COVID-19 Self-Test Kit

Transport and Accelerated Aging Stability Report

1. Purpose

This study is intended to verify validate the real-time stability of COVID-19 Self-Test kit in order to make sure that it meets the requirements of clinical testing.

Moreover, transport simulation was carried out before accelerated aging, thus the results demonstrate transport stability as well.

2. Scope

This study is applicable to COVID-19 Self-Test kit.

3. Referenced documents

Tab 1. Referenced documents

S.N.	Document No.	Document name
1	/	Antigen Template for Manufacturers
2	/	Technical review guidance for analytical performance evaluation of IVD reagents
3	ASTM D4169-16	ASTM D4169-16: Standard practice for performance testing of shipping containers and systems
4	CLSI EP25	EP25-A Evaluation of Stability of in Vitro Diagnostic Reagents

4. Personnel and Responsibility

Tab 2. Personnel and Responsibility

Title	Name	Educational background	Responsibility
[redacted]	[redacted]	[redacted]	Approving Accelerated Aging Stability Report.
[redacted]	[redacted]	[redacted]	Reviewing Accelerated Aging Stability Report.
[redacted]	[redacted]	[redacted]	Evaluating Accelerated Aging Stability Study Process.
			Participating In Reviewing Testing Results.
	[redacted]	[redacted]	Performing Accelerated Aging tability Study.

[redacted]			Recording, Analyzing Testing Results.
			Compiling Accelerated Aging Stability Report.

5. Acceptance criteria

Tab 3. Acceptance criteria

S.N.	Test item		Acceptance criteria
1	Physical examination	Appearance	Complete and free of liquid leakage
		Liquid velocity	≥10mm/min
2	Accuracy(positive coincidence)		While testing new buffers of 5 replicates using each positive controls respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 15/15, +/ +.
	Accuracy (negative coincidence)		While testing new buffers of 5 replicates using each negative controls respectively, number of invalid results (Ri) should be 0 and percentage of negative results (Rp%) should be 15/15, -/ -..
4	Repeatability	Intra-Lot Precision	While testing new buffers of 10 replicates using each positive controls respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 10/10, +/ +. While testing new buffers of 10 replicates using each negative controls respectively, number of invalid results (Ri) should be 0 and percentage of negative results (Rp%) should be 10/10, -/ -., 10/10, -/ -.
		Inter-Lot Precision	While testing new buffers of 10 replicates using each positive controls respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be30/30, +/ +. While testing new buffers of 10 replicates using each negative controls respectively, number of invalid results (Ri) should be 0 and percentage of negative results (Rp%) should be 30/30, -/ -., 30/30, -/ -.

6. Material and Equipment

Tab 4. Used equipment, instrument and material

No.	**Equipment/Device/Material Name**	**Batch No.**	**Code**
1	COVID-19 Self-Test kit	X200816-1	P1
2	COVID-19 Self-Test kit	X200816-2	P2
3	COVID-19 Self-Test kit	X200816-3	P3
4	Oven	SC-SB-365	/
5	Refrigerator（-40~0℃）	SC-SB-104	/
6	Programmable Constant Temperature/Humidity Incubator	ZJ-SB-139	/
7	Sealing Tester with Vacuum	ZJ-SB-140	/
8	Temperature and Humidity Data Logger	SC-SB-478 SC-SB-479 SC-SB-480 SC-SB-481 SC-SB-482	/
9	Positive control	FDS01	/
10	Negative control	FDN01	/

7. Method

7.1 The design of Analysis of stimated real time (t_e)

(1) COVID-19 Self-Test kit from three continuous lots were subjected to transport simulation by vibrating at 45℃ for 7 days, and then stored at 45℃,55℃ and 65℃ respectively afterwards for accelerated aging.

Note: the detail information of the transport simulation as per the ***real-time study***.

(2) Test all performance items listed in table 3 after storing for 0, 14, 28, 42, 56, 70 and 84days under each accelerated aging temperature respectively. Record the accelerated aging time duration(AATD) by which all results meet the acceptance criteria for each performance items.

(3) Find out the shortest accelerated aging time duration (AATD) under each accelerated aging temperature by which acceptance criteria were met for all stability performance items.

(4) Check if the AATD of 45℃ is 70 days. If it is 84 day, move to the next step. Otherwise jump to step (7) and use the AATD of 45 ℃ to calculate estimated real time (t_e).

(5) Check if the AATD of 55℃ is 70 days. If it is 84 day, move to the next step. Otherwise jump to step (7) and use the AATD of 55 ℃ to calculate estimated real time (t_e).

(6) Use the AATD of 65 ℃ to calculate estimated real time (t_e).

