Changsha China, June 24,2020

TO WHOM IT MAY CONCERN:

We hereby declare, on behalf of Changsha Sinocare Inc. that our product " SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method) " has an intended shelf- life of 12 months according to our *SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method) Strip Stability Test Report*.

Below we summarized the result of our *SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method) Strip Stability Test Report*:

According to Arrehenius 10 degree principle, use 45°C accelerate stability test data to calculate shelf life of this test strip (intended shelf-life is 12 months)

$TIME_{TI}=TIME_{RT}/Q_{10}^{[(T1-TRT)/10]}$

Accelerate time(week): $TIME_{TI}$

Accelerate temperature(°C): T1=45

Storage temperature(°C): $T_{RT}=30$

Reaction rate coefficient: Q10=3

Therefore, $TIME_{TI}=52/3^{1.5}=10$ weeks=70 days. The test data on 74 days still meet acceptance criteria. The shelf-life of this test kit is 12 months (52 weeks) under 4~30°C.

Sincerely,

Carlly zhao.

Quality Assurance Manager

SARS-CoV-2 Antibody Test Strip
(Colloidal Gold Method)
Strip Stability Test Report

Document No.: NPI041-SR-004

1. Purpose

This report is intended to evaluate the real-time stability, accelerate stability, open bag stability of test strip and open bottle stability of sample diluent of SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method).

2. Reference

（1）《胶体金免疫层析法检测试剂盒（征求意见稿）》;

（2）《病原体特异性 M 型免疫球蛋白定性检测试剂注册技术审查指导原则》；

（3） 《2019 新型冠状病毒抗原/抗体检测试剂注册技术审评要点（试行）》;

（4）新型冠状病毒（SARS-CoV-2）抗体检测试剂盒（胶体金法）产品技术要求。

（5）医疗器械加速老化实验确定有效期的基本原理和方法。《中国医疗器械信息》2008 年第 14 卷第 5 期 Vol.14 No.5.

3. Material

Table 1：Material List

Product	Spec.	Lot	Manufacturer	Note
SARS-CoV-2 Antibody Test Strip (Colloidal Gold Method)	25 strips/box	20200218 20200219 20200220	Sinocare Inc.	Strips to be tested.

4. Acceptance Criteria

4.1 Appearance

Out package should be completed without any damaged. Labelling should be clear. Test Strip should be clean, complete, without any damage or contamination. Sample dilution should be transparent liquid, without any floccule or sediment.

4.2 Strip width

Strip width should be no less than 2.5mm.

4.3 Liquid migration velocity

Liquid migration velocity should be no less than 10mm/min.

4.4 Detection Limit

Use manufacturer's reference perform test. Results of L01, L02 reference should be negative. Results of L05, L06 reference should be positive. Results of L03, L04 reference can either negative or positive.

4.5 Negative reference consistency rate

Use manufacturer's negative reference perform test. All test results should be negative. Negative consistency rate is (-/-)10/10.

4.6 Positive reference consistency rate

Use manufacturer's positive reference perform test. All test results should be positive. Positive consistency rate is (+/+)5/5.

4.7 Repeatability

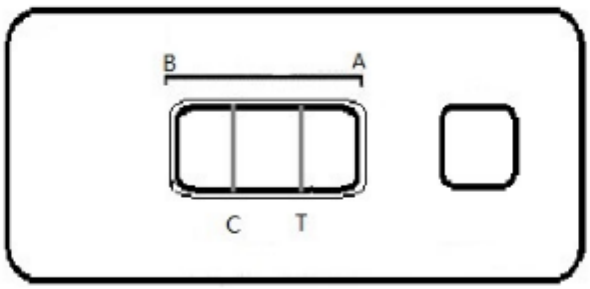
Use manufacturer's negative reference R01 and manufacturer's weakly positive reference R02 test 20 times respectively. Negative consistency range and positive consistency rate should be no less than 95%.

5. Test Method

5.1. Appearance: Random take out 3 test strips. Visual observe strip under nature light.

5.2. Strip width: Random take out 3 test strips. Use vernier caliper measure strip width for each strip.

5.3. Liquid moving velocity: Use dropper add N01 negative reference into sampling area. Then add 2 drops sample diluent into sampling area. Start timing when liquid reaches to A line and stop timing when the liquid reaches to B line. Mark time as t. Use vernier caliper measure length from A to B, mark as L. Moving velocity is L/t.



5.4. Detection Limit: Use strip test 6 manufacturer references (L01~L06). Each reference test 1 time.

5.5. Negative consistency rate: Use strip test 10 negative manufacturer references (N01~N10). Each reference test 1 time.

