

<b>Stability Test report</b> <b>COVID-19 IgG/IgM Rapid Test Kit</b>		Prepared by	XueMei Bao	
		Checked by	Juan Zhang	
Doc. No.	EGENS/CE- Appendix 5		Approved by	WeiJun Ou
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## Stability Test Report

Three batches of COVID-19 IgG/IgM Rapid Test Kit (cassette) were used to detect urine samples with standards(L1, L2, L3, L4, L5, L6) to ensure a stable device performance in the shelf-life 12 months, and the stability after first opening at different humidity.

### 1. Objective

To investigate the stability of the device, with accelerated stability test, real-time stability, stability after first opening .

### 2. Acceptance Criteria

the stability test would be considered as success that:

For IgG :L1, L2 shows positive result and L3 shows negative result.

For IgM:L4, L5 shows positive result and L6 shows negative result.

### 3. Material and Methods

#### 3.1 Material

(1) Test kit

Kit Name: COVID-19 IgG/IgM Rapid Test Kit

Lots used: 20200217, 20200218, 20200219

Testing Date: From 1/2/2020 to 10/3/2020

(2) Test Reagents

COVID-19 IgG/IgM Antibody Internal Reference Substance(Lot:20200211)

#### 3.2 Methods

##### 3.2.1 Accelerated Stability Test

Accelerated Stability of COVID-19 IgG/IgM Rapid Test Kit was evaluated using samples from three different lots. These samples were placed in an incubator with the temperature calibrated at  $50\pm 2^{\circ}\text{C}$  and relative humidity (RH) calibrated at  $60\pm 5\%$ . A series of stability tests were performed at the days list in table below. Products were tested using the controls(IgG:L1, L2, L3, IgM: L4, L5, L6).

Testing at each specific time interval consisted of duplicates for each specimen.

The tests were performed according to the package insert. And when the result shows the same with according to internal product acceptance criteria, the time interval considered as effective. If one test result is failed, the time interval considered as failed.

The study was performed with the table below:

Accelerated Term	Stability	1Year Shelf-Life	2Year Shelf-Life	3 Years Shelf-Life
	$50\pm 2^{\circ}\text{C}$	1 months	2 months	3 months

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In accelerated stability test, put three lots each of One-step and Midstream in  $50 \pm 2^\circ\text{C}$  incubator respectively. Test their performance in 0<sup>th</sup>, 5<sup>th</sup>, 10<sup>th</sup>, 15<sup>th</sup>, 20<sup>th</sup>, 25<sup>th</sup>, 30<sup>th</sup>, 35<sup>th</sup> day intervals.

### 3.2.2 Shelf Life Tests

Real-time Stability of the COVID-19 IgG/IgM Rapid Test Kit was evaluated using samples from three different lots. These samples were placed in two incubators with the temperature calibrated at  $2\sim 8^\circ\text{C}$ , and  $25\sim 32^\circ\text{C}$ . A series of stability tests were performed at the days list in table below. Products were tested using the controls(IgG:L1, L2, L3, IgM: L4, L5, L6).

Testing at each specific time interval consisted of duplicates for each specimen.

The tests were performed according to the package insert. And when the result shows the same with according to internal product acceptance criteria, the time interval considered as effective. If one test result is failed, the time interval considered as failed.

The study was performed with the table below:

2~8°C, and 25~32°C	Intervals (Months)							
	0	3	6	8	10	11	12	13

### 3.2.3 Stability after first opening

Stability study after the first opening was performed using samples from 3 different lots. The products were opened in different environment conditions for proper time, and then tested using the controls(IgG:L1, L2, L3, IgM: L4, L5, L6).

Testing at each specific condition consisted of duplicates for each specimen.

Testing at each specific time interval consisted of duplicates for each specimen.

The tests were performed according to the package insert. And when the result shows the same with according to internal product acceptance criteria, the time interval considered as effective. If one test result is failed, the time interval considered as failed.

## 4. Results

### 4.1 The Tests for Accelerated Stability Studies

Three laboratory assistants perform each test. The final result is confirmed by two same results at least. The result from  $50^\circ\text{C}$  accelerated stability studies were listed as followings(Testing is still going on):

**Table 1 : Result from  $50 \pm 2^\circ\text{C}$**

#### A. Lot I : 20200217

<b>Sample</b>	Intervals (Days)															
	0		5		10		15		20		25		30		35	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM

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L1	+	-	+	-	+	-	+	-	+	-						
L2	+	-	+	-	+	-	+	-	+	-						
L3	-	-	-	-	-	-	-	-	-	-						
L4	-	+	-	+	-	+	-	+	-	+						
L5	-	+	-	+	-	+	-	+	-	+						
L6	-	-	-	-	-	-	-	-	-	-						