(7) Calculate the estimated real time (t_e)of stability according to Arrhenius reaction rate theory with formula (1) and (2) below:

t_e=AATD*AAR (1)

t_e: Estimated real time

AATD: Accelerated aging time duration

AAR: Accelerated aging rate

$AAR=Q10^{((Te-Ta)/10)}$ (2)

Ta: Ambient temperature

Te: Elevated temperature

Q10:Reaction Rate

Note 1: Q10 =2 is the most commonly used according to Arrhenius reaction rate theory and was what we used in our study.

Note 2: Since the shelf life storage temperature of SARS-CoV-2 antigen Rapid Qualitative Test is 2~30 ℃, we used 30℃of the upper limit range as **estimating ambient temperatur**e (Ta)

(8) Check if the estimated real time (t_e) is no less than 730 days (24 months)

7. 2 Physical examination

(1) Visually inspect the appearance of the reagents, if the appearance was smooth; and if materials were attached firmly; an if contents of the reagent kit were complete and there was no liquid leakage, the results record as "Yes", otherwise the result was record as "No".

(2) Randomly test 2 cartridges from each lot with detection buffer. Measure the distance (L) from "S" well to the end of chromatography window. Measure time (t) spend from drip detection buffer into "S" well to liquid reaches the end of chromatography window. Then calculate average liquid velocity(v) of each lot using formulas below: v=(L1/t1+L2/t2)/2.

(3) Record the up-mentioned results as **Physical Examination.**

7.3 Analytical performance

(1) The study was performed testing 3 lot devices of 5 replicates using controls respectively. At each test, 75 µL extraction solutions were controls and then tested as per IFU.

(2) Record the results of T lines and C lines respectively.

(3) Positive signals are recorded as "+" and negative signals are recorded as "-" .

Note:

For positive signals: F indicates a faint line and M indicates a moderate or strong line

(4) Check if there were "-" for C line, which indicates invalid test results (Ri). Count and record the total number of Ri.

(5) For results which are not invalid, check the "+" for T line of each test. If a "+" is observed on T line of a test, this test should be regard as a positive result (Rp), If a "-" is observed on T line of a test, this test should be regard as a negative result (Rn).

6) While testing the positive controls, calculate the percentage of positive results (Rp) of testing each controls versus the test number of Rt with following formula: Rp/ Rt, +/ +. Record the calculating result as the **Positive Confidence.**

(7) While testing the negative controls, calculate the percentage of negative results (Rn) versus the total test number (Rt) with following formula: Rn/Rt, -/-. Record the calculating result as the **Negative Confidence.**

(8) Visually inspect the signal intensities of each line of each test and compare results of tests for each control. Record "Y" if a signal intensity is obviously different from same lines of other tests of same controls of all lots. Record "N" if a signal intensity is not obviously different from same lines of other tests of same contrived controls of all lots. Record "N/A" if a line show no signal.

(9) Count the number of "Y" for each lot for the same controls, and summarize the number of Y for all lots.

(10) Record the calculating result in (8) and (9) as the **Repeatability.**

7.4 The determination of the result.

Record the longest accelerated time of the kits by which all test results meet the performance acceptance criteria and chose the previous accelerated time to the longest time as the acceptance of the accelerated aging time of the kits.

8. **Testing schedule**

Tab 5. Test Schedule

S.N.	Verified item	Start time	Completion time
1	Day0 testing	2020.08.16	2020.08.17
2	Day14 testing	2020.09.01	2020.09.02
3	Day28 testing	2020.09.16	2020.09.17
4	Day42 testing	2020.10.01	2020.10.02
5	Day56 testing	2020.10.16	2020.10.17
6	Day70 testing	2020.10.31	2020.11.01
7	Day84 testing	2020.11.15	2020.11.16
8	Final report	2020.11.18	2020.11.21

9. Results

9.1 The result of appearances

Tab1.Test result of appearances

	LOT	Day 0	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84
45℃	P1	YES	YES	YES	YES	YES	YES	YES
	P2	YES	YES	YES	YES	YES	YES	YES
	P3	YES	YES	YES	YES	YES	YES	YES
55℃	P1	YES	YES	YES	YES	YES	YES	YES
	P2	YES	YES	YES	YES	YES	YES	YES
	P3	YES	YES	YES	YES	YES	YES	YES
65℃	P1	YES	YES	YES	YES	YES	YES	YES
	P2	YES	YES	YES	YES	YES	YES	YES
	P3	YES	YES	YES	YES	YES	YES	YES