5.6. Positive consistency rate: Use strip test 5 positive manufacturer references

(P01~P10). Each reference test 1 time.

5.7. Repeatability: Use same lot strip replicate test negative manufacturer reference R01 20 times and weakly positive manufacturer reference R02 20 times.

6. Test Progress

6.1 Accelerate Stability

Put strip under 45℃ ± 2℃. Perform test refer to below test time point.

Storage	0d	7d	8d	14d	21d	28d	30d	37d	44d	51d	58d	62d	70d	74d
45 ± 2 ℃	√	√	√	√	√	√	√	√	√	√	√	√	√	√

6.2 Real-time Stability

Use 3 lot strip perform test refer to below test time point.

Storage(months)	0	1	2	4	6	8	10	11	12	13
2-8 ℃	√	√	√	√	√	√	√	√	√	√
28~32℃ (RH90 ± 5%)	√	√	√	√	√	√	√	√	√	√

Test refer to 5.1~5.7 when storage 0 month and 13 months.

Test refer to 5.4~5.6 when storage 1 months to 12 months.

6.3 Open Bag Stability of Test Strip

Because high temperature and high humidity will affect strip performance, this evaluation is focus on these two aspects. Choose 3 lots test strips. Take out sample dilute, open and close cap immediately, stored at 4~30℃.Take out strips from foil pouch, then put the strips at different temperature/humidity condition for 0min、10min、20min、 30min. Test appearance, strip width, liquid moving velocity, detection limit, negative consistency rage, positive consistency rate and repeatability.

Environment condition are as below:

(1) RH 50 ± 5%, 25±2℃;

(2) RH 50±5%, 40±2℃;

(3) RH 90%±5%, 25±2℃

6.3 Open Bottle Stability of Sample Diluent

Choose 3 lots test kit. Take 2 bottles diluent from each lot. One is store at 2-8℃, the other is stored at 28-32℃. Perform test according to 5.4 (diluent should be matched

with test strip) according to test point: day 0, 4, 7, 14, 21, 28, 30. Equilibrate diluent to room temperature and mix well 3 times before each test. Re-capped diluent immediately after test and store at 2-8 ℃ and 28-32 ℃ . Test results should meet requirement in 4.4.

7. Test Result

Table 2-Accelrate Stability Test Result

Storage		45℃ 0 day			45℃ 7 days			45℃ 8 days		
Lot		20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
Appearance		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip Width (mm)		3.02	3.02	3.02	3.00	3.02	3.00	3.02	3.02	3.04
		3.02	3.02	3.02	3.00	3.00	3.02	3.00	3.02	3.02
		3.04	3.02	3.02	3.02	3.02	3.02	3.02	3.02	3.00
Liquid migration velocity (mm/min)		19.6	20.3	19.8	19.5	20.0	19.5	19.4	20.1	19.9
Detection Limit	L01	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)

Storage		45℃ 14 day			45℃ 21 days			45℃ 28 days		
Lot		20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
Appearance		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip Width (mm)		3.00	3.02	3.00	3.02	3.02	3.00	3.02	3.02	3.02
		3.02	3.00	3.02	3.00	3.02	3.02	3.00	3.02	3.02
		3.00	3.02	3.02	3.00	3.02	3.00	3.02	3.00	3.00
Liquid migration velocity (mm/min)		18.9	19.1	19.9	18.8	19.3	19.6	19.1	18.4	18.8
Detection Limit	L01	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)
Storage		45℃ 30 day			45℃ 37 days			45℃ 44 days		
Lot		20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
Appearance		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip Width (mm)		3.02	3.02	3.02	3.04	3.02	3.02	3.02	3.00	3.02
		3.04	3.00	3.02	3.00	3.02	3.00	3.00	3.02	3.02
		3.00	3.02	3.02	3.02	3.02	3.00	3.04	3.00	3.02
Liquid migration velocity (mm/min)		18.7	19.3	19.1	18.6	19.0	19.4	19.0	18.6	18.9

Detection Limit	L01	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)
Storage		45℃ 51 day			45℃ 58 days			45℃ 62 days		
Lot		20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
Appearance		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip Width (mm)		3.00	3.02	3.04	3.00	3.02	3.00	3.02	3.02	3.02
		3.02	3.00	3.00	3.00	3.00	3.00	3.02	3.02	3.00
		3.02	3.02	3.04	3.02	3.04	3.00	3.02	3.00	3.00
Liquid migration velocity (mm/min)		18.9	19.1	19.5	18.3	18.7	19.1	19.2	18.7	18.1
Detection Limit	L01	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+	+	+
Negative Reference Consistency	N01	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-

