

**SARS-CoV-2 Antigen Rapid Qualitative Test**

**Stability Study Report**

**SARS-R059**

1. Sample Preparation And Handling .....	1
2. Transportation And Real-Time Stability .....	8
3. In-Use Stability .....	61

## 1. Sample Preparation and Handling

### 1.1. Sample preparation

#### 1.1.1 Material

(1) **Name:** Heat-inactivated **positive samples (6)**

Source: Chongqing Public Health Medical Center;

Requirement: Clear, no impurity, positive (confirmed for SARS-CoV-2 by PCR kits from Shengxiang Bio-Tech Co., Ltd.)

Detail information:

Tab 1. Detail information of positive samples

S.N.(Hospital ID)	Property	Matrix	Sources (Donor Number )
2020032801	Positive	sputum matrix	00034011
2020032802	Positive	NP swabs with and without VTM	00034011
2020032901	Positive	sputum matrix	00034023
2020032902	Positive	NP swabs with and without VTM	00034023
2020032909	Positive	sputum matrix	00034136
2020032910	Positive	NP swabs with and without VTM	00034136

(2) **Name:** **negative samples**

Source: Chongqing Public Health Medical Center;

Requirement: Clear, no impurity, positive (confirmed negative for SARS-CoV-2 by PCR kits from Shengxiang Bio-Tech Co., Ltd.)

Tab 2. Detail information of negative sample

S.N.(Hospital ID)	Property	Matrix	Sources (Donor Number )
2020033001	negative	sputum matrix	00036125
2020033002	negative	NP swabs with and without VTM	00036125
2020033003	negative	sputum matrix	00036126
2020033004	negative	NP swabs with and without VTM	00036126
2020033005	negative	sputum matrix	00036127
2020033006	negative	NP swabs with and without VTM	00036127

(3) **Name:** **SARS-CoV-2 Antigen Rapid Qualitative Test**

Source: Xiamen Biotime;

Detail information

Tab 3. Test kits

No.	Equipment/Device/Material Name	Batch No.	Code
1	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003011	P1
2	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003012	P2
3	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003013	P3

### 1.1.2 Method of determination by SARS-CoV-2 Antigen Rapid Qualitative Test

(1) The study was performed testing devices in triplicate using contrived samples in sputum matrix or NP swabs with and without VTM of 3 replicates respectively. At each test, 75  $\mu$ L contrived samples were added to sputum matrix or NP swabs with and without VTM 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 contrived samples, 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 contrived samples, 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**.

### 1.1.3Preparation procedure and confirmation

(1) **Contrived negative sample of the sputum matrix specimen matrix**

Record the negative sample 2020033001 as contrived negative sample SNC01 for sputum matrix;

Record the negative sample 2020033003 as contrived negative sample SNC02 f for sputum matrix;

Record the negative sample 2020033005 as contrived negative sample SNC03 f for sputum matrix;

**(2) Contrived negative sample of the human nasal specimen matrix**

Record the negative sample 2020033002 as contrived negative sample SNC04 for NP swabs samples without VTM;

Record the negative sample 2020033004 as contrived negative sample SNC05 f for NP swabs samples without VTM;

Record the negative sample 2020033006 as contrived negative sample SNC06 f for NP swabs samples without VTM.

**(3) The determination of negative sample**

The results of negative sample were indicated as follows

Tab 4. The results of negative sample

Control ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Based on the study, the results of the negative samples tested by three batches of SARS-CoV-2 Antigen Rapid Qualitative Test were all negative.

**(4) Contrived positive sample SPC01~12**

The positive samples (see table 1) was spiked into negative samples respectively with different fold dilution to find and obtain the contrived samples (record as contrived samples ID SPC01, SPC03, SPC05, SPC07, SPC09, SPC011) with moderate lines in lines T and the contrived samples (record as contrived samples ID SPC02, SPC04, SPC06, SPC08, SPC10, SPC012) with the analyte level of 4xLOD. The contrived samples were tested in 5 duplicate with each lot indicated above.

The results of negative sample

**a. Positive sample (2020032801)**

Tab 5. The results of dilution o and confirmation of positive sample (2020032801)

Fold	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1:100	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)
1:200	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)
1:400	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:800	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:1600	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:3200	T	-	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:6400	T	-	+(F)	-	+(F)	-	+(F)	+(F)	-	+(F)	+(F)	-	+(F)	+(F)	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Based on study indicated in the table above, the 100-fold dilution of the positive sample (2020032801) was made in negative sputum samples that recorded as “SPC01”. As well as the 400-fold dilution of that was recorded as” SPC02” with the analyte level of 4xLOD.

**b. Positive sample (2020032901)**

Tab 6. The results of dilution and confirmation of positive sample (2020032901)

Fold	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1:100	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)
1:200	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)
1:400	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)
1:800	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)
1:1600	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:3200	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:6400	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:9600	T	+(F)	-	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	-	-	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:12800	T	-	+(F)	-	+(F)	-	+(F)	+(F)	-	+(F)	-	+(F)	-	-	-	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Based on study, indicated in the table above, the 400-fold dilution of the positive sample (2020032901) was made in negative sputum samples that recorded as “SPC03”. As well as the 1600-fold dilution of that was recorded as “SPC04 ”with the analyte level of 4xLOD.

**c. Positive sample (2020032909)**

Tab 7. The results of dilution o and confirmation of positive sample (2020032909)

Fold	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1:100	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)
1:200	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)
1:400	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)
1:800	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:1600	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:3200	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:6400	T	+(F)	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	-	-	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:12800	T	-	-	+(F)	+(F)	-	+(F)	+(F)	-	+(F)	-	+(F)	-	-	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Based on study, indicated in the table above, the 200-fold dilution of the positive sample (2020032909) was made in negative sputum samples that recorded as “SPC05”. As well as the 800-fold dilution of that was recorded as “ SPC06 ” with the analyte level of 4xLOD.

**d. Positive sample (2020032802)**

Tab 8. The results of dilution o and confirmation of positive sample (2020032802)

Fold	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1:100	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)
1:200	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)
1:400	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:800	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:1600	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:3200	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:3200	T	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)	-	-	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Based on study, indicated in the table above, the 100-fold dilution of the positive sample (2020032802) was made in negative NP swabs with and without VTM samples that recorded as “SPC07”. As well as the 400-fold dilution of that was recorded as” SPC08” with the analyte level of 4xLOD.