9.2 The result of packing

Tab2.Test result of packing

	LOT	Day 0	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84
45℃	P1	YES	YES	YES	YES	YES	YES	YES
	P2	YES	YES	YES	YES	YES	YES	YES
	P3	YES	YES	YES	YES	YES	YES	YES
55℃	P1	YES	YES	YES	YES	YES	YES	YES
	P2	YES	YES	YES	YES	YES	YES	YES
	P3	YES	YES	YES	YES	YES	YES	YES
65℃	P1	YES	YES	YES	YES	YES	YES	YES
	P2	YES	YES	YES	YES	YES	YES	YES
	P3	YES	YES	YES	YES	YES	YES	YES

9.3 The result of liquid leakage

Tab3. Test result of liquid leakage

	LOT	Day 0	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84
45℃	P1	No	No	No	No	No	No	No
	P2	No	No	No	No	No	No	No
	P3	No	No	No	No	No	No	No
55℃	P1	No	No	No	No	No	No	No
	P2	No	No	No	No	No	No	No

	P3	No	No	No	No	No	No	No
65℃	P1	No	No	No	No	No	No	No
	P2	No	No	No	No	No	No	No
	P3	No	No	No	No	No	No	No

9.4 The result of precipitate

Tab4. Test result of precipitate

	LOT	Day 0	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84
45℃	P1	No	No	No	No	No	No	No
	P2	No	No	No	No	No	No	No
	P3	No	No	No	No	No	No	No
55℃	P1	No	No	No	No	No	No	No
	P2	No	No	No	No	No	No	No
	P3	No	No	No	No	No	No	No
65℃	P1	No	No	No	No	No	No	No
	P2	No	No	No	No	No	No	No
	P3	No	No	No	No	No	No	No

As illustrated in the above table, after storing for 37 days at 45℃, 55℃ and 65℃ respectively, all results meet the requirement of acceptance criteria.

The accelerated aging time duration(AATD) for physical examination performance under each accelerated aging temperature is:

Tab5.accelerated aging temperature

Accelerated aging temperature	AATD of liquid velocity
45℃	84 days
55℃	84days
65℃	70 days

9.5 Physical examination (liquid velocity)

Tab5.Test result of Liquid velocity

	LOT	Day 0	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84
45℃	P1	21.23	21.79	20.76	20.68	19.50	18.98	18.32
	P2	21.97	20.28	19.80	18.23	18.87	19.86	20.58
	P3	19.70	21.35	21.93	19.91	20.48	20.46	19.20
55℃	P1	20.82	18.98	18.11	21.21	20.99	19.10	19.20
	P2	19.63	19.40	18.88	21.89	20.70	18.26	20.71
	P3	19.86	18.03	20.44	21.62	20.07	18.25	19.82

65℃	P1	20.54	21.44	21.84	21.48	21.47	19.54	18.98
	P2	19.66	20.46	19.35	20.40	20.94	21.99	19.21
	P3	20.06	20.23	21.72	18.06	18.23	21.57	19.85

As illustrated in the above table, liquid velocities were no less than 10mm/min after storing for 37 days at 45℃, 55℃ and 65℃ respectively. All results meet the requirement of acceptance criteria.

The accelerated aging time duration(AATD) for physical examination(liquid velocity) performance under each accelerated aging temperature is:

Tab8.The accelerated aging temperature

Accelerated aging temperature	AATD of liquid velocity
45℃	84 days
55℃	84days
65℃	84days

9.2 Accuracy (coincidence)

Tab9. Test result of coincidence (45℃)

45℃	ID	Lines	P1					P2					P3				
			Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
0Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
14Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
28Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
42Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
56Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

70Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
84Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Tab7. Test result of coincidence(55℃)

55℃	ID	Lines	P1					P2					P3				
			Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
0Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
14Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
28Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
42Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
56Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
70Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
84Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Tab8. Test result of coincidence(65℃)

65℃	ID	Lines	P1					P2					P3				
			Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
0Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
14Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
28Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
42Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
56Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
70Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
84Day	FDS01	T	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	FDN01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
		C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

As illustrated in the above table, test results of each positive controls are all are valid (Ri=0) and positive (Rp%=100%) after aging for 84 days under 45 ℃ and 55 ℃, and under 65 ℃.

The accelerated aging time duration(AATD) for accuracy(positive coincidence) performance under each accelerated aging temperature is:

Tab12.accelerated aging temperature

Accelerated aging temperature	AATD of accuracy(positive coincidence)
45℃	84 days

55℃	84 days
65℃	84days

As illustrated in the above table, test results of each negative controls are all are valid (Ri=0) and negative (Rn%=100%) after aging for 84 days under 45 ℃ and 55 ℃, and under 65 ℃.