Rate	N04	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)
Storage		45℃ 64 day			45℃ 70 days			45℃ 74 days		
Lot		20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
Appearance		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip Width (mm)		3.02	3.02	3.00	3.00	3.02	3.02	3.00	3.00	3.00
		3.02	3.02	3.00	3.00	3.00	2.98	3.02	3.00	3.00
		3.02	3.02	3.02	3.00	3.02	3.00	2.98	3.00	3.00
Liquid migration velocity (mm/min)		18.5	19.4	19.0	18.4	19.1	18.8	18.8	19.4	19.0
Detection Limit	L01	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-
Positive	P01	+	+	+	+	+	+	+	+	+

Reference Consistency Rate	P02	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)

Note: Take example as 100% (20/20-), 100% means positive rate, "20/20-" means 20 test results are negative in 20 tests.

Table 3-Real-Time Stability Detection Limit Test Result (1~12 months)

2~8℃									
Months	1			2			4		
Lot	20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
L01	-	-	-	-	-	-			
L02	-	-	-	-	-	-			
L03	-	-	-	-	-	-			
L04	+	+	+	+	+	+			
L05	+	+	+	+	+	+			
L06	+	+	+	+	+	+			
Months	6			8			10		
Lot	20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
L01									
L02									
L03									
L04									
L05									
L06									
Months	11			12					
Lot	20200218	20200219	20200220	20200218	20200219	20200220			
L01									
L02									
L03									
L04									
L05									
L06									

Table 4-Real-Time Stability Detection Limit Test Result (1~12 months)

28~32℃									
Months	1			2			4		
Lot	20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
L01	-	-	-	-	-	-			
L02	-	-	-	-	-	-			
L03	-	-	-	-	-	-			
L04	+	+	+	+	+	+			
L05	+	+	+	+	+	+			
L06	+	+	+	+	+	+			
Months	6			8			10		
Lot	20200218	20200219	20200220	20200218	20200219	20200220	20200218	20200219	20200220
L01									
L02									
L03									
L04									
L05									
L06									
Months	11			12					
Lot	20200218	20200219	20200220	20200218	20200219	20200220			
L01									
L02									
L03									
L04									
L05									
L06									

Table 5 – Real-Time Stability Test Result (1~12 months)

2~8℃								
Lot		20200218	20200219	20200220	Lot	20200218	20200219	20200220
Months	1				2			
Negative Reference Consistency Rate	N01	-	-	-	N01	-	-	-
	N02	-	-	-	N02	-	-	-
	N03	-	-	-	N03	-	-	-
	N04	-	-	-	N04	-	-	-
	N05	-	-	-	N05	-	-	-
	N06	-	-	-	N06	-	-	-
	N07	-	-	-	N07	-	-	-
	N08	-	-	-	N08	-	-	-
	N09	-	-	-	N09	-	-	-

	N10	-	-	-	N10	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	P01	+	+	+
	P02	+	+	+	P02	+	+	+
	P03	+	+	+	P03	+	+	+
	P04	+	+	+	P04	+	+	+
	P05	+	+	+	P05	+	+	+

Table 6 – Real-Time Stability Test Result (1~12 months)

28~32℃								
Lot		20200218	20200219	20200220	Lot	20200218	20200219	20200220
Months		1			2			
Negative Reference Consistency Rate	N01	-	-	-	N01	-	-	-
	N02	-	-	-	N02	-	-	-
	N03	-	-	-	N03	-	-	-
	N04	-	-	-	N04	-	-	-
	N05	-	-	-	N05	-	-	-
	N06	-	-	-	N06	-	-	-
	N07	-	-	-	N07	-	-	-
	N08	-	-	-	N08	-	-	-
	N09	-	-	-	N09	-	-	-
	N10	-	-	-	N10	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	P01	+	+	+
	P02	+	+	+	P02	+	+	+
	P03	+	+	+	P03	+	+	+
	P04	+	+	+	P04	+	+	+
	P05	+	+	+	P05	+	+	+

Table 7-Open Bag Stability Test Result

20200218												
Environment		25℃，RH50%				40℃，RH50%				25℃，RH90%			
Time		0min	10min	20min	30min	0min	10min	20min	30min	0min	10min	20min	30min
Appearance		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip width (mm)		3.00	3.02	3.00	3.00	3.02	3.00	3.02	3.00	3.00	3.02	3.00	3.02
		3.02	3.04	3.00	3.00	3.02	3.02	3.00	3.02	3.02	3.00	3.02	3.02
		3.02	3.02	3.00	3.02	3.02	3.00	3.02	3.00	3.02	3.04	3.02	3.02
Liquid migration velocity (mm/min)		19.6	20.1	19.5	19.9	18.9	18.7	19.0	18.8	19.2	18.9	19.3	19.2
Detection Limit	L01	-	-	-	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	+	-	+	-	+	+