**e. Positive sample (2020032902)**

Tab 9. The results of dilution and confirmation of positive sample (2020032902)

Fold	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test 1	Test 2	Test3	Test 4	Test5	Test1	Test2	Test3	Test 4	Test5
1:100	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)
1:200	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)
1:400	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)



1:800	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)
1:160	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	0	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:320	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	0	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:640	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	0	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:960	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	-	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)
	0	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:128	T	+(F)	-	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	-
	00	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Based on study, indicated in the table above, the 400-fold dilution of the positive sample (2020032902) was made in negative NP swabs with and without VTM samples that recorded as “SPC09”. As well as the 1600-fold dilution of that was recorded as” SPC10 with the analyte level of 4xLOD.

**f. positive sample (2020032910)**

Tab 10. The results of dilution o and confirmation of positive sample (2020032910)

Fold	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
1:100	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)
1:200	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)
1:400	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)
1:800	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:1600	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:3200	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:6400	T	-	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
1:12800	T	+(F)	+(F)	-	+(F)	+(F)	+(F)	-	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	-	-

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
--	---	------	------	------	------	------	------	------	------	------	------	------	------	------	------	------

Based on study, indicated in the table above, the 200-fold dilution of the positive sample (2020032910) was made in negative NP swabs with and without VTM samples that recorded as "SPC11". As well as the 800-fold dilution of that was recorded as "SPC12" with the analyte level of 4xLOD.

#### (5) Summary of the Contrived samples

Tab 11. The list of contrived samples

Contrived Sample	Titer	Property	Signal Intensity
SNC01	/	negative	NA
SNC02	/	negative	NA
SNC03	/	negative	NA
SNC04	/	negative	NA
SNC05	/	negative	NA
SNC06	/	negative	NA
SPC01	1:100	positive	+(M)
SPC02	1:400	positive	+(F)
SPC03	1:400	positive	+(M)
SPC04	1:1600	positive	+(F)
SPC05	1:200	positive	+(M)
SPC06	1:800	positive	+(F)
SPC07	1:100	positive	+(M)
SPC08	1:400	positive	+(F)
SPC09	1:400	positive	+(M)
SPC10	1:1600	positive	+(F)
SPC11	1:200	positive	+(M)
SPC12	1:800	positive	+(F)

As showed in the above-mentioned list, the contrived samples were recorded as "**Contrived Samples Groups M**" with the code of **S2020040701**

Thus, in the subsequent study report, we addressed the "**Contrived Samples Groups M**" as the contrived samples indicated in the above-mentioned list.

#### 1.2. Contrived Sample Handling

In this study, the "**Contrived Samples Groups M**" was storage at -40°C in the Refrigerator.

## 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 SARS-CoV-2 Antigen Rapid Qualitative Test 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 SARS-CoV-2 Antigen Rapid Qualitative Test.

### 2.3. Referenced documents

Tab 12. 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 13. 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 14. Schedule

S.N.	Verified item	Start time	Completion time
1	Material Preparation	2020.03.24	2020.04.07
2	Time 0 testing	2020.04.07	2020.04.07
3	Mimic transportation cycles	2020.04.07	2020.04.14
4	Month 0 testing	2020.04.15	2020.04.16
5	Month 1 testing	2020.05.15	2020.05.16
6	Month 2 testing	2020.06.15	2020.06.16
7	Month 3 testing	2020.07.15	2020.07.16
8	Month 6 testing	2020.10.15	2020.10.16
9	Month 9 testing	2021.01.15	2021.01.16
10	Month 12 testing	2021.04.15	2021.04.16
11	Month 18testing	2021.10.15	2021.10.16
12	Month 24 testing	2022.04.15	2022.04.16
11	Month 27testing	2022.07.15	2022.07.16
13	Final report	2022.07.18	2022.07.21

## 2.6. Instructions for Use

Refer to the *Instructions for Use* of SARS-CoV-2 Antigen Rapid Qualitative Test and .

## 2.7. Acceptance criteria

Tab 15. Acceptance criteria

S.N.	Test item		Acceptance criteria
1	Physical examination	Appearance	Complete and free of liquid leakage
		Liquid velocity	$\geq 10\text{mm/min}$
2	Accuracy(positive coincidence)		While testing positive contrived samples of 5 replicates of each SARS-CoV-2 Antigen Rapid Qualitative Test 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 contrived samples of 5 replicates of each SARS-CoV-2 Antigen Rapid Qualitative Test

			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 contrived samples of 10 replicates of SARS-CoV-2 Antigen Rapid Qualitative Test respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 10/10, +/ +.  While testing negative contrived samples of 10 replicates of SARS-CoV-2 Antigen Rapid Qualitative Test 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 contrived samples of 10 replicates of each lot of SARS-CoV-2 Antigen Rapid Qualitative Test respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 30/30, +/ +.  While testing negative contrived samples of 10 replicates of each lot of SARS-CoV-2 Antigen Rapid Qualitative Test 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 16. Used equipment, instrument and material

No.	Equipment/Device/Material Name	Batch No.	Code
1	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003011	P1
2	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003012	P2
3	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003013	P3
4	<b>Contrived Samples Groups M</b>	<b>S2020040701</b>	/
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**

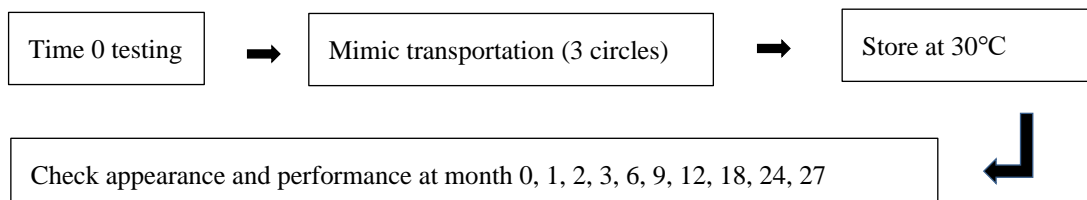
2.9.1 The design of study

**a. SARS-COV-2 Antigen Rapid Qualitative Test Handling**

Based on the previous stability study, the SARS-CoV-2 Antigen Rapid Qualitative Test at 30 °C. 3 lots of SARS-CoV-2 Antigen Rapid Qualitative Test are test with 1 lots of contrived samples 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 SARS-CoV-2 Antigen Rapid Qualitative Test were checked and were stored at 30 °C for 0, 1, 2, 3, 6, 9, 12, 18, 24 and 27months for a real time stability study with 1 lot of SARS-CoV-2 Antigen contrived samples set.



