

COVID-19 IgG/IgM Rapid Test Cassette

Stability research materials

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Stability research materials

1. Basis for the determination of stability research methods

The basis for determining the stability research method is "Internal Stability Test Method".

2. Specific methods and processes of stability research

2.1 Specific methods for stability studies

2.1.1(45 ± 1) °C heat accelerated thermal stability test

The three batches of finished product kits for trial production were calculated according to the Arrhenius equation, placed in a constant temperature environment of (45 ± 1) °C and stored for 48 days, and an assessment test was conducted every 8 days, that is, on the 8, 16, 24, 32, 40, An assessment test will be conducted once every 48 days. Use the company's internal quality control products as the evaluation sample, and the test items are carried out according to the standards for the inspection of finished products. At the same time, the extent of the change in the quality of the kit with the storage time increases. The kit is stored at a constant temperature of (45 ± 1) °C, and it should be stable for more than 40 days. That is, after 40 days of storage under this condition, the quality of the kit must still be able to meet the verification standards of the finished product.

2.1.2 Stability test under storage temperature conditions after opening

For the stability test under storage temperature conditions after opening, this kit uses a test card and an aluminum foil bag for single serving packaging, and there is no situation of multiple use after opening. However, considering that the test card may not be tested immediately after it is taken out of the aluminum foil bag, we conducted the following

experiment: remove the test card from the aluminum foil bag and place it at room temperature (15-30 °C) for 1 hour for testing. The quality of the kit must still meet the verification standards for the finished product.

2.1.3 Simulated stability test during transportation

In order to investigate the stability of the products, we packaged the finished three batches of COVID-19 IgG/IgM Rapid Test Cassette and placed them on the company's trucks on the first day, 4th, 7th, 10th, 13th, and 15th days, the quality of the reagents were tested. The main routes traveled by the company's CMB are: national highways, highways, township highways, etc. During the test, record the daily temperature and humidity conditions and the mileage of the car. The kits after the 8th day of simulated transportation are stored under the temperature of $(45 \pm 1 \text{ } ^\circ\text{C})$, and stored for 40 days before testing..

It is required that the kits should be kept stable for more than 15 days under transportation conditions (our kits are generally controlled within 15 days when they reach the target customers), that is, after storage under these conditions for 15 days and after transportation, they are stored at temperature For 15 days under the condition of $(45 \pm 1 \text{ } ^\circ\text{C})$, the quality of the kit must still be able to meet the verification standard of the finished product..

3. The specific process of stability study

3.1 $(45 \pm 1) \text{ } ^\circ\text{C}$ accelerated thermal stability test

We put the three batches of trial kits (packaging specifications: 20 servings / box, batch numbers are: 20200301, 20200302, 20200303) at $(45 \pm 1) \text{ } ^\circ\text{C}$ temperature conditions for 48 days, according to Arrhenius equation to formulate the assessment Scheme, in which an assessment test is conducted on days 8, 16, 24, 32, 40, and 48, respectively. The relevant data statistics of the test results are shown in the table below.

LOT20200301 batch of finished kits are stored at $(45 \pm 1) \text{ } ^\circ\text{C}$

Storage time	Storage environment	Test results										result
8day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
		L1		L2		L3		L4				
		+++		++		+		-				
16day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
		L1		L2		L3		L4				
		+++		++		+		-				
24day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	

32day	45°C	Reference product with minimum detection limit (L1-L4)								Pass		
		L1	L2	L3	L4							
		+++	++	+	-							
		Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
10 parallel inspections												
++	++	++	++	++	++	++	++	++	++			
Reference product with minimum detection limit (L1-L4)										Pass		
L1	L2	L3	L4									
+++	++	+	-									
40day	45°C	Negative reference (N1-N10)								Pass		
		N1	N2	N3	N4	N5	N6	N7	N8		N9	N10
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1	L2	L3	L4									
+++	++	+	-									
48day	45°C	Negative reference (N1-N10)								Pass		
		N1	N2	N3	N4	N5	N6	N7	N8		N9	N10
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
Precision Reference										Pass		
10 parallel inspections												

		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
		L1		L2		L3		L4				
		+++		++		+		-				

