COVID-19 Self-Test

Stability Study Report

1. Sample Preparation and Handling

1.1. Sample preparation

1.1.1 Material

(1) **Positive controls: FDS01**

(2) **Negative samples: FDN01**

(3) **COVID-19 Self- test kits**

Source: Xiamen Biotime;

Detail information

Tab 1.   Test kits

No.	Equipment/Device/Material Name	Batch No.	Code
1	COVID-19 Self- test kits	X200816-1	P1
2	COVID-19 Self- test kits	X200816-2	P2
3	COVID-19 Self- test kits	X200816-3	P3

1.1.2 Method of determination by COVID-19 Self- test

(1) The study was performed testing devices in triplicate using controls of 3 replicates respectively. At each test, 75 µL extraction solution was added to 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 indicate 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 specimen 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.**

2. Transportation and Real-Time Stability

2.1. Study Purpose

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

2.2. Scope

This study is applicable to the transportation and real-time stability evaluation of COVID-19 Self- Test kit.

2.3. Referenced documents

Tab 2. 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

2.4. Personnel and Responsibility

Tab 3. Personnel and Responsibility

Title	Name	Educational background	Responsibility
██████ ██████	█████	██	Approving Stability Report.
██████ ████	████ ████	██████	Reviewing Stability Report.
██████	████ ████	██████	Evaluating Stability Study Process.
			Participating In Reviewing Testing Results.
████ ████	██████	██████	Performing Performance Stability Study.
			Recording, Analyzing Testing Results.
			Compiling Stability Report.

2.5. Testing schedule

Tab 4. Schedule

S.N.	Verified item	Start time	Completion time
1	Material Preparation	2020.08.02	2020.08.16
2	Time 0 testing	2020.08.16	2020.08.17
3	Mimic transportation cycles	2020.8.17	2020.08.24

4	Month 0 testing	2020.08.24	2020.08.25
5	Month 1 testing	2020.09.24	2020.09.25
6	Month 2 testing	2020.10.24	2020.10.25
7	Month 3 testing	2020.11.24	2020.11.25
8	Month 6 testing	2021.02.24	2021.02.25
9	Month 9 testing	2021.05.24	2021.05.25
10	Month 12 testing	2021.08.24	2021.08.25
11	Month 18testing	2022.02.24	2022.02.25
12	Month 24 testing	2022.08.24	2022.08.25
11	Month 27testing	2022.11.24	2022.11.25
13	Final report	2022.11.27	2022.11.30

2.6. Instructions for Use

Refer to the *Instructions for Use* of COVID-19 Self-Test Kit.

2.7. Acceptance criteria

Tab 5. 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 positive controls of 5 replicates of each COVID-19 Self-Test Kit respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 15/15, +/ +.
	Accuracy (negative coincidence)		While testing negative controls of 5 replicates of each COVID-19 Self-Test Kit respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 15/15, -/ -.
4	Repeatability	Intra-Lot Precision	While testing positive controls of 10 replicates of COVID-19 Self-Test Kit respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 10/10, +/ +.

		While testing negative controls of 10 replicates of COVID-19 Self-Test Kit respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 10/10, -/ -.
	Inter-Lot Precision	While testing positive controls of 10 replicates of each lot of COVID-19 Self-Test Kit respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be30/30, +/ +. While testing negative controls of 10 replicates of each lot of COVID-19 Self-Test Kit respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 30/30, -/ -.

2.8.   Used equipment, instrument and material

Tab 6.   Used equipment, instrument and material

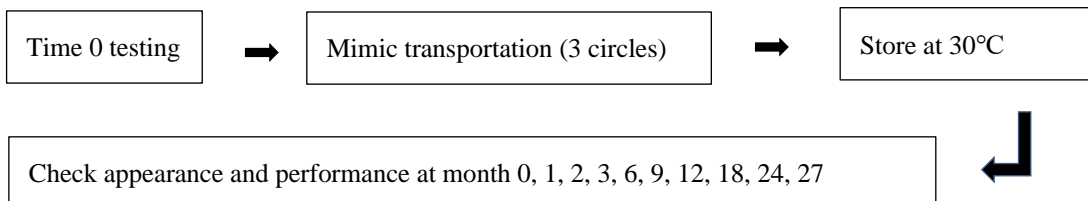| No.	Equipment/Device/Material Name	Batch No.	Code
1	COVID-19 Self-Test Kit	X200901-1	P1
2	COVID-19 Self-Test Kit	X200901-2	P2
3	COVID-19 Self-Test Kit	X200901-3	P3
4	**Contrived Samples Groups M**	**S2020040701**	/
5	Cold Room(2~8°C)	SC-SB-353	/
6	Refrigerator（-40~0°C）	SC-SB-104	/
7	Programmable Constant Temperature/Humidity Incubator	ZJ-SB-139	/
8	Sealing Tester with Vacuum	ZJ-SB-140	/
9	Shaker	ZJ-SB-071	/
10	Temperature and Humidity Data Logger	SC-SB-478 SC-SB-479 SC-SB-480 SC-SB-481 SC-SB-482	/
11	Oven	SC-SB-365	/