The detail information of test is showing as follows:

Take three lots of SARS-CoV-2 Antigen Rapid Quantitative Test . Sample 6000 reagents randomly from each lot of SARS-CoV-2 Antigen Rapid Quantitative Test and store them at 30±2°C for 27 months, respectively. Take samples to test contrived samples materials at 30±2°C 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 SARS-CoV-2 Antigen Rapid Qualitative Test (25T/kit) was sealed with plastic film and then put into a large foam transport box. Foam box is capped and sealed and subjected to mimic transportation. The SARS-CoV-2 Antigen Rapid Qualitative Test 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 17. 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 18. Demonstration of mimic distribution circle

Sequence	Test schedule	Methods	Environment
----------	---------------	---------	-------------

1	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°C )
2	Vehicle stacking	Compression of foam box with 300N(30kg) force	perform under room temperature(~25°C )
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°C )
4	vehicle vibration	Vibrate with shaker at 60Hz for 60 min	perform under room temperature(~25°C )
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°C )
6	vehicle vibration	Vibrate with sharer at 120Hz for 13 hour	perform under room temperature(~25°C )
7	Cold chain gap	Incubate at 45°C for 120min	perform under room temperature(~25°C )
8	Concentrated impact	Drop weight of 1 kg vertically from 0.8m on to the surface	perform under room temperature(~25°C )
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°C )

### 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 cartridge 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 contrived samples set of 3 replicates by sputum matrix or NP swabs with and without VTM respectively. At each test, 50  $\mu$ L contrived samples were added to sputum matrix or NP swabs with and without VTM 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 indicate a faint line and M indicate a moderate or strong line

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

(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 ( $R_p$ ), If a “-” is observed on T line of a test, this test should be regard as a negative result ( $R_n$ ).

7) While testing the positive contrived samples, calculate the percentage of positive results ( $R_p$ ) of testing each specimen versus the test number of  $R_t$  with following formula:  $R_p/R_t, +/+$ . Record the calculating result as the **Positive Confidence**.

(7) While testing the negative contrived samples, calculate the percentage of negative results ( $R_n$ ) versus the total test number ( $R_t$ ) with following formula:  $R_n/R_t, -/-$ . 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 contrived samples. Record “Y” if a signal intensity is obviously different from same lines of other tests of same contrived samples of all lots. Record “N” if a signal intensity is not obviously different from same lines of other tests of same contrived samples of all lots. Record “N/A” if a line show no signal.

(9) Count the number of “Y” for each lot for the same contrived samples, 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 19. Appearance examination results

Time	P1	P2	P3
0month	"Yes"	"Yes"	"Yes"
1month	"Yes"	"Yes"	"Yes"
2month	"Yes"	"Yes"	"Yes"
3month	"Yes"	"Yes"	"Yes"
4month	"Yes"	"Yes"	"Yes"

Tab 20. Liquid velocity examination results-( mm/min)

Time	P1	P2	P3
0month	18.1	16.9	20.7
1month	17.1	19.8	17.0
2month	19.5	19.5	19.6
3month	16.5	18.1	17.8
4month	17.6	20.8	20.7

2.10.2 Accuracy (positive coincidence)

**For sputum matrix-0month:**

Tab 21. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3					
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	
SPC01	T	+(M)	+(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)	+(M)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	T	+(M)	+(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)	+(M)

SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-1month:**

Tab 22. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-2month:**

Tab 23. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-3month:**

Tab 24. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-4month:**

Tab 25. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -0month:**

Tab 26. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -1month:**

Tab 27. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)

SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -2month:**

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Tab 28. Testing results of accuracy(positive coincidence)

**For NP swabs samples without VTM matrix -3month:**

Tab 29. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -4month:**

Tab 30. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

2.10.3 Accuracy (negative coincidence)

**For sputum matrix-0month:**

Tab 31. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-1month:**

Tab 32. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-2month:**

Tab 33. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-3month:**

Tab 34. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-4month:**

Tab 35. Testing results of accuracy(negative coincidence)



ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -0month:**

Tab 36. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -1month:**

Tab 37. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -2month:**

Tab 38. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
----	-------	----	--	--	--	--	----	--	--	--	--	----	--	--	--	--

		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -3month:**

Tab 39. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -4month:**

Tab 40. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

2.10.4 Accuracy (Repeatability)

**For sputum matrix-0month**

Tab 41. Testing results of repeatability(for sputum matrix)

ID	Tests #	P1	P2	P3
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		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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 42. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30
	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30

	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

**For sputum matrix-1month**

Tab 43. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
	SNC02	1	-	+(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)
SNC03	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 44. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30



	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30
	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

**For sputum matrix-2month**

Tab 45. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 46. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30
	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30
	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

**For sputum matrix-3month**

Tab 47. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 48. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30
	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30
	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

**For sputum matrix-4month**

Tab 49. Testing results of repeatability(for sputum matrix)

ID	Tests #	P1	P2	P3
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		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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)



	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 50. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA "	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30
	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30

	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

**For NP swabs samples without VTM matrix -0month**

Tab 51. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 52. Signal intensities of testing results (for NP swabs samples without VTM)

ID	lines	Number of "N"	Number of "NA "	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30

SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For NP swabs samples without VTM matrix -1month**

Tab 53. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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)
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Tab 54. Signal intensities of testing results (for NP swabs samples without VTM)

ID	lines	Number of "N"	Number of "NA "	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For NP swabs samples without VTM matrix -2month**

Tab 55. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 56. Signal intensities of testing results (for NP swabs samples without VTM)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For NP swabs samples without VTM matrix -3month**

Tab 57. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 58. Signal intensities of testing results (for NP swabs samples without VTM)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30

	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For NP swabs samples without VTM matrix -4month**

Tab 59. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 60. Signal intensities of testing results (for NP swabs samples without VTM)