LOT20200301 batch of finished kits are stored at $(45 \pm 1) ^\circ\text{C}$

Storage time	Storage environment	Test results										result
8day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						
16day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						
24day	45°C	Negative reference (N1-N10)										Pass

		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
		L1		L2		L3		L4				
+++		++		+		-						
32day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						
40day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						

48day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						

LOT20200301 batch of finished kits are stored at $(45 \pm 1) ^\circ\text{C}$

Storage time	Storage environment	Test results										result
8day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						
16day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
Precision Reference										Pass		
10 parallel inspections												

		++	++	++	++	++	++	++	++	++	++			
		Reference product with minimum detection limit (L1-L4)										Pass		
		L1	L2	L3	L4									
		+++	++	+	-									
24day	45°C	Negative reference (N1-N10)										Pass		
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10			
		-	-	-	-	-	-	-	-	-	-			
				Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10			
		+	+	+	++	++	++	++	+++	+++	+++			
				Precision Reference										Pass
				10 parallel inspections										
				++	++	++	++	++	++	++	++	++	++	
				Reference product with minimum detection limit (L1-L4)										Pass
		L1	L2	L3	L4									
		+++	++	+	-									
32day	45°C	Negative reference (N1-N10)										Pass		
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10			
		-	-	-	-	-	-	-	-	-	-			
				Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10			
		+	+	+	++	++	++	++	+++	+++	+++			
				Precision Reference										Pass
				10 parallel inspections										
				++	++	++	++	++	++	++	++	++	++	
				Reference product with minimum detection limit (L1-L4)										Pass
		L1	L2	L3	L4									
		+++	++	+	-									
40day	45°C	Negative reference (N1-N10)										Pass		
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10			
		-	-	-	-	-	-	-	-	-	-			
				Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10			
		+	+	+	++	++	++	++	+++	+++	+++			
		Precision Reference										Pass		

		10 parallel inspections										Pass			
		++	++	++	++	++	++	++	++	++	++				
		Reference product with minimum detection limit (L1-L4)													
		L1		L2		L3		L4							
		+++		++		+		-							
		48day	45°C	Negative reference (N1-N10)										Pass	
				N1	N2	N3	N4	N5	N6	N7	N8		N9		N10
				-	-	-	-	-	-	-	-		-		-
				Positive reference (P1-P10)											
				P1	P2	P3	P4	P5	P6	P7	P8		P9		P10
+	+			+	++	++	++	++	+++	+++	+++				
Precision Reference															
10 parallel inspections															
++	++			++	++	++	++	++	++	++	++				
Reference product with minimum detection limit (L1-L4)										Pass					
L1		L2		L3		L4									
+++		++		+		-									

From the above results, it can be concluded that the kits developed by our company are stored at $(45 \pm 1) ^\circ\text{C}$ for 48 days and the results of testing quality control products are within the control range. Therefore, the kit can be stored at $(45 \pm 1) ^\circ\text{C}$ temperature conditions can be stable for more than 40 days, according to Arrhenius equation calculation kit validity period is not less than 1 year, the kit thermal stability test reached the expected requirements..

3.2 Stability test and data statistics after opening and storing under temperature (15-30 °C) (take the test card out of the aluminum foil bag and place it at room temperature)

We removed the test cards of the three batches of test kits (packaging specifications: 24 servings / box, batch numbers: 20200301, 20200302, and 20200303) from the aluminum foil bag and placed them at room temperature for 1 hour for testing. See the table for relevant data statistics:

Three batches of finished kits are stored at room temperature for 1 hour after opening

Lot No.	Test results										result
20200301	Negative reference (N1-N10)										Pass
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
	-	-	-	-	-	-	-	-	-	-	
	Positive reference (P1-P10)										Pass
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	+	+	+	++	++	++	++	+++	+++	+++	
	Precision Reference										Pass
	10 parallel inspections										
	++	++	++	++	++	++	++	++	++	++	
	Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4					
+++		++		+		-					
20200302	Negative reference (N1-N10)										Pass
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
	-	-	-	-	-	-	-	-	-	-	
	Positive reference (P1-P10)										Pass
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	+	+	+	++	++	++	++	+++	+++	+++	
	Precision Reference										Pass
	10 parallel inspections										
	++	++	++	++	++	++	++	++	++	++	
	Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4					
+++		++		+		-					
20200303	Negative reference (N1-N10)										Pass
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
	-	-	-	-	-	-	-	-	-	-	
	Positive reference (P1-P10)										Pass
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	+	+	+	++	++	++	++	+++	+++	+++	
Precision Reference										Pass	
10 parallel inspections											