	L04	+	-	+	-	+	-	+	-	-	+	-	-
	L05	+	+	+	+	+	+	+	+	+	+	+	-
	L06	+	+	+	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+	+	+	-
	P04	+	+	+	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	18/20 (+)

20200219												
Environment	25℃，RH50%				40℃，RH50%				25℃，RH90%			
Time	0min	10min	20min	Time	0min	10min	20min	Time	0min	10min	20min	Time
Appearance	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip width (mm)	3.00	3.00	3.02	3.00	3.00	3.02	3.02	3.00	3.02	3.02	3.00	3.00
	3.00	3.00	3.02	3.00	3.02	3.00	3.02	3.02	3.00	3.00	3.00	3.00
	3.02	3.04	3.02	3.02	3.02	3.00	3.00	3.00	3.02	3.00	3.04	3.02
Liquid moving velocity (mm/min)	19.2	19.9	19.6	19.8	18.8	18.5	19.2	18.9	19.1	18.7	19.2	19.0
Detection Limit	L01	-	-	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-	-	-
	L03	+	-	-	-	+	-	-	-	-	-	-
	L04	+	+	+	-	-	+	+	-	+	+	+	-
	L05	+	+	+	+	+	+	+	+	+	+	+	-
	L06	+	+	+	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-	-	-	-

	N06	-	-	-	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+	+	+	-
	P05	+	+	+	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	19/20 (+)
20200220													
Environment		25℃，RH50%				40℃，RH50%				25℃，RH90%			
Time		0min	10min	20min	Time	0min	10min	20min	Time	0min	10min	20min	Time
Appearance		Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Strip width (mm)		3.02	3.00	3.00	3.00	3.02	3.02	3.02	3.00	3.00	3.02	3.02	3.00
		3.02	3.02	3.02	3.02	3.02	3.02	3.00	3.00	3.02	3.02	3.00	3.02
		3.00	3.02	3.02	3.00	3.02	3.00	3.02	3.00	3.02	3.02	3.00	3.02
Liquid moving velocity (mm/min)		19.5	19.7	20.1	19.5	19.2	18.9	19.1	18.7	19.0	19.2	19.0	19.3
Detection Limit	L01	-	-	-	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	+	-	-	-	-	-	+
	L04	+	+	+	+	+	-	+	+	+	+	+	-
	L05	+	+	+	+	+	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-	-	-	-
Positive Reference Consistency	P01	+	+	+	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+	+	+	+

Rate	P04	+	+	+	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)	20/20 (-)
	R02	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)	20/20 (+)

Note: Take example as 100% (20/20-) , 100% means positive rate, "20/20-" means 20 test results are negative in 20 tests.

Table 9 – Open Bottle Stability Test Result for Sample Diluent

/	2-8℃							
	Day	0d	4d	7d	14d	21d	28d	30d
20200218	L01	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+
20200219	L01	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+
20200220	L01	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+
/	28~32℃							
	Day	0d	4d	7d	14d	21d	28d	30d
20200218	L01	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+
20200219	L01	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+

	L05	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+
20200220	L01	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	-
	L04	+	+	+	+	+	+	+
	L05	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+

8. Conclusion

8.1 Accelerate Stability:

According to Arrehenius 10 degree principle, use 45℃ accelerate stability test data to calculate shelf life of this test strip (intended shelf-life is 12 months)

$$TIME_{TI}=TIME_{RT}/Q_{10}^{[(T1-TRT)/10]}$$

Accelerate time (week) : $TIME_{TI}$

Accelerate temperature (℃) : T1=45

Storage temperature (℃) : T_{RT}=30

Reaction rate coefficient: Q10=3

Therefore, $TIME_{TI}=52/3^{1.5}=10$ weeks=70 days. The test data on 74 days still meet acceptance criteria. The shelf-life of this test kit is 12 months (52 weeks) under 4~30℃.

8.2 Real-time Stability: Test is on-going. Data will be updated.

8.3 Open bag Stability for Test Strip: After open the foil bag, SARS-CoV-2 antibody test strip meet requirements after opened within 20 minutes. But test results will fail after opened 30 minutes. Therefore, the open bag stability is defined as 10 minutes.

8.4 Open bottle stability for Sample Diluent: Test results until day 30 meet acceptance criteria. Considering risk during use, the open bottle shelf life is defined as 28 days.