARS-CoV-2 IgM/IgG antibody detection kit (colloidal gold method).

### 1.2 Experimental method

In order to study the transportation stability of the kits, three batches of kits were selected after simulated transportation and tested the appearance, strip width, the indexes such as the liquid migration speed, the conformity rate of the positive reference product, the conformity rate of the negative reference product, the detection limit and the repeatability shall be tested according to the operation method of the instruction manual. And the results should meet the quality control standards.

Stability research survey indicators and quality control standards as follows:

Table 1 Quality control standards of stability of the IVD

Items	Quality control standards
Appearance	Kit should have complete label and composition; The reagent strip should be kept airtight, no damage and no pollution.
Width	The width of the film strip shall not be less than 2.8mm.
Liquid migration speed	The migration speed shall not be lower than 10.0mm/min.
Compliance rate of positive references	Five positive references P1-P5 of SARS-CoV-2 antibody were detected, the results should be positive.
Compliance rate of negative reference	Six negative references N1-N6 of SARS-CoV-2 antibody were detected, and the results should be negative.
Minimum detection limit	Use the minimum detection limit reference (L1-L3) for testing, L1 should be detected as positive, L2 can be detected as positive or negative, L3 should be detected as negative.
Repeatability	The test is performed 10 times with a concentration level reference, the results should be positive and the color development is uniform.

### 1.3 Experimental program

**Kit sampling:** 18 kits were selected from three lots of SARS-CoV-2 IgM/IgG antibody detection kits (colloidal gold method) with lots SA200201, SA200202, and SA200203. **Kit sealing:** Sealed according to normal delivery, one box per batch.

**Simulated transportation:** The reagent will be sent to the company's Guangdong office through express. After receiving the reagent, the Guangdong office staff will send the reagents back to the company as they were and it about 10 days.

**Kit acceleration and dropping:** Unpack the reagent box after the simulated transportation,

put the reagent box at 37 °C for 5 days, after acceleration, let the reagent box fall from one meter for five times.

Re-storage: Put the reagent box in the quality department at 2-30 °C to save the kits for future use.

Take three lots of SA200201, SA200202, SA200203 of SARS-CoV-2 IgM/IgG antibody detection kits (colloidal gold method) and test the appearance, the width of the film strip, the speed of liquid migration, the coincidence rate of positive reference products, the coincidence rate of negative reference products, the detection limit, repeatability. And the results should meet the quality control standards.

The type of test samples is serum sample.

#### 1.4 Test results

Table 2 Experimental result of transportation stability study

SA200201					
Technical index		0 <sup>th</sup> day		10 <sup>th</sup> day	
Appearance		Label and composition complete		Label and composition complete	
Width(mm)		3.69		3.75	
Liquid migration speed(mm/min)		27.94		27.09	
Test results		IgM	IgG	IgM	IgG
Minimum detection limit(L1-L3)	L1	positive	positive	positive	positive
	L2	positive	negative	positive	positive
	L3	negative	negative	negative	negative
Compliance rate of positive references(P1-P5)	P1	positive	positive	positive	positive
	P2	positive	positive	positive	positive
	P3	positive	positive	positive	positive
	P4	positive	positive	positive	positive
	P5	positive	positive	positive	positive
Compliance rate of negative reference(N1-N6)	N1	negative	negative	negative	negative
	N2	negative	negative	negative	negative
	N3	negative	negative	negative	negative
	N4	negative	negative	negative	negative
	N5	negative	negative	negative	negative
	N6	negative	negative	negative	negative
Repeatability	/	positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive

		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
SA200202					
Technical index		0 <sup>th</sup> day		10 <sup>th</sup> day	
Appearance		Label and composition complete		Label and composition complete	
Width(mm)		3.68		3.69	
Liquid migration speed(mm/min)		27.37		27.65	
Test results		IgM	IgG	IgM	IgG
Minimum detection limit(L1-L3)	L1	positive	positive	positive	positive
	L2	positive	positive	positive	positive
	L3	negative	negative	negative	negative
Compliance rate of positive references(P1-P5)	P1	positive	positive	positive	positive
	P2	positive	positive	positive	positive
	P3	positive	positive	positive	positive
	P4	positive	positive	positive	positive
	P5	positive	positive	positive	positive
Compliance rate of negative reference(N1-N6)	N1	negative	negative	negative	negative
	N2	negative	negative	negative	negative
	N3	negative	negative	negative	negative
	N4	negative	negative	negative	negative
	N5	negative	negative	negative	negative
	N6	negative	negative	negative	negative
Repeatability	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
	/	positive	positive	positive	positive
SA200203					
Technical index		0 <sup>th</sup> day		10 <sup>th</sup> day	
Appearance		Label and composition complete		Label and composition complete	

