



# **Accelerated Stability Study Report for VivaDiag™ SARS-CoV-2 Ag Rapid Test**

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**Ver1.0**

## 1 Purpose

The purpose of this testing is to summarize the accelerated stability evaluation results and provide evidence that the accelerated stability for the shelf life testing meet the protocol requirement for VivaDiag™ SARS-CoV-2 Ag Rapid Test.

## 2 Scope

Apply to VivaDiag™ SARS-CoV-2 Ag Rapid Test.

## 3 Reference Document

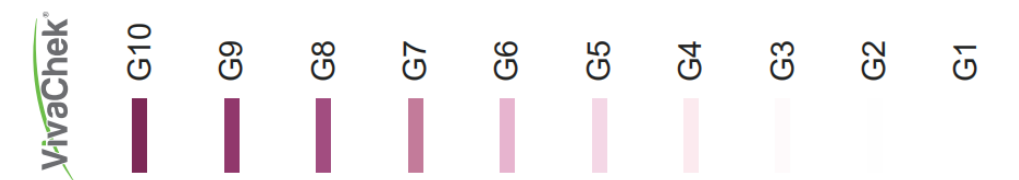
- 3.1 ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
- 3.2 EP 25-A Evaluation of Stability of in Vitro Diagnostic Reagents

## 4 Responsibilities

R&D will be responsible for protocol preparation and testing.

## 5 Materials and Equipment

- 5.1 3 VivaDiag™ SARS-CoV-2 Ag Rapid Test Lots  
(Lot 1: T2006001, Lot 2: T2006002, Lot 3: T2006003)
- 5.2 Color Grade (F-0021-RE-02 Intensity Grading Card (Rev 0))



### 5.3 Test Samples

The test sample is prepared by supplementing recombinant SARS-CoV-2 nucleocapsid protein antigen to the extraction solution. The concentrations of samples are described in below table 1:

Table 1 – Recombinant Virus Protein Ag Concentration Levels

Level	Recombinant Virus Protein Ag Concentration (ng/mL)	Range of Detection Results
N1-N20	0	T < G3
P1	1	G3 ≤ T ≤ G4
P2	2	G4 ≤ T ≤ G5
P3	4	G5 ≤ T ≤ G6
P4	8	G6 ≤ T ≤ G7
P5	16	G7 ≤ T ≤ G8
P6	32	G8 ≤ T ≤ G9
P7	64	G9 ≤ T ≤ G10
P8	128	>G10
S2	4	G5 ≤ T ≤ G6
S5	0.5	G3
S6	0	G1 ≤ T ≤ G2
R1	1	G3 ≤ T ≤ G4
R2	4	G5 ≤ T ≤ G6

#### 5.4 Test Line

N1-N20: T < G3

P1, R1: G3 ≤ T ≤ G4

P2: G4 ≤ T ≤ G5

P3, S2, R2: G5 ≤ T ≤ G6

P4: G6 ≤ T ≤ G7

P5: G7 ≤ T ≤ G8

P6: G8 ≤ T ≤ G9

P7: G9 ≤ T ≤ G10

P8: >G10

S5: T = G3

S6: G1 ≤ T ≤ G2

Cline: C ≥ G8

#### 5.5 UV Spectrophotometer (S/N: 0482)

#### 5.6 Pipettes and pipette tips

5.7 Oven (S/N: 0542)

5.8 Timer (S/N: 0220)

## 6 Acceptance Criteria

The 55 °C accelerated stability study shall meet the acceptance criteria as follows:

### 6.1 Sensitivity Evaluation

Testing sample of S6, the negative detection rate should be 100% and the color grades are G1 or G2.

Testing sample of S2 and S5, the positive detection rate should be 100%.

### 6.2 Negative Evaluation:

Testing sample of N1-N20, the negative detection rate should be 100%.

### 6.3 Positive Evaluation:

Testing sample of P1-P8, the positive detection rate should be 100%.

### 6.4 Precision Evaluation:

Testing sample of R1 and R2, the positive detection rate should be 100% and chrominance is the same.