The accelerated aging time duration(AATD) for accuracy(negative coincidence) performance under each accelerated aging temperature is:

Tab16.accelerated aging temperature

Accelerated aging temperature	AATD of accuracy(negative coincidence)
45℃	84 days
55℃	84 days
65℃	84 days

9.4 Repeatability

(1) **Testing results of repeatability 0day:**

Tab21. Testing results of repeatability (45℃)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC01	1	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	2	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	3	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	4	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	5	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	6	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	7	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	8	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	9	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	10	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC01	1	-	+(M)	-	+(M)	-	+(M)
	2	-	+(M)	-	+(M)	-	+(M)
	3	-	+(M)	-	+(M)	-	+(M)
	4	-	+(M)	-	+(M)	-	+(M)
	5	-	+(M)	-	+(M)	-	+(M)
	6	-	+(M)	-	+(M)	-	+(M)
	7	-	+(M)	-	+(M)	-	+(M)
	8	-	+(M)	-	+(M)	-	+(M)
	9	-	+(M)	-	+(M)	-	+(M)
	10	-	+(M)	-	+(M)	-	+(M)

Tab22. Testing results of repeatability (55℃)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC01	1	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	2	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	3	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	4	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	5	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	6	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	7	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	8	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	9	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	10	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC01	1	-	+(M)	-	+(M)	-	+(M)
	2	-	+(M)	-	+(M)	-	+(M)
	3	-	+(M)	-	+(M)	-	+(M)
	4	-	+(M)	-	+(M)	-	+(M)
	5	-	+(M)	-	+(M)	-	+(M)
	6	-	+(M)	-	+(M)	-	+(M)
	7	-	+(M)	-	+(M)	-	+(M)
	8	-	+(M)	-	+(M)	-	+(M)
	9	-	+(M)	-	+(M)	-	+(M)
	10	-	+(M)	-	+(M)	-	+(M)

Tab23. Testing results of repeatability (65℃)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC01	1	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	2	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	3	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	4	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	5	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	6	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	7	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	8	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	9	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	10	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC01	1	-	+(M)	-	+(M)	-	+(M)
	2	-	+(M)	-	+(M)	-	+(M)
	3	-	+(M)	-	+(M)	-	+(M)

	4	-	+(M)	-	+(M)	-	+(M)
	5	-	+(M)	-	+(M)	-	+(M)
	6	-	+(M)	-	+(M)	-	+(M)
	7	-	+(M)	-	+(M)	-	+(M)
	8	-	+(M)	-	+(M)	-	+(M)
	9	-	+(M)	-	+(M)	-	+(M)
	10	-	+(M)	-	+(M)	-	+(M)

As illustrated in the above tables, test results for positive controls are all valid(Ri=0) and positive and test results for negative controls are all valid (Ri=0) and negative for each lot after aging for 84 days at 45℃ and 55 ℃, and at 65℃. No obvious difference in signal intensities(Y=0) of T and C lines respectively between all test for each controls each lot after aging for 84 days at 45℃ and 55 ℃, and at 65℃.

The accelerated aging time duration(AATD) for intra-lot repeatability under each accelerated aging temperature is:

Tab27.accelerated aging temperature

Accelerated aging temperature	AATD of intra-lot repeatability
45℃	84 days
55℃	84 days
65℃	84 days

9.5 Analysis of estimated AATD

Tab38.Analysis of estimated aging time

Series	Performance items		AATD of 45℃	AATD of 55℃	AATD of 65℃
1	Physical examination	Liquid velocity	84days	84 days	84 days
2	Accuracy(positive coincidence)		84 days	84 days	84 days
	Accuracy (negative coincidence)		84days	84days	84 days
3	Repeatability	Intra-Lot Precision	84days	84days	84days
		Inter-Lot Precision	84 days	84 days	84 days

Since the AATD of all performance items is 84 days for accelerated aging test under both 45℃ and 55℃. We used the AATD of accelerated aging under 65℃ to calculate the estimated real time (t_e), as well as the accelerated aging temperature is 65℃ (Te=65℃), and the ambient temperature of COVID-19 Self-Test kit is 30℃ (Ta=30℃) and Q10 is set to 2.

Based on the longest accelerated aging time duration is 84 days. As per the requirements of *the Antigen Template For Manufacture*, the acceptance accelerated aging time duration of 70 days was chosen as the acceptance accelerated aging time(ATTM).

The estimated real time (t_e) of COVID-19 Self-Test kit is be calculated as following:

$AAR=Q10^{((Te-Ta)/10)}=2^{((65-30)/10)}=11.3$

t_e=AATD*AAR=70*11.3=791.6 days > 730days(24 months)

10 **Conclusion**

Three lots of COVID-19 Self-Test kit were subjected to transport simulation and accelerated aging. After transport simulation, the estimated real time (t_e) of stability study is 791.6 days, which is no less than the claimed shelf life (24 months) of COVID-19 Self-Test kit. The results meet the acceptance criteria of transport and accelerated aging stability study.