2.9.   Method

2.9.1 The design of study

a. COVID-19 Self-Test Handling

Based on the previous stability study, the COVID-19 Self-Test Kit stored at 30 ℃. 3 lots of COVID-19 Self-Test kit ere test with 1 lot of controls set as time 0 testing and then subjected to mimic transportation. For mimic transportation, considering of international shipping, distribution cycle 13 (Air(intercity) and motor freight(local), signal package up to 150 lb) was employed based on ASTM D4169. And the inner package temperature and humidity was monitored and recorded with data logger.

After mimic transportation, appearance of the COVID-19 Self-Test kits were checked and were stored at 30 ℃ for 0, 1, 2, 3, 6, 9, 12 , 18, 24 and 27months for a real time stability study with1 lot of SARS-CoV-2 Antigen controls set.

Time 0 testing	➡	Mimic transportation (3 circles)	➡	Store at 30℃

Check appearance and performance at month 0, 1, 2, 3, 6, 9, 12, 18, 24, 27	↵

The detail information of test is showing as follows:

Take three lots of COVID-19 Self-Test kits. Sample 1000 reagents randomly from each lot of COVID-19 Self-Test kit and store them at $30\pm2℃$ for 27 months, respectively. To test controls materials at $30\pm2℃$ after storing for 0,1,2,3, 6, 9, 12, 18, 24, 27 months, respectively. Physical examination and Product performances, including accuracy and repeatability should be tested. Furthermore, the testing condition was recorded by a hygrothermograph during the calibration period.

b. Packaging

The packaging demonstration is in appendix A.

The COVID-19 Self-Test Kit (3T/7T) was sealed with plastic film and then put into a large foam transport box. Foam box is caped and sealed and subjected to mimic transportation. The COVID-19 Self-Test Kit were put facing up, facing down and facing side with even amount distribution while placing into the foam transport box.

c. Shipping unit define

Shipping unit to be tested are single packages.

d. Assurance Level

Assurance Level II is used based on value and appearance of shipment.

e. Acceptance criteria

No product damage, items to be check are listed below:

Tab 7.   Acceptance criteria of appearance

Items		Acceptance criteria
Box	Appearance	No damage
	Labels and marks	Clear
	Contents	No missing
Test Cartridge	Appearance	No damage/leakage
	Labels and marks	Clear
IFU	Appearance	No damage
	Text	Clear
Swabs	Appearance	No damage
Extraction solution	Appearance	No damage
	Tightness	no liquid leakage

f. Mimic transport schedules

Distribution cycle 13, Air(intercity) and motor freight(local), signal pack up tp 150 lb, will be used based on ASTM D4168 were added into the schedule based on the transportation design.

g. Mimic transport Plan

Three continuous repeating mimic distribution circles demonstrated below were performed:

Tab 8.　Demonstration of mimic distribution circle

Sequence	Test schedule	Methods	Environment
1	Handling-manual	One drop on top, two drops on adjacent bottom edge, two drops diagonally opposite bottom corners, one drop on bottom. Drop height 381mm.	perform under room temperature (~25℃)
2	Vehicle stacking	Compression of foam box with 300N(30kg) force	perform under room temperature(~25℃)
3	Loose-load vibration	Vibrate on shaker at 60Hz for 20 min on bottom, 10 min on each of two adjacent side	perform under room temperature(~25℃)
4	vehicle vibration	Vibrate with shaker at 60Hz for 60 min	perform under room temperature(~25℃)
5	Low pressure	Vacuum air pressure to 60Kpa(mimic of 4200m elevation), vibrate with shaker at 120Hz for 60 min	perform under room temperature(~25℃)

6	vehicle vibration	Vibrate with sharer at 120Hz for 13 hour	perform under room temperature(~25℃)
7	Cold chain gap	Incubate at 45℃ for 120min	perform under room temperature(~25℃)
8	Concentrated impact	Drop weight of 1 kg vertically from 0.8m on to the surface	perform under room temperature(~25℃)
9	Handling-manual	one drop on top, two drop on adjacent bottom edge, two drop diagonally opposite bottom corners, one drop on bottom. Drop height 381mm.	perform under room temperature(~25℃)

2.9.2.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.**

2.9. 3 Analytical performance

(1) The study was performed testing devices in triplicate using controls set of 3 replicates by controls respectively. At each test, 50 µL extraction solutions were added to control 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 indicated a faint line and M indicate 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 control 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 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 result.**

1.9.4 The determination of the real-time.

Record the longest storage time of the kits by which all test results meet the performance acceptance criteria as the minimum real-time of the kits.