## 7 Accelerated Stability Procedure

### 7.1 Study Site

The 55°C accelerated stability for test device study will be conducted at the VivaChek Biotech (Hangzhou) Co., Ltd.

### 7.2 55°C Accelerated Stability Condition

The VivaDiag™ SARS-CoV-2 Ag Rapid Test will be placed in an oven at 55 °C±2 °C for up to 33 days.

After storing the packaged devices for 14 days at 55°C oven, these packaged devices will be removed from the oven and placed at room temperature for at least thirty (30) minutes to stabilize before testing.

After storing the packaged devices for 22 days at 55°C oven, these packaged

devices will be removed from the oven and placed at room temperature for at least 30 minutes to stabilize before testing.

After storing the packaged devices for 30 days at 55°C oven, these packaged devices will be removed from the oven and placed at room temperature for at least 30 minutes to stabilize before testing.

And after storing the packaged devices for 33 days at 55°C oven, these packaged devices will be removed from the oven and placed at room temperature for at least 30 minutes to stabilize before testing.

55°C accelerated stability study conditions will be shown in Table 3

Table 2 - 55°C Accelerated Stability Conditions

Test Condition	Control Condition
-----	RT room temperature, not stressed), Time Zero
55 °C for 14 days	RT (room temperature, not stressed)
55 °C for 22 days	RT (room temperature, not stressed)
55 °C for 30 days	RT (room temperature, not stressed)
55°C for 33 days	RT (room temperature, not stressed)

Extrapolation of shelf life using accelerated stability data calculated with Arrhenius Equation.

According to Arrhenius Equation which relates chemical reaction rate (k) to the absolute temperature (T):

$$d(\ln k) / dT = \Delta E_a / RT^2$$

Where: E<sub>a</sub> is the activation energy; and R is the universal gas constant.

Assuming E<sub>a</sub> = approx. 19.5 Kcal/mol, the following table, derived from the Arrhenius Equation illustrates the estimated length of time at a particular storage temperature required to achieve a one-year shelf life.

Table 3 - Storage Temperature and Time

Storage Temperature	Days Required for
---------------------	-------------------

°C	One (1) Year Stability
90.4	0.8
85.2	1.2
80.2	1.8
74.9	2.7
70.1	4.0
65.0	6.0
60.1	9.2
<b>55.1</b>	<b>14.6</b>
50.1	23.0
45.0	37.5
40.1	64.4
37.0	91.0
30.1	193.0
25.1	343.7
22.1	494.8
20.1	617.7
15.1	1145.3
12.0	1688.4

According to the above table, the test device must perform satisfactorily and meet preset stability criteria after storing at 55°C for 30 days at least for supporting a two-year (24 months) shelf life for the product.

### 7.3 Evaluation Procedure

The evaluation will be performed in the following sequence.

7.3.1 Take out the test kit and keep it at room temperature.

7.3.2 Put a test device on a clean and level surface.

7.3.3 Gently unscrew the cap of an extraction tube (prefilled with 300µL extraction solution).

7.3.4 Apply 10µL sample into the extraction tube. Mix it thoroughly with the extraction solution.

7.3.5 Insert a filtered nozzle into extraction tube containing extracted specimen.

7.3.6 Invert extraction tube and apply 3 drops (about 60µL) of extracted specimen onto the specimen well.

7.3.7 Read the test result at 15 minutes comparing with Color Grade. Don't read the result after 20 minutes.

**8 Results**

8.1 Storing for 0 day

Condition		RT					
Time		0 Day					
Lot		Result					
		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line
S6	Rep.1	G9	G1	G9	G1	G9	G1
	Rep.2	G9	G1	G9	G1	G9	G1
	Rep.3	G9	G1	G9	G1	G9	G1
S5	Rep.1	G9	G3	G9	G3	G9	G3
	Rep.2	G9	G3	G9	G3	G9	G3
	Rep.3	G9	G3	G9	G3	G9	G3
S2	Rep.1	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6