	++	++	++	++	++	++	++	++	++	++	
	Reference product with minimum detection limit (L1-L4)										Pass
	L1		L2		L3		L4				
	+++		++		+		-				

From the results in the table above, it can be concluded that the results of testing the quality control products after being opened at room temperature (15-30 °C) for 1 hour after the kits developed by our company are within the control range. Therefore, after the test card of the kit is removed from the aluminum foil bag, the test can be completed within 1 hour.

3.5 Simulated stability test during transportation

During the simulation of transportation, we put the mobile temperature and humidity meter in the car and record the temperature and humidity in the CMB bus every day. See data for temperature and humidity.

Simulate temperature and humidity during transportation

TIME condition	1day	4day	7day	10day	13day	15day
temperature (°C)	35~40°C	35~40°C	40~45°C	35~40°C	40~45°C	40~45°C
Relative humidity (%)	45~70%	45~70%	40~70%	45~75%	45~70%	45~70%
Mileage (km)	321 km	306 km	284 km	295 km	304 km	264 km

Total mileage: 1774 km

LOT20200301batch of finished product kits simulated transportation stability test results

Storage time	Storage environment	Test results										result
1day		Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	

Simulated transportation	-										Pass
	Positive reference (P1-P10)										
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	+										Pass
	Precision Reference										
	10 parallel inspections										
	+										Pass
	Reference product with minimum detection limit (L1-L4)										
	L1	L2	L3	L4							
	+++		++		+		-				
4day	Negative reference (N1-N10)										Pass
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
	-										
	Positive reference (P1-P10)										Pass
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	+										
	Precision Reference										Pass
	10 parallel inspections										
	++										
	Reference product with minimum detection limit (L1-L4)										Pass
L1	L2	L3	L4								
+++		++		+		-					
7day	Negative reference (N1-N10)										Pass
	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
	-										
	Positive reference (P1-P10)										Pass
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
	+										
	Precision Reference										Pass
	10 parallel inspections										
	++										
	Reference product with minimum detection limit (L1-L4)										Pass
L1	L2	L3	L4								
+++		++		+		-					
10day	Negative reference (N1-N10)										Pass

Simulated transportati on		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	++
		Reference product with minimum detection limit (L1-L4)										Pass
		L1		L2		L3		L4				
+++		++		+		-						
13day	37°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	-
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	++
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						
15day	37°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	-
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	++
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						

40day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										
		L1	L2	L3	L4	Pass						
		+++	++	+	-							

LOT20200302batch of finished product kits simulated transportation stability test results

Storage time	Storage environment	Test results										result
1day	Simulated transportation	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		+	+	+	+	+	+	+	+	+	+	
		Reference product with minimum detection limit (L1-L4)										
		L1	L2	L3	L4	Pass						
		+++	++	+	-							
4day	Simulated transportation	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
Precision Reference										Pass		

		10 parallel inspections										
		++	++	++	++	++	++	++	++	++		
		Reference product with minimum detection limit (L1-L4)										
		L1		L2		L3		L4		Pass		
		+++		++		+		-				
7day	Simulated transportati on	Negative reference (N1-N10)										
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	Pass
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										
		10 parallel inspections								Pass		
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										
L1		L2		L3		L4		Pass				
+++		++		+		-						
10day	Simulated transportati on	Negative reference (N1-N10)										
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	Pass
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										
		10 parallel inspections								Pass		
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										
L1		L2		L3		L4		Pass				
+++		++		+		-						
13day	37°C	Negative reference (N1-N10)										
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	Pass
		+	+	+	++	++	++	++	+++	+++	+++	

