New buffer Stability Research Report

1. Sample preparation

1.1Material

positive control FDS01, negative control FDNO1 , 3 Lot of new extraction solution

2. Results

2.1 Physical examination

2.1.1 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

2.1.2 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

2.1.3 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

2.1.4 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

2.2 Accuracy(coincidence)

Tab6. 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 tables, test results for positive controls are all valid(Ri=0) and positive and test results for negative samples are all valid (Ri=0) and negative for each lot after aging for 84 days at 45℃ and 55 ℃, and for 70days at 65℃. No obvious difference in signal intensities(Y=0) of T and C lines respectively between all test for each control each lot after aging for 84 days at 45℃ and 55 ℃, and for 70 days at 65℃.

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

Tab9.accelerated aging temperature

Accelerated aging temperature	AATD of intra-lot repeatablity
45℃	84 days
55℃	84 days
65℃	70 days

2.3 Analysis of estimated AATD

Tab10.Analysis of estimated aging time

Series	Performance items	AATD of 45℃	AATD of 55℃	AATD of 65℃
1	Physical examination	84days	84 days	70 days
2	Accuracy(positive coincidence)	84 days	84 days	70 days
	Accuracy (negative coincidence)	84days	84days	70 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)

Based on the accelerated aging time duration is 70 days (AATD=70), accelerated aging temperature is 65℃ (Te=65℃), ambient temperature of SARS-CoV-2 Antigen Rapid Qualitative Test is 30℃ (Ta=30℃) and Q10 is set to 2, the estimated real time (t_e) of new buffer 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

3. Conclusion

Three lots of new buffers were subjected to transport simulation and accelerated aging. After transport simulation, the estimated real time (t_e) of stability study is 791.6days, which is no less than the claimed shelf life (24 months) of SARS-CoV-2 Antigen Rapid Qualitative Test. The results meet the acceptance criteria of transport and accelerated aging stability study.