ID	lines	Number of "N"	Number of "NA "	Rt
SPC07	T line	30	0	30

	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

### Data summary

Tab 61. Summary of positive results

Time	ID	Ri	Rp	Rn	Rt	Positive coincidence
0month	SPC01	0	30	0	30	30/30, +/ +
	SPC02	0	30	0	30	30/30, +/ +
	SPC03	0	30	0	30	30/30, +/ +
	SPC04	0	30	0	30	30/30, +/ +
	SPC05	0	30	0	30	30/30, +/ +
	SPC06	0	30	0	30	30/30, +/ +
	SPC07	0	30	0	30	30/30, +/ +
	SPC08	0	30	0	30	30/30, +/ +
	SPC09	0	30	0	30	30/30, +/ +
	SPC10	0	30	0	30	30/30, +/ +
	SPC11	0	30	0	30	30/30, +/ +
	SPC12	0	30	0	30	30/30, +/ +
1month	SPC01	0	30	0	30	30/30, +/ +
	SPC02	0	30	0	30	30/30, +/ +

	SPC03	0	30	0	30	30/30, +/ +	
	SPC04	0	30	0	30	30/30, +/ +	
	SPC05	0	30	0	30	30/30, +/ +	
	SPC06	0	30	0	30	30/30, +/ +	
	SPC07	0	30	0	30	30/30, +/ +	
	SPC08	0	30	0	30	30/30, +/ +	
	SPC09	0	30	0	30	30/30, +/ +	
	SPC10	0	30	0	30	30/30, +/ +	
	SPC11	0	30	0	30	30/30, +/ +	
	SPC12	0	30	0	30	30/30, +/ +	
	2month	SPC01	0	30	0	30	30/30, +/ +
		SPC02	0	30	0	30	30/30, +/ +
SPC03		0	30	0	30	30/30, +/ +	
SPC04		0	30	0	30	30/30, +/ +	
SPC05		0	30	0	30	30/30, +/ +	
SPC06		0	30	0	30	30/30, +/ +	
SPC07		0	30	0	30	30/30, +/ +	
SPC08		0	30	0	30	30/30, +/ +	
SPC09		0	30	0	30	30/30, +/ +	
SPC10		0	30	0	30	30/30, +/ +	
SPC11		0	30	0	30	30/30, +/ +	
SPC12		0	30	0	30	30/30, +/ +	
3month	SPC01	0	30	0	30	30/30, +/ +	
	SPC02	0	30	0	30	30/30, +/ +	
	SPC03	0	30	0	30	30/30, +/ +	
	SPC04	0	30	0	30	30/30, +/ +	
	SPC05	0	30	0	30	30/30, +/ +	
	SPC06	0	30	0	30	30/30, +/ +	
	SPC07	0	30	0	30	30/30, +/ +	
	SPC08	0	30	0	30	30/30, +/ +	
	SPC09	0	30	0	30	30/30, +/ +	
	SPC10	0	30	0	30	30/30, +/ +	
	SPC11	0	30	0	30	30/30, +/ +	
	SPC12	0	30	0	30	30/30, +/ +	
4month	SPC01	0	30	0	30	30/30, +/ +	
	SPC02	0	30	0	30	30/30, +/ +	

SPC03	0	30	0	30	30/30, +/ +
SPC04	0	30	0	30	30/30, +/ +
SPC05	0	30	0	30	30/30, +/ +
SPC06	0	30	0	30	30/30, +/ +
SPC07	0	30	0	30	30/30, +/ +
SPC08	0	30	0	30	30/30, +/ +
SPC09	0	30	0	30	30/30, +/ +
SPC10	0	30	0	30	30/30, +/ +
SPC11	0	30	0	30	30/30, +/ +
SPC12	0	30	0	30	30/30, +/ +

Tab 62. Summary of negative results

Time	ID	Ri	Rp	Rn	Rt	Negative coincidence
0month	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
1month	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
2month	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
3month	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -

	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
4month	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -

Tab 63. Summary of signal intensities record –Number of “Y”

ID	0month	1month	2month	3month	4month
SPC01	0	0	0	0	0
SPC02	0	0	0	0	0
SPC03	0	0	0	0	0
SPC04	0	0	0	0	0
SPC05	0	0	0	0	0
SPC06	0	0	0	0	0
SPC07	0	0	0	0	0
SPC08	0	0	0	0	0
SPC09	0	0	0	0	0
SPC10	0	0	0	0	0
SPC11	0	0	0	0	0
SPC12	0	0	0	0	0

## 2.11. Conclusion

### (1) Positive Coincidence

Based on the study, while testing positive contrived samples using throat swabs or NP swabs respectively at 30°C with 3 lots of SARS-CoV-2 Antigen Rapid Qualitative Test after storing at 2-30°C for 4months, test result showed no invalid result (Ri=0), positive coincidence was 15/15,, +/ +.

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

### (2) Negative Coincidence

Based on the study, while testing negative contrived samples using throat swabs or NP swabs respectively at 30°C with 3 lots of SARS-CoV-2 Antigen Rapid Qualitative Test after storing at 2-30°C for 4months, test result showed no invalid result (Ri=0), positive coincidence was 15/15, -/ -.

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

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

While testing “contrived samples M” with 3 lots of SARS-CoV-2 Antigen Rapid Qualitative Test using throat swabs or NP swabs respectively at 30°C after storing at 2-30°C for 4months, all test results are valid (Ri=0). All test results for positive contrived samples are positive and all test results for negative contrived samples are negative. No obvious difference in signal intensities(Y=0) of T and C lines respectively between all test for each contrived samples. 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 SARS-CoV-2 Antigen Rapid Quantitative Test showed: all testing results conformed to the requirements of quality standard after storing at 2-30°C for 4 months.

The study is on going. So far the expiry period(real- time stability) of SARS-CoV-2 Antigen Rapid Quantitative Test is specified as 4 months temporary and it should be stored at 2~30°C.

## 3. In-Use Stability

### 3.1 Study Purpose

This study is intended to verify and evaluate the in-use stability of SARS-CoV-2 Antigen Rapid Qualitative Test in order to make sure that it meets the requirements of clinical testing.

### 3.2 Scope

This study is applicable to SARS-CoV-2 Antigen Rapid Qualitative Test.