Condition		RT					
Time		0 Day					
Lot		Result					
		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line
N1		G9	G1	G9	G1	G9	G1
N2		G9	G1	G9	G1	G9	G1
N3		G9	G1	G9	G1	G9	G1
N4		G9	G1	G9	G1	G9	G1
N5		G9	G1	G9	G1	G9	G1
N6		G9	G1	G9	G1	G9	G1
N7		G9	G1	G9	G1	G9	G1
N8		G9	G1	G9	G1	G9	G1
N9		G9	G1	G9	G1	G9	G1
N10		G9	G1	G9	G1	G9	G1
N11		G9	G1	G9	G1	G9	G1
N12		G9	G1	G9	G1	G9	G1
N13		G9	G1	G9	G1	G9	G1
N14		G9	G1	G9	G1	G9	G1
N15		G9	G1	G9	G1	G9	G1
N16		G9	G1	G9	G1	G9	G1
N17		G9	G1	G9	G1	G9	G1
N18		G9	G1	G9	G1	G9	G1
N19		G9	G1	G9	G1	G9	G1
N20		G9	G1	G9	G1	G9	G1
Negative Rate		100%		100%		100%	

**VivaChek Biotech (Hangzhou) Co., Ltd**

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,  
311100, Zhejiang, China

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Condition	RT					
Time	0 Day					
Lot	Result					
	T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line
P1	G9	G4	G9	G4	G9	G4
P2	G9	G5	G9	G5	G9	G5
P3	G9	G6	G9	G6	G9	G6
P4	G9	G7	G9	G7	G9	G7
P5	G9	G8	G9	G8	G9	G8
P6	G9	G9	G9	G9	G9	G9
P7	G9	G10	G9	G10	G9	G10
P8	G9	G10	G9	G10	G9	G10
Positive Rate	100%		100%		100%	

Condition	RT					
Time	0 Day					
Lot	Result					
	T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line
Rep.1	G9	G4	G9	G4	G9	G4
Rep.2	G9	G4	G9	G4	G9	G4
Rep.3	G9	G4	G9	G4	G9	G4
Rep.4	G9	G4	G9	G4	G9	G4
Rep.5	G9	G4	G9	G4	G9	G4
Rep.6	G9	G4	G9	G4	G9	G4
Rep.7	G9	G4	G9	G4	G9	G4
Rep.8	G9	G4	G9	G4	G9	G4
Rep.9	G9	G4	G9	G4	G9	G4
Rep.10	G9	G4	G9	G4	G9	G4
Positive Rate	100%		100%		100%	

Condition	RT					
Time	0 Day					
Lot	Result					
	T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line
Rep.1	G9	G6	G9	G6	G9	G6
Rep.2	G9	G6	G9	G6	G9	G6
Rep.3	G9	G6	G9	G6	G9	G6
Rep.4	G9	G6	G9	G6	G9	G6
Rep.5	G9	G6	G9	G6	G9	G6
Rep.6	G9	G6	G9	G6	G9	G6
Rep.7	G9	G6	G9	G6	G9	G6
Rep.8	G9	G6	G9	G6	G9	G6
Rep.9	G9	G6	G9	G6	G9	G6
Rep.10	G9	G6	G9	G6	G9	G6
Positive Rate	100%		100%		100%	



**VivaChek Biotech (Hangzhou) Co., Ltd**

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,  
311100, Zhejiang, China

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**8.2 Storing for 14 days**

Condition		RT						55°C					
Time		14 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
S6	Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
S5	Rep.1	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.2	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
S2	Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6

Condition		RT						55°C					
Time		14 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
N1		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N2		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N3		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N4		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N5		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N6		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N7		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N8		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N9		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N10		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N11		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N12		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N13		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N14		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N15		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N16		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N17		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N18		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N19		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N20		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Negative Rate		100%		100%		100%		100%		100%		100%	

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Condition	RT						55°C					
Time	14 Days											
Lot	Result											
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
P1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
P2	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5
P3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
P4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
P5	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8
P6	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9
P7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
P8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Positive Rate	100%		100%		100%		100%		100%		100%	

Condition	RT						55°C						
Time	14 Days												
Lot	Result												
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003		
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	
R1	Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.7	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Positive Rate	100%		100%		100%		100%		100%		100%		