Width(mm)		3.66		3.68	
Liquid migration speed(mm/min)		27.09		28.23	
Test results		IgM	IgG	IgM	IgG
Minimum detection limit(L1-L3)	L1	positive	positive	positive	positive
	L2	positive	negative	positive	positive
	L3	negative	negative	negative	negative
Compliance rate of positive references(P1-P5)	P1	positive	positive	positive	positive
	P2	positive	positive	positive	positive
	P3	positive	positive	positive	positive
	P4	positive	positive	positive	positive
	P5	positive	positive	positive	positive
Compliance rate of negative reference(N1-N6)	N1	negative	negative	negative	negative
	N2	negative	negative	negative	negative
	N3	negative	negative	negative	negative
	N4	negative	negative	negative	negative
	N5	negative	negative	negative	negative
	N6	negative	negative	negative	negative
Repeatability	/	positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive
		positive	positive	positive	positive

### 1.5 Experimental conclusion

The kit transport for 10 days. The components of the kit are complete and complete; the label is clear, accurate and firm; the width of the film strip is not less than 2.8mm; the speed of liquid migration is not less than 10mm/min; six negative references are tested to be negative; five positive reference products are tested to be positive; Use the enterprise's minimum detection limit reference products (L1-L3) for testing , L1 is tested as positive, L2 is tested as positive or negative, and L3 is tested as negative; A concentration level reference product is tested 10 times, and the results are positive and the color is uniform. All performance indicators meet the requirements.

The results of the transportation stability test showed that the performance test of the three lots of trial production kits still met the technical requirements of the kits during 10 days transportation test. It shows that the kit has good thermal stability .

## 2 Accelerated stability study

**The initiation and conclusion dates:** 2020.05.05-2020.05.26.

### 2.1 Purpose

To study the accelerated stability of SARS-CoV-2 IgM/IgG antibody detection kit (colloidal gold method).

### 2.2 Experimental method

Three batches of SARS-CoV-2 IgM/IgG antibody detection kits (colloidal gold method) were taken at 54°C for 21 days, and the samples were collected for 14 days and 21 days respectively. The appearance, width, speed of liquid migration, positive reference rate, negative reference rate, minimum detection limit and repeatability were detected. And the results should meet the quality control standards

Stability research survey indicators and quality control standards as follows:

Table 3 Quality control standards of stability of the IVD

Items	Quality control standards
Appearance	Kit should have complete label and composition; The reagent strip should be kept airtight, no damage and no pollution.
Width	The width of the film strip shall not be less than 2.8mm.
Liquid migration speed	The migration speed shall not be lower than 10.0mm/min.
Compliance rate of positive references	Five positive references P1-P5 of SARS-CoV-2 antibody were detected, the results should be positive.
Compliance rate of negative reference	Six negative references N1-N6 of SARS-CoV-2 antibody were detected, and the results should be negative.
Minimum detection limit	Use the minimum detection limit reference (L1-L3) for testing, L1 should be detected as positive, L2 can be detected as positive or negative, L3 should be detected as negative.
Repeatability	The test is performed 10 times with a concentration level reference, the results should be positive and the color development is uniform.

### 2.3 Experimental program

Take three lots of SA200201, SA200202, SA200203 of SARS-CoV-2 IgM/IgG antibody detection kits (colloidal gold method) each for 6 boxes and place them at 54°C for accelerating 21 days. Take 2 boxes of three lots of kits accelerated to 14 days and 21 days and test the appearance, the width of the film strip, the speed of liquid migration, the coincidence rate of positive reference products, the coincidence rate of negative reference products, the detection limit, repeatability. And the results should meet the quality control standards.