### 3.3 Acceptance criteria

Tab 64. 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 contrived samples of 5 replicates of each SARS-CoV-2 Antigen Rapid Qualitative Test 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 contrived samples of 5 replicates of each SARS-CoV-2 Antigen Rapid Qualitative Test respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 15/15, -/ -.
4	Repeatability	Intra-Lot Precision	<p>While testing positive contrived samples of 10 replicates of SARS-CoV-2 Antigen Rapid Qualitative Test respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 10/10, +/ +.</p> <p>While testing negative contrived samples of 10 replicates of SARS-CoV-2 Antigen Rapid Qualitative Test respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 10/10, -/ -.</p>
		Inter-Lot Precision	<p>While testing positive contrived samples of 10 replicates of each lot of SARS-CoV-2 Antigen Rapid Qualitative Test respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 30/30, +/ +.</p> <p>While testing negative contrived samples of 10 replicates of each lot of SARS-CoV-2 Antigen Rapid Qualitative Test respectively, number of invalid results (Ri) should be 0 and percentage of positive results (Rp%) should be 30/30, -/ -.</p>

### 3.4 The design of the “in use” study



#### 3.4.1 The design of open- bottles stability study

- 1) Test all performance items listed in 2.3 with SARS-CoV-2 Antigen Rapid Qualitative Test kit from three continuous lots. Bottles of detection buffer were reopened for 0, 15, 30 and 45 times respectively before each test.

Evaluate and record the most times of reopening (MRT) of each performance item under which all results met the acceptance criteria.

Use the minimal “MRT” among all performance item as the acceptable time of reopening (ART) of the study.

- 2) The determination of the open- bottles times.

Record the “MRT” of the kits by which all test results meet the performance acceptance criteria as minimum time of the open -bottles times.

#### 3.4.2 The design of opened kit stability study

- 1) The reaction of immunochromatographic reagents requires the liquid to be chromatographed with the NC membrane. Humidity has a great influence on the chromatography. If the NC membrane is damp, it may cause abnormal chromatography and lead to inaccurate detection results. Take 3 batches of new coronavirus SARS-CoV-2 Antigen Rapid Qualitative Test kit, disassemble the test card, and place it horizontally on the experimental table under the condition of humidity at the range of 30%-90%. At the following times point: 0 Minutes, 10 Minutes,30 minutes, 60 minutes, and 90 minutes, run the sampling test, record test results, and establish the expiration date of the bag opening time of the test card.
- 2) The determination of the opened kit.

Record the longest time of the kits by which all test results meet the performance acceptance criteria as minimum open-kit time (MOT) of the kits .

### 3.5 Method

#### 3.5.1 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 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**.

### 3.5.2 Analytical performance

(1) The study was performed testing devices in triplicate using contrived samples set of 3 replicates by sputum matrix or NP swabs with and without VTM respectively. At each test, 50  $\mu$ L contrived samples were added to sputum matrix or NP swabs with and without VTM 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 contrived samples, 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 contrived samples, 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 contrived samples. Record “Y” if a signal intensity is obviously different from same lines of other tests of same contrived samples of all lots. Record “N” if a signal intensity is not obviously different from same lines of other tests of same contrived samples of all lots. Record “N/A” if a line showing no signal.

(9) Count the number of “Y” for each lot for the same contrived samples, and summarize the number of Y for all lots.

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

### 3.6 Materials

Tab 65. Used equipment, instrument and material

No.	Equipment/Device/Material Name	Batch No.	Code
1	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003011	P1
2	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003012	P2
3	SARS-CoV-2 Antigen Rapid Qualitative Test	X2003013	P3
4	<b>Contrived Samples Groups M</b>	<b>S2020040701</b>	/

### 3.7 Results

#### 3.7.1 Result- open- bottles study

##### 1) Physical examination(liquid velocity)

Tab 66. Liquid velocity examination results-( mm/min)

Time	P1	P2	P3
0times	16.4	17.2	11.4
15times	18.8	14.9	18.1
30times	14.7	16.0	18.2
45times	16.8	18.0	17.0

As illustrated in the above table, while all results of liquid velocity meet the acceptance criteria, the most times of reopening (MRT) is 45 times

##### 2) Accuracy(positive coincidence)

##### For sputum matrix-0times:

Tab 67. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-15times:**

Tab 68. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-30times:**

Tab 69. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
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**For sputum matrix-45times:**

**Tab 70. Testing results of accuracy(positive coincidence)**

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -0times:**

**Tab 71. Testing results of accuracy(positive coincidence)**

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -15times:**

Tab 72. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -30times:**

Tab 73. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -45times:**

Tab 74. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

As illustrated in the above table, while all results of accuracy (positive coincidence) meet the acceptance criteria, the most times of reopening (MRT) is 45 times

3) Accuracy (negative coincidence)

**For sputum matrix-0times:**

Tab 75. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-15times:**

Tab 76. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-30times:**

Tab 77. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-45times:**

Tab 78. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -0times:**

Tab 79. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -15times:**

Tab 80. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3					
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -30times:**

Tab 81. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3					
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -45times:**

Tab 82. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3					
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

As illustrated in the above table, while all results of accuracy (negative coincidence) meet the acceptance criteria, the most times of reopening (MRT) is 45 times.

4) Repeatability

**For sputum matrix-0times:**

Tab 83. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
	SNC02	1	-	+(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)
SNC03	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 84. Signal intensities of testing results (for sputum matrix)

ID	Lines	Number Of "N"	Number Of "Na"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30

	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30
	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

For sputum matrix-15times:

Tab 85. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 86. Signal intensities of testing results (for sputum matrix)

ID	Lines	Number Of "N"	Number Of "Na"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30
	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30
	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

**For sputum matrix-30times:**

Tab 87. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 88. Signal intensities of testing results (for sputum matrix)

ID	Lines	Number Of "N"	Number Of "Na"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30
	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30
	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30
	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

For sputum matrix-45 times:

Tab 89. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 90. Signal intensities of testing results (for sputum matrix)

ID	Lines	Number Of "N"	Number Of "Na"	Rt
SPC01	T line	30	0	30
	C line	30	0	30
SPC02	T line	30	0	30
	C line	30	0	30
SPC03	T line	30	0	30
	C line	30	0	30
SPC04	T line	30	0	30
	C line	30	0	30
SPC05	T line	30	0	30

	C line	30	0	30
SPC06	T line	30	0	30
	C line	30	0	30
SNC01	T line	0	30	30
	C line	30	0	30
SNC02	T line	0	30	30
	C line	30	0	30
SNC03	T line	0	30	30
	C line	30	0	30

**For NP swabs samples without VTM matrix - 0times:**

Tab 91. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
	SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)
2		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
3		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
4		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
5		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
6		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
7		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
8		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
9		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
10		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)



	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 92. Signal intensities of testing results (for NP swabs samples without VTM)

ID	Lines	Number Of "N"	Number Of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For NP swabs samples without VTM matrix -15 times:**