		Precision Reference								Pass		
		10 parallel inspections										
		++	++	++	++	++	++	++	++		++	++
		Reference product with minimum detection limit (L1-L4)										
		L1	L2	L3	L4					Pass		
		+++	++	+	-							
		Negative reference (N1-N10)									Pass	
		N1	N2	N3	N4	N5	N6	N7	N8			N9
-	-	-	-	-	-	-	-	-	-			
Positive reference (P1-P10)								Pass				
P1	P2	P3	P4	P5	P6	P7	P8		P9	P10		
+	+	+	++	++	++	++	+++		+++	+++		
Precision Reference									Pass			
10 parallel inspections												
++	++	++	++	++	++	++	++	++		++		
Reference product with minimum detection limit (L1-L4)								Pass				
L1	L2	L3	L4									
+++	++	+	-									
Negative reference (N1-N10)									Pass			
N1	N2	N3	N4	N5	N6	N7	N8	N9		N10		
-	-	-	-	-	-	-	-	-		-		
Positive reference (P1-P10)								Pass				
P1	P2	P3	P4	P5	P6	P7	P8		P9	P10		
+	+	+	++	++	++	++	+++		+++	+++		
Precision Reference									Pass			
10 parallel inspections												
++	++	++	++	++	++	++	++	++		++		
Reference product with minimum detection limit (L1-L4)								Pass				
L1	L2	L3	L4									
+++	++	+	-									

LOT20200303batch of finished product kits simulated transportation stability test results

Storage time	Storage environment	Test results	result
1day		Negative reference (N1-N10)	Pass

	Simulated transportation	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	Pass	
		-	-	-	-	-	-	-	-	-	-		-
		Positive reference (P1-P10)											Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10		
		+	+	+	++	++	++	++	+++	+++	+++		
		Precision Reference											Pass
		10 parallel inspections											
		+	+	+	+	+	+	+	+	+	+	+	
		Reference product with minimum detection limit (L1-L4)											Pass
		L1		L2		L3		L4					
+++		++		+		-							
4day	Simulated transportation	Negative reference (N1-N10)											Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10		
		-	-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)											Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10		
		+	+	+	++	++	++	++	+++	+++	+++		
		Precision Reference											Pass
		10 parallel inspections											
		++	++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)											Pass
L1		L2		L3		L4							
+++		++		+		-							
7day	Simulated transportation	Negative reference (N1-N10)											Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10		
		-	-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)											Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10		
		+	+	+	++	++	++	++	+++	+++	+++		
		Precision Reference											Pass
		10 parallel inspections											
		++	++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)											Pass
L1		L2		L3		L4							
+++		++		+		-							

10day	Simulated transportati on	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						
13day	37°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						
15day	37°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
L1		L2		L3		L4						
+++		++		+		-						

		+++	++	+	-							
40day	45°C	Negative reference (N1-N10)										Pass
		N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	
		-	-	-	-	-	-	-	-	-	-	-
		Positive reference (P1-P10)										Pass
		P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	
		+	+	+	++	++	++	++	+++	+++	+++	+++
		Precision Reference										Pass
		10 parallel inspections										
		++	++	++	++	++	++	++	++	++	++	
		Reference product with minimum detection limit (L1-L4)										Pass
		L1		L2		L3		L4				
		+++		++		+		-				

From the above results, it can be concluded that the kit developed by our company is transported for 15 days under Simulated transportation conditions and stored for 40 days at a temperature of $(45 \pm 1 \text{ }^\circ\text{C})$ after transportation. The results of testing quality control products are within the control range Within. It shows that the simulated transportation stability test of the kit has reached the expected requirements.

4. Summary and conclusion of stability test

Based on the comprehensive stability test results, we can see that the $(45 \pm 1) \text{ }^\circ\text{C}$ accelerated thermal stability test and the stability of the card stored at room temperature ($15\text{-}30 \text{ }^\circ\text{C}$) for 1 hour after opening the package, we developed The stability of COVID-19 IgG / IgM Rapid Test Cassette has fully met the expected requirements, and the test indicators of the kit can meet the quality standards required by the finished product. Therefore, based on the data of the above test results, we set the validity period of this kit to be stored at $2\text{-}30 \text{ }^\circ\text{C}$ as 18 months.

At the same time, according to the stability test results under our simulated transportation conditions, it shows that the kit has been transported for 15 days under the simulated

transportation conditions and the quality is stable.