2.10. Results

2.10.1 Physical examination

Tab 9.   Appearance examination results

Time	P1	P2	P3
0month	"Yes"	"Yes"	"Yes"
1month	"Yes"	"Yes"	"Yes"
2month	"Yes"	"Yes"	"Yes"
3month	"Yes"	"Yes"	"Yes"

Tab 10.   Liquid velocity examination results-(mm/min)

Time	P1	P2	P3
0month	20.07	21.57	21.08
1month	19.81	19.08	20.67
2month	19.71	21.04	20.65
3month	20.68	19.53	21.87

2.10.2 Accuracy

Tab 11.　Testing results of accuracy

Date	ID	Lines	P1					P2					P3				
			Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
0Month	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)
1Month	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)
2Month	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)
3Month	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)

2.10.4 Accuracy (Repeatability)

0month:

Tab 12.　Testing results of repeatability

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
FDS01	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)

	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
	9	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
	10	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
FDN01	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)

Tab 13.   Signal intensities of testing results

ID	lines	Number of "N"	Number of "NA"	Rt
FDS01	T line	30	0	30
	C line	30	0	30
FDN01	T line	30	0	30
	C line	30	0	30

1month

Tab 14.   Testing results of repeatability

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
FDS01	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)

ID	Tests #	P1 T line	P1 C line	P2 T line	P2 C line	P3 T line	P3 C line
FDN01	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)

Tab 15. Signal intensities of testing results

ID	lines	Number of "N"	Number of "NA"	Rt
FDS01	T line	30	0	30
	C line	30	0	30
FDN01	T line	30	0	30
	C line	30	0	30

2month

Tab 16. Testing results of repeatability

ID	Tests #	P1 T line	P1 C line	P2 T line	P2 C line	P3 T line	P3 C line
FDS01	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)
FDN01	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)

Tab 17. Signal intensities of testing results

ID	lines	Number of "N"	Number of "NA"	Rt
FDS01	T line	30	0	30
	C line	30	0	30
FDN01	T line	30	0	30
	C line	30	0	30

3month:

Tab 18. Testing results of repeatability

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
FDS01	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)
FDN01	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)

Tab 19.   Signal intensities of testing results

ID	lines	Number of "N"	Number of "NA"	Rt
FDS01	T line	30	0	30
	C line	30	0	30
FDN01	T line	30	0	30
	C line	30	0	30

Data summary

Tab 20.   Summary of results

Time	ID	Ri	Rp	Rn	Rt	Positive coincidence
0month	FDS01	0	30	0	30	30/30, +/ +
	FDN01	0	30	0	30	30/30, +/ +
1month	FDS01	0	30	0	30	30/30, +/ +
	FDN01	0	30	0	30	30/30, +/ +
2month	FDS01	0	30	0	30	30/30, +/ +
	FDN01	0	30	0	30	30/30, +/ +
3month	FDS01	0	30	0	30	30/30, +/ +
	FDN01	0	30	0	30	30/30, +/ +

Tab 21.   Summary of signal intensities record –Number of "Y"

ID	0month	1month	2month	3month
FDS01	0	0	0	0
FDN01	0	0	0	0

2.11.   Conclusion

(1) Positive Coincidence

Based on the study, while testing positive controls respectively at 30℃ with 3 lots of COVID-19 Self-Test Kits after storing at 2-30℃ for 3 months, test result showed no invalid result (Ri=0), positive coincidence was 15/15,, +/ +.

The test conclusion meets the acceptance criteria of accuracy (positive coincidence).

(2) Negative Coincidence

Based on the study, while testing negative controls at 30℃ with 3 lots of COVID-19 Self-Test Kits after storing at 2-30℃ for 3 months, test result showed no invalid result (Ri=0), positive coincidence was 15/15, -/ -.

The test conclusion meets the acceptance criteria of accuracy (negative coincidence).

(3) Intro-Lot Precision and Inter-Lot Precision

While testing positive controls and negative controls with 3 lots of COVID-19 Self-Test Kit respectively at 30℃ after storing at 2-30℃ for 3 months, all test results are valid (Ri=0). All test results for positive controls are positive and all test results for negative controls are negative. No obvious difference in signal intensities(Y=0) of T and C lines respectively between all test for each controls. Test results of three lots meet the acceptance criteria of repeatability, including intro-lot precision and inter-lot precision.

(4)Summary

Testing results of real-time stability of COVID-19 Self-Test kit showed: all testing results conformed to the requirements of quality standard after storing at 2-30℃ for 3 months.

The study is ongoing. So far the expiry period(real- time stability) of COVID-19 Self-Test kit is specified as 3 months temporary and it should be stored at 2~30℃.