Tab 93. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	SPC09	1	+(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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 94. Signal intensities of testing results (for NP swabs samples without VTM)

ID	Lines	Number Of "N"	Number Of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For NP swabs samples without VTM matrix 30 times:**

Tab 95. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
	SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)
2		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
3		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
4		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
5		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
6		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
7		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
8		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
9		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
10		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)	
	SNC06	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 96. Signal intensities of testing results (for NP swabs samples without VTM)

ID	Lines	Number Of "N"	Number Of "NA "	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30



	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

For NP swabs samples without VTM matrix 45 times:

Tab 97. Testing results of repeatability(for NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 98. Signal intensities of testing results (for NP swabs samples without VTM)

ID	Lines	Number Of "N"	Number Of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30

	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

### Data summary

Tab 99. Summary of positive results

Time	ID	Ri	Rp	Rn	Rt	Positive coincidence
0times	SPC01	0	30	0	30	30/30, +/ +
	SPC02	0	30	0	30	30/30, +/ +
	SPC03	0	30	0	30	30/30, +/ +
	SPC04	0	30	0	30	30/30, +/ +
	SPC05	0	30	0	30	30/30, +/ +
	SPC06	0	30	0	30	30/30, +/ +
	SPC07	0	30	0	30	30/30, +/ +
	SPC08	0	30	0	30	30/30, +/ +
	SPC09	0	30	0	30	30/30, +/ +
	SPC10	0	30	0	30	30/30, +/ +
	SPC11	0	30	0	30	30/30, +/ +
	SPC12	0	30	0	30	30/30, +/ +
15times	SPC01	0	30	0	30	30/30, +/ +
	SPC02	0	30	0	30	30/30, +/ +
	SPC03	0	30	0	30	30/30, +/ +
	SPC04	0	30	0	30	30/30, +/ +
	SPC05	0	30	0	30	30/30, +/ +
	SPC06	0	30	0	30	30/30, +/ +

	SPC07	0	30	0	30	30/30, +/- +
	SPC08	0	30	0	30	30/30, +/- +
	SPC09	0	30	0	30	30/30, +/- +
	SPC10	0	30	0	30	30/30, +/- +
	SPC11	0	30	0	30	30/30, +/- +
	SPC12	0	30	0	30	30/30, +/- +
30times	SPC01	0	30	0	30	30/30, +/- +
	SPC02	0	30	0	30	30/30, +/- +
	SPC03	0	30	0	30	30/30, +/- +
	SPC04	0	30	0	30	30/30, +/- +
	SPC05	0	30	0	30	30/30, +/- +
	SPC06	0	30	0	30	30/30, +/- +
	SPC07	0	30	0	30	30/30, +/- +
	SPC08	0	30	0	30	30/30, +/- +
	SPC09	0	30	0	30	30/30, +/- +
	SPC10	0	30	0	30	30/30, +/- +
	SPC11	0	30	0	30	30/30, +/- +
	SPC12	0	30	0	30	30/30, +/- +
45times	SPC01	0	30	0	30	30/30, +/- +
	SPC02	0	30	0	30	30/30, +/- +
	SPC03	0	30	0	30	30/30, +/- +
	SPC04	0	30	0	30	30/30, +/- +
	SPC05	0	30	0	30	30/30, +/- +
	SPC06	0	30	0	30	30/30, +/- +
	SPC07	0	30	0	30	30/30, +/- +
	SPC08	0	30	0	30	30/30, +/- +
	SPC09	0	30	0	30	30/30, +/- +
	SPC10	0	30	0	30	30/30, +/- +
	SPC11	0	30	0	30	30/30, +/- +
	SPC12	0	30	0	30	30/30, +/- +

Tab 100. Summary of negative results

Time	ID	Ri	Rp	Rn	Rt	Negative coincidence
0times	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -

	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
15times	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
30times	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
45times	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -

Tab 101. Summary of signal intensities record –Number of “Y”

ID	0times	15times	30times	45times
SPC01	0	0	0	0
SPC02	0	0	0	0
SPC03	0	0	0	0
SPC04	0	0	0	0
SPC05	0	0	0	0
SPC06	0	0	0	0
SPC07	0	0	0	0
SPC08	0	0	0	0
SPC09	0	0	0	0
SPC10	0	0	0	0

SPC11	0	0	0	0
SPC12	0	0	0	0

## (5) Analysis of acceptable times of reopening times (ART)

Tab49. Performance parameter

SN	Performance parameter	ART	
1	Liquid velocity	45 times.	
2	Accuracy(positive coincidence)	45 times.	
	Accuracy (negative coincidence)	45 times.	
3	Repeatability	Intra-Lot Precision	45 times.
		Inter-Lot Precision	45 times.

The minimal “MRT” among all performance items is 45 times. Thus the acceptable times of reopening (ART) is 45 times.

## 3.7.2 Result-Opened kit stability

## 1) Physical examination(liquid velocity)

Tab 102. Liquid velocity examination results-( mm/min)

Time	P1	P2	P3
0minutes	18.9	19.2	16.0
10 minutes	18.0	19.0	20.3
30 minutes	18.7	18.2	17.2
60 minutes	18.2	19.8	16.4
90 minutes	20.8	16.7	20.2

As illustrated in the above table, within 90 minutes to open the kit, all results of liquid velocity meet the acceptance criteria.

## 2) Accuracy(positive coincidence)

**For sputum matrix-0 minutes:**

Tab 103. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3					
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	
SPC01	T	+(M)	+(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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-10 minutes:**

Tab 104. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-30 minutes:**

Tab 105. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5



SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-60 minutes:**

Tab 106. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-90 minutes:**

Tab 107. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC01	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)
SPC02	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC03	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)
SPC04	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC05	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)
SPC06	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix - 0minutes:**

Tab 108. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -10 minutes:**

Tab 109. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5

SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -30 minutes:**

Tab 110. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -60 minutes:**

Tab 111. Testing results of accuracy(positive coincidence)

ID	Lines	P1	P2	P3
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		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For NP swabs samples without VTM matrix -90 minutes:**

Tab 112. Testing results of accuracy(positive coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SPC07	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)
SPC08	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC09	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)
SPC10	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SPC11	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)
SPC12	T	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)	+(F)
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

As illustrated in the above table, while all results of accuracy (positive coincidence) meet the acceptance criteria, the most times of open-kit (MOT) are **90** minutes.