**B. Lot II: 20200218**

Sample	Intervals (Days)															
	0		5		10		15		20		25		30		35	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-	+	-	+	-	+	-	+	-						
L2	+	-	+	-	+	-	+	-	+	-						
L3	-	-	-	-	-	-	-	-	-	-						
L4	-	+	-	+	-	+	-	+	-	+						
L5	-	+	-	+	-	+	-	+	-	+						
L6	-	-	-	-	-	-	-	-	-	-						

**C. Lot III: 20200219**

Sample	Intervals (Days)															
	0		5		10		15		20		25		30		35	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-	+	-	+	-	+	-	+	-						
L2	+	-	+	-	+	-	+	-	+	-						
L3	-	-	-	-	-	-	-	-	-	-						
L4	-	+	-	+	-	+	-	+	-	+						
L5	-	+	-	+	-	+	-	+	-	+						
L6	-	-	-	-	-	-	-	-	-	-						

**4.2 Real-time stability**

**4.2.1** Three laboratory assistants perform each test. The final result is confirmed by two same results at least. Results are summarized for 2~8 °C in the following (Testing is still going on):

**Table 2: Result at 2~8 °C**

**A. Lot I :20200217**

Sample	Intervals (month)															
	0		3		6		8		10		11		12		13	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-														

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L2	+	-														
L3	-	-														
L4	-	+														
L5	-	+														
L6	-	-														

**B. Lot II :20200218**

Sample	Intervals (Days)															
	0		3		6		8		10		11		12		13	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-														
L2	+	-														
L3	-	-														
L4	-	+														
L5	-	+														
L6	-	-														

**C. Lot III :20200219**

Sample	Intervals (month)															
	0		3		6		8		10		11		12		13	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-														
L2	+	-														
L3	-	-														
L4	-	+														
L5	-	+														
L6	-	-														

4.2.2 Three laboratory assistants perform each test. The final result is confirmed by two same results at least. Results are summarized for 25~32°C in the following (Testing is still going on):

**Table 3-1 : Result at 25~32°C**

**A. Lot I :20200217**

Sample	Intervals (month)															
	0		3		6		8		10		11		12		13	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-														
L2	+	-														

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L3	-	-														
L4	-	+														
L5	-	+														
L6	-	-														

### B. Lot II :20200218

Sample	Intervals(month)															
	0		3		6		8		10		11		12		13	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-														
L2	+	-														
L3	-	-														
L4	-	+														
L5	-	+														
L6	-	-														

### C. Lot III:20200219

Sample	Intervals (month)															
	0		3		6		8		10		11		12		13	
	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM	IgG	IgM
L1	+	-														
L2	+	-														
L3	-	-														
L4	-	+														
L5	-	+														
L6	-	-														

#### 4.3 After first opening stability

Three laboratory assistants perform each test. The final result is confirmed by two same results at least. We did four experiments with 3 batches of COVID-19 IgG/IgM Rapid Test Kit. All the experiments were completed at 2~30 °C . Results are summarized in the following tables:

**Table 8-1: Result of Strip of After first opening stability**

#### A. Lot I :20200217

Humidity: ≤65% 0h after Opening	tomography velocity (mm/min)	15~21					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-

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	IgM	-	-	-	+	+	-
Humidity: ≤65% 1h after Opening	tomography velocity (mm/min)	13~18					
	Sampl	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: ≤65% 2h after Opening	tomography velocity (mm/min)	10~13					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: >65% 0h after Opening	tomography velocity (mm/min)	15~21					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: >65% 1h after Opening	tomography velocity (mm/min)	12~15					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	-	-	-	-	-
	IgM	-	-	-	-	-	-
Humidity: >65% 0h after Opening	tomography velocity (mm/min)	8~11					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	-	-	-	-	-	-
	IgM	-	-	-	-	-	-

**B. Lot II : 20200218**

Humidity: ≤65% 0h after Opening	tomography velocity (mm/min)	14~20					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-

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	IgM	-	-	-	+	+	-
Humidity: ≤65% 1h after Opening	tomography velocity (mm/min)	12~15					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: ≤65% 2h after Opening	tomography velocity (mm/min)	9~13					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: >65% 0h after Opening	tomography velocity (mm/min)	14~20					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: >65% 1h after Opening	tomography velocity (mm/min)	10~13					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	-	-	-	-	-
	IgM	-	-	-	-	-	-
Humidity: >65% 0h after Opening	tomography velocity (mm/min)	7~10					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	-	-	-	-	-	-
	IgM	-	-	-	-	-	-

**C. Lot III:20200219**

Humidity: ≤65% 0h after Opening	tomography velocity (mm/min)	15~22					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-

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Humidity: ≤65% 1h after Opening	tomography velocity (mm/min)	13~15					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: ≤65% 2h after Opening	tomography velocity (mm/min)	9~13					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: >65% 0h after Opening	tomography velocity (mm/min)	15~22					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	+	-	-	-	-
	IgM	-	-	-	+	+	-
Humidity: >65% 1h after Opening	tomography velocity (mm/min)	10~13					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	+	-	-	-	-	-
	IgM	-	-	-	-	-	-
Humidity: >65% 0h