### 2.4 Test results

Table 4 Experimental result of accelerated stability study

SA200201							
Technical index		0 <sup>th</sup> day		14 <sup>th</sup> day		21 <sup>th</sup> day	
Appearance		Label and composition complete		Label and composition complete		Label and composition complete	
Width(mm)		3.82		3.81		3.78	
Liquid migration speed(mm/min)		29.25		26.82		25.95	
Test results		IgM	IgG	IgM	IgG	IgM	IgG
Minimum detection limit(L1-L3)	L1	positive	positive	positive	positive	positive	positive
	L2	positive	negative	negative	positive	positive	negative
	L3	negative	negative	negative	negative	negative	negative
Compliance rate of positive references(P1-P5)	P1	positive	positive	positive	positive	positive	positive
	P2	positive	positive	positive	positive	positive	positive
	P3	positive	positive	positive	positive	positive	positive
	P4	positive	positive	positive	positive	positive	positive
	P5	positive	positive	positive	positive	positive	positive
Compliance rate of negative reference(N1-N6)	N1	negative	negative	negative	negative	negative	negative
	N2	negative	negative	negative	negative	negative	negative
	N3	negative	negative	negative	negative	negative	negative
	N4	negative	negative	negative	negative	negative	negative
	N5	negative	negative	negative	negative	negative	negative
	N6	negative	negative	negative	negative	negative	negative
Repeatability	/	positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
SA200202							
Technical index		0 <sup>th</sup> day		14 <sup>th</sup> day		21 <sup>th</sup> day	
Appearance		Label and composition complete		Label and composition complete		Label and composition complete	
Width(mm)		3.80		3.78		3.77	
Liquid migration speed(mm/min)		24.76		24.38		29.8	
Test results		IgM	IgG	IgM	IgG	IgM	IgG

Minimum detection limit(L1-L3)	L1	positive	positive	positive	positive	positive	positive
	L2	positive	positive	negative	negative	positive	negative
	L3	negative	negative	negative	negative	negative	negative
Compliance rate of positive references(P1-P5)	P1	positive	positive	positive	positive	positive	positive
	P2	positive	positive	positive	positive	positive	positive
	P3	positive	positive	positive	positive	positive	positive
	P4	positive	positive	positive	positive	positive	positive
	P5	positive	positive	positive	positive	positive	positive
Compliance rate of negative reference(N1-N6)	N1	negative	negative	negative	negative	negative	negative
	N2	negative	negative	negative	negative	negative	negative
	N3	negative	negative	negative	negative	negative	negative
	N4	negative	negative	negative	negative	negative	negative
	N5	negative	negative	negative	negative	negative	negative
	N6	negative	negative	negative	negative	negative	negative
Repeatability	/	positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
SA200203							
Technical index		0 <sup>th</sup> day		14 <sup>th</sup> day		21 <sup>th</sup> day	
Appearance		Label and composition complete		Label and composition complete		Label and composition complete	
Width(mm)		3.76		3.76		3.76	
Liquid migration speed(mm/min)		27.74		24.38		24.02	
Test results		IgM	IgG	IgM	IgG	IgM	IgG
Minimum detection limit(L1-L3)	L1	positive	positive	positive	positive	positive	positive
	L2	positive	negative	positive	negative	positive	negative
	L3	negative	negative	negative	negative	negative	negative
Compliance rate of positive references(P1-P5)	P1	positive	positive	positive	positive	positive	positive
	P2	positive	positive	positive	positive	positive	positive
	P3	positive	positive	positive	positive	positive	positive
	P4	positive	positive	positive	positive	positive	positive
	P5	positive	positive	positive	positive	positive	positive



Compliance rate of negative reference(N1-N6)	N1	negative	negative	negative	negative	negative	negative
	N2	negative	negative	negative	negative	negative	negative
	N3	negative	negative	negative	negative	negative	negative
	N4	negative	negative	negative	negative	negative	negative
	N5	negative	negative	negative	negative	negative	negative
	N6	negative	negative	negative	negative	negative	negative
Repeatability	/	positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive
		positive	positive	positive	positive	positive	positive

## 2.5 Experimental conclusion

The kit is accelerated at 54°C for 21 days. The components of the kit are complete and complete; the label is clear, accurate and firm; the width of the film strip is not less than 2.8mm; the speed of liquid migration is not less than 10mm/min; six negative references are tested to be negative; five positive reference products are tested to be positive; Use the enterprise's minimum detection limit reference products (L1-L3) for testing , L1 is tested as positive, L2 is tested as positive or negative, and L3 is tested as negative; A concentration level reference product is tested 10 times, and the results are positive and the color is uniform. All performance indicators meet the requirements.

The results of the accelerated stability test showed that the performance test of the three lots of trial production kits still met the technical requirements of the kits during the 21 days accelerated test at 54°C. It shows that the kit has good thermal stability within 21 days at 54°C.