3) Accuracy (negative coincidence)

**For sputum matrix-0 minutes:**

Tab 113. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-10 minutes:**

Tab 114. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-30 minutes:**

Tab 115. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-60 minutes:**

Tab 116. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For sputum matrix-90 minutes:**

Tab 117. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC01	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC02	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC03	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -0 minutes:**

Tab 118. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
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**For the matrix of NP swabs with and without VTM -10 minutes:**

Tab 119. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -30 minutes:**

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

Tab 120. Testing results of accuracy(negative coincidence)

**For the matrix of NP swabs with and without VTM -60 minutes:**

Tab 121. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

**For the matrix of NP swabs with and without VTM -90 minutes:**

Tab 122. Testing results of accuracy(negative coincidence)

ID	Lines	P1					P2					P3				
		Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5	Test1	Test2	Test3	Test4	Test5
SNC04	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC05	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)
SNC06	T	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	C	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)	+(M)

As illustrated in the above table, while all results of accuracy (negative coincidence) meet the acceptance criteria, the longest time of open-kit (MOT) is **90** minutes.

4) Repeatability

**For sputum matrix-0** minutes:

Tab 123. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)



	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 124. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA "	Rt
SPC01	T line	30	0	30
	Cline	30	0	30
SPC02	T line	30	0	30
	Cline	30	0	30
SPC03	T line	30	0	30
	Cline	30	0	30
SPC04	T line	30	0	30
	Cline	30	0	30
SPC05	T line	30	0	30
	Cline	30	0	30
SPC06	T line	30	0	30
	Cline	30	0	30
SNC01	T line	0	30	30
	Cline	30	0	30
SNC02	T line	0	30	30
	Cline	30	0	30
SNC03	T line	0	30	30
	Cline	30	0	30

**For sputum matrix-10 minutes:**

Tab 125. Testing results of repeatability(for sputum matrix)

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)
	SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)
2		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
3		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
4		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
5		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
6		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
7		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
8		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
9		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
10		+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)	
	SNC03	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 126. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC01	T line	30	0	30
	Cline	30	0	30
SPC02	T line	30	0	30
	Cline	30	0	30
SPC03	T line	30	0	30
	Cline	30	0	30
SPC04	T line	30	0	30
	Cline	30	0	30
SPC05	T line	30	0	30
	Cline	30	0	30
SPC06	T line	30	0	30
	Cline	30	0	30
SNC01	T line	0	30	30
	Cline	30	0	30
SNC02	T line	0	30	30

	Cline	30	0	30
SNC03	T line	0	30	30
	Cline	30	0	30

**For sputum matrix-30 minutes:**

Tab 127. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 128. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC01	T line	30	0	30
	Cline	30	0	30
SPC02	T line	30	0	30
	Cline	30	0	30
SPC03	T line	30	0	30

	Cline	30	0	30
SPC04	T line	30	0	30
	Cline	30	0	30
SPC05	T line	30	0	30
	Cline	30	0	30
SPC06	T line	30	0	30
	Cline	30	0	30
SNC01	T line	0	30	30
	Cline	30	0	30
SNC02	T line	0	30	30
	Cline	30	0	30
SNC03	T line	0	30	30
	Cline	30	0	30

**For sputum matrix-60 minutes:**

Tab 129. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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)
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Tab 130. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA "	Rt
SPC01	T line	30	0	30
	Cline	30	0	30
SPC02	T line	30	0	30
	Cline	30	0	30
SPC03	T line	30	0	30
	Cline	30	0	30
SPC04	T line	30	0	30
	Cline	30	0	30
SPC05	T line	30	0	30
	Cline	30	0	30
SPC06	T line	30	0	30
	Cline	30	0	30
SNC01	T line	0	30	30
	Cline	30	0	30
SNC02	T line	0	30	30
	Cline	30	0	30
SNC03	T line	0	30	30
	Cline	30	0	30

**For sputum matrix-90 minutes:**

Tab 131. Testing results of repeatability(for sputum matrix)

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)
SPC02	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC03	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)
SPC04	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC05	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)
SPC06	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(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)
SNC02	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)
SNC03	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 132. Signal intensities of testing results (for sputum matrix)

ID	lines	Number of "N"	Number of "NA"	Rt
SPC01	T line	30	0	30
	Cline	30	0	30
SPC02	T line	30	0	30
	Cline	30	0	30
SPC03	T line	30	0	30
	Cline	30	0	30
SPC04	T line	30	0	30
	Cline	30	0	30
SPC05	T line	30	0	30
	Cline	30	0	30
SPC06	T line	30	0	30
	Cline	30	0	30
SNC01	T line	0	30	30
	Cline	30	0	30
SNC02	T line	0	30	30
	Cline	30	0	30
SNC03	T line	0	30	30
	Cline	30	0	30

**For the matrix of NP swabs samples without VTM -0 minutes:**



Tab 133. Testing results of repeatability(for the matrix of NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 134. Signal intensities of testing results (for the matrix of NP swabs samples without VTM)

ID	Lines	Number of "N"	Number of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30

	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For the matrix of NP swabs samples without VTM -10 minutes:**

Tab 135. Testing results of repeatability(for the matrix of NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 136. Signal intensities of testing results (for the matrix of NP swabs samples without VTM)

ID	Lines	Number of "N"	Number of "NA"	Rt
SPC07	T line	30	0	30

	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For the matrix of NP swabs samples without VTM-30 minutes:**

Tab 137. Testing results of repeatability(for the matrix of NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 138. Signal intensities of testing results (for the matrix of NP swabs samples without VTM)

ID	Lines	Number of "N"	Number of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

**For the matrix of NP swabs samples without VTM-60 minutes:**

Tab 139. Testing results of repeatability(for the matrix of NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)

	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 140. Signal intensities of testing results (for the matrix of NP swabs samples without VTM)

ID	Lines	Number of "N"	Number of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30
	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30

	Cline	30	0	30
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**For the matrix of NP swabs samples without VTM-90 minutes:**

Tab 141. Testing results of repeatability(for the matrix of NP swabs samples without VTM)

ID	Tests #	P1		P2		P3	
		T line	C line	T line	C line	T line	C line
SPC07	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)
SPC08	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC09	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)
SPC10	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SPC11	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)
SPC12	1	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	2	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	3	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	4	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	5	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	6	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	7	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	8	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	9	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
	10	+(F)	+(M)	+(F)	+(M)	+(F)	+(M)
SNC04	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)
SNC05	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)
SNC06	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 142. Signal intensities of testing results (for the matrix of NP swabs samples without VTM)