Condition	RT						55°C						
Time	14 Days												
Lot	Result												
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003		
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	
R2	Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.4	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.5	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.7	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.8	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.9	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.10	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Positive Rate	100%		100%		100%		100%		100%		100%		

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8.3 Storing for 22 days

Condition		RT						55°C					
Time		22 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
S6	Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
S5	Rep.1	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.2	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
S2	Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6

Condition		RT						55°C					
Time		22 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
N1		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N2		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N3		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N4		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N5		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N6		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N7		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N8		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N9		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N10		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N11		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N12		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N13		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N14		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N15		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N16		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N17		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N18		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N19		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N20		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Negative Rate		100%		100%		100%		100%		100%		100%	

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Condition	RT						55°C					
Time	22 Days											
Lot	Result											
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
P1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
P2	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5
P3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
P4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
P5	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8
P6	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9
P7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
P8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Positive Rate	100%		100%		100%		100%		100%		100%	

Condition	RT						55°C						
Time	22 Days												
Lot	Result												
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003		
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	
R1	Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.7	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Positive Rate	100%		100%		100%		100%		100%		100%		

Condition	RT						55°C						
Time	22 Days												
Lot	Result												
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003		
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	
R2	Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.4	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.5	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.7	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.8	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.9	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.10	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Positive Rate	100%		100%		100%		100%		100%		100%		

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**8.4 Storing for 30 days**

Condition		RT						55°C					
Time		30 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
S6	Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
S5	Rep.1	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.2	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
S2	Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6

Condition		RT						55°C					
Time		30 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
N1		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N2		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N3		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N4		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N5		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N6		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N7		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N8		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N9		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N10		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N11		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N12		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N13		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N14		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N15		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N16		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N17		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N18		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N19		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N20		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Negative Rate		100%		100%		100%		100%		100%		100%	

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Condition	RT						55°C					
Time	30 Days											
Lot	Result											
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
P1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
P2	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5
P3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
P4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
P5	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8
P6	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9
P7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
P8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Positive Rate	100%		100%		100%		100%		100%		100%	

Condition	RT						55°C						
Time	30 Days												
Lot	Result												
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003		
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	
R1	Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.7	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
	Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Positive Rate	100%		100%		100%		100%		100%		100%		

Condition	RT						55°C						
Time	30 Days												
Lot	Result												
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003		
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	
R2	Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.4	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.5	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.7	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.8	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.9	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.10	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Positive Rate	100%		100%		100%		100%		100%		100%		

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**8.5 Storing for 33 days**

Condition		RT						55°C					
Time		33 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
S6	Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
	Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
S5	Rep.1	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.2	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
	Rep.3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3	G9	G3
S2	Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
	Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6

Condition		RT						55°C					
Time		33 Days											
Lot		Result											
		T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample		C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
N1		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N2		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N3		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N4		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N5		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N6		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N7		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N8		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N9		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N10		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N11		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N12		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N13		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N14		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N15		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N16		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N17		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N18		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N19		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
N20		G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Negative Rate		100%		100%		100%		100%		100%		100%	

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Condition	RT						55°C					
Time	33 Days											
Lot	Result											
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
P1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
P2	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5	G9	G5
P3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
P4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
P5	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8	G9	G8
P6	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9	G9
P7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
P8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Positive Rate	100%		100%		100%		100%		100%		100%	

Condition	RT						55°C					
Time	33 Days											
Lot	Result											
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.7	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Positive Rate	100%		100%		100%		100%		100%		100%	

Condition	RT						55°C					
Time	33 Days											
Lot	Result											
	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Test Sample	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line	C line	T line
Rep.1	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.2	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.3	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.4	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.5	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.7	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.8	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.9	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Rep.10	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6	G9	G6
Positive Rate	100%		100%		100%		100%		100%		100%	



## **9 Conclusion**

The test results for the accelerated stability evaluation at 55 °C for 33 days met the acceptance Criteria.

Therefore, the test results support a two-year (24 months) shelf life for the VivaDiag™ SARS-CoV-2 Ag Rapid Test.