Stability Study Report

1. Purpose:

To investigate stability of the device, accelerate stability, shelf life determination and transport simulation are performed.

2. Material and Methods

2.1 Material

(1) Test kit

Kit Name: Safecare COVID-19 Antigen Rapid Test Kit(Swab)

Lots used: COV20081001，COV20081002, COV20081003

(2) Test Reagents

Negative control: Extraction buffer

Positive control: Recombinant COVID-19 Antigen (500pg/ml，1ng/ml)

2.2 Methods

Sensitivity and Specificity will be evaluated during the stability tests.

Samples Conc.	Concentration
Sensitivity(Positive Control)	500pg/ml
	1ng/ml
Specificity(Negative control) (n=3)	/

2.2.1 Accelerate Stability Test

For accelerate stability test, three lots devices are set in 55℃ incubator. The performance is evaluated at 0, 7, 14, 21, 28, 35days.

2.2.2 Shelf Life Tests

To determine shelf life of the cup, panel and cassette devices, three lots of each device are stored at 2-8℃ and 30±3℃. The performance is determined at 1,3,6,9,12,15,18,21,24,27months.

2.2.3 Transport Simulation

The extreme shipping temperatures were simulated by storing device at –20℃ and 40℃. Three lots each of cup, panel and cassette were stored at –20℃ and 40℃. The performance is tested at 1st, 7th, 14th, 21st, 24th, 28th, 31st and 35th days.

3. Results

3.1 Accelerate Stability Studies

The study is performed by three lab technicians for each lot.

Table 1 : Results for the device stored at 55℃

LOT	Sample	Days					
		0	7	14	21	28	35
LOT1	500pg/ml	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+
	Negative	-	-	-	-	-	-
LOT2	500pg/ml	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+
	Negative	-	-	-	-	-	-
LOT3	500pg/ml	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+
	Negative	-	-	-	-	-	-

3.2 Shelf Life Tests

The study is performed by QC for each format.

Table 2   Shelf Stability data stored at 2-8℃

LOT	Sample	Months									
		1	3	6	9	12	15	18	21	24	27
LOT1	500pg/ml	+									
	1ng/ml	+									
	Negative	-									
LOT2	500pg/ml	+									
	1ng/ml	+									
	Negative	-									
LOT3	500pg/ml	+									
	1ng/ml	+									
	Negative	-									

Table 3 Shelf Stability data stored at 30±3℃

LOT	Sample	Months									
		1	3	6	9	12	15	18	21	24	27

LOT			
LOT1	500pg/ml	+	
	1ng/ml	+	
	Negative	-	
LOT2	500pg/ml	+	
	1ng/ml	+	
	Negative	-	
LOT3	500pg/ml	+	
	1ng/ml	+	
	Negative	-	

3.3 Transport Simulation

The study is performed by three lab technicians for each lot.

The data is followed in Table 4&5.

Table 4 Transport Simulation data stored at -20℃

LOT	Sample	Days							
		1	7	14	21	24	28	31	35
LOT1	500pg/ml	+	+	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+	+	+
	Negative	-	-	-	-	-	-	-	-
LOT2	500pg/ml	+	+	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+	+	+
	Negative	-	-	-	-	-	-	-	-
LOT3	500pg/ml	+	+	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+	+	+
	Negative	-	-	-	-	-	-	-	-

Table 5 Transport Simulation data stored at 40℃

LOT	Sample	Days							
		1	7	14	21	24	28	31	35
LOT1	500pg/ml	+	+	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+	+	+
	Negative	-	-	-	-	-	-	-	-
LOT2	500pg/ml	+	+	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+	+	+
	Negative	-	-	-	-	-	-	-	-
LOT3	500pg/ml	+	+	+	+	+	+	+	+
	1ng/ml	+	+	+	+	+	+	+	+

4. Conclusion:

In the accelerated stability study, the COVID-19 Antigen Rapid Test is stable at 55℃ for 35 days. According to the principle of Arrhenius, the test-strip's stable shelf life is at least 24 months. The shelf life would be updated when the study is going on. It should be finished by the year 2022, August.