ID	Lines	Number of "N"	Number of "NA"	Rt
SPC07	T line	30	0	30
	Cline	30	0	30
SPC08	T line	30	0	30
	Cline	30	0	30
SPC09	T line	30	0	30
	Cline	30	0	30
SPC10	T line	30	0	30



	Cline	30	0	30
SPC11	T line	30	0	30
	Cline	30	0	30
SPC12	T line	30	0	30
	Cline	30	0	30
SNC04	T line	0	30	30
	Cline	30	0	30
SNC05	T line	0	30	30
	Cline	30	0	30
SNC06	T line	0	30	30
	Cline	30	0	30

### Data summary

Tab 143. Summary of positive results

Time	ID	Ri	Rp	Rn	Rt	Positive coincidence
0minutes	SPC01	0	30	0	30	30/30, +/ +
	SPC02	0	30	0	30	30/30, +/ +
	SPC03	0	30	0	30	30/30, +/ +
	SPC04	0	30	0	30	30/30, +/ +
	SPC05	0	30	0	30	30/30, +/ +
	SPC06	0	30	0	30	30/30, +/ +
	SPC07	0	30	0	30	30/30, +/ +
	SPC08	0	30	0	30	30/30, +/ +
	SPC09	0	30	0	30	30/30, +/ +
	SPC10	0	30	0	30	30/30, +/ +
	SPC11	0	30	0	30	30/30, +/ +
	SPC12	0	30	0	30	30/30, +/ +
10minutes	SPC01	0	30	0	30	30/30, +/ +
	SPC02	0	30	0	30	30/30, +/ +
	SPC03	0	30	0	30	30/30, +/ +
	SPC04	0	30	0	30	30/30, +/ +
	SPC05	0	30	0	30	30/30, +/ +
	SPC06	0	30	0	30	30/30, +/ +
	SPC07	0	30	0	30	30/30, +/ +
	SPC08	0	30	0	30	30/30, +/ +

	SPC09	0	30	0	30	30/30, +/- +
	SPC10	0	30	0	30	30/30, +/- +
	SPC11	0	30	0	30	30/30, +/- +
	SPC12	0	30	0	30	30/30, +/- +
30minutes	SPC01	0	30	0	30	30/30, +/- +
	SPC02	0	30	0	30	30/30, +/- +
	SPC03	0	30	0	30	30/30, +/- +
	SPC04	0	30	0	30	30/30, +/- +
	SPC05	0	30	0	30	30/30, +/- +
	SPC06	0	30	0	30	30/30, +/- +
	SPC07	0	30	0	30	30/30, +/- +
	SPC08	0	30	0	30	30/30, +/- +
	SPC09	0	30	0	30	30/30, +/- +
	SPC10	0	30	0	30	30/30, +/- +
	SPC11	0	30	0	30	30/30, +/- +
	SPC12	0	30	0	30	30/30, +/- +
60times	SPC01	0	30	0	30	30/30, +/- +
	SPC02	0	30	0	30	30/30, +/- +
	SPC03	0	30	0	30	30/30, +/- +
	SPC04	0	30	0	30	30/30, +/- +
	SPC05	0	30	0	30	30/30, +/- +
	SPC06	0	30	0	30	30/30, +/- +
	SPC07	0	30	0	30	30/30, +/- +
	SPC08	0	30	0	30	30/30, +/- +
	SPC09	0	30	0	30	30/30, +/- +
	SPC10	0	30	0	30	30/30, +/- +
	SPC11	0	30	0	30	30/30, +/- +
	SPC12	0	30	0	30	30/30, +/- +
90month	SPC01	0	30	0	30	30/30, +/- +
	SPC02	0	30	0	30	30/30, +/- +
	SPC03	0	30	0	30	30/30, +/- +
	SPC04	0	30	0	30	30/30, +/- +
	SPC05	0	30	0	30	30/30, +/- +
	SPC06	0	30	0	30	30/30, +/- +
	SPC07	0	30	0	30	30/30, +/- +
	SPC08	0	30	0	30	30/30, +/- +

SPC09	0	30	0	30	30/30, +/ +
SPC10	0	30	0	30	30/30, +/ +
SPC11	0	30	0	30	30/30, +/ +
SPC12	0	30	0	30	30/30, +/ +

Tab 144. Summary of negative results

Time	ID	Ri	Rp	Rn	Rt	Negative coincidence
0minutes	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
10minutes	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
30minutes	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
60minutes	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -
	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -
90minutes	SNC01	0	0	30	30	30/30, -/ -
	SNC02	0	0	30	30	30/30, -/ -
	SNC03	0	0	30	30	30/30, -/ -
	SNC04	0	0	30	30	30/30, -/ -

	SNC05	0	0	30	30	30/30, -/ -
	SNC06	0	0	30	30	30/30, -/ -

Tab 145. Summary of signal intensities record –Number of “Y”

ID	0minutes	10minutes	30minutes	60minutes	90minutes
SPC01	0	0	0	0	0
SPC02	0	0	0	0	0
SPC03	0	0	0	0	0
SPC04	0	0	0	0	0
SPC05	0	0	0	0	0
SPC06	0	0	0	0	0
SPC07	0	0	0	0	0
SPC08	0	0	0	0	0
SPC09	0	0	0	0	0
SPC10	0	0	0	0	0
SPC11	0	0	0	0	0
SPC12	0	0	0	0	0

## 5) Analysis of acceptable times of open-kit (AOT)

Tab 146. Performance parameter

SN	Performance parameter	MOT	
1	Liquid velocity	90minutes	
2	Accuracy(positive coincidence)	90minutes	
	Accuracy (negative coincidence)	90minutes	
3	Repeatability	Intra-Lot Precision	90minutes
		Inter-Lot Precision	90minutes

The minimal “MOT” among all performance items is 90minutes.

Thus the acceptable time of open-kit (AOT) is the time point -60minutes. Thus the time point –“60minutes” was chose as the claimed time of open-kit.

## 3.8 Conclusion

3.8.12 The extraction of SARS-CoV-2 Antigen Rapid Qualitative Test could have the acceptance times of reopening (ART) is 30 times at 30°C under the humidity of 30%~90%.

3.8.1 The test cartridge of SARS-cov-2 Antigen Rapid Qualitative Test should be test within 60minutes after the kits opened at 30°C under the humidity of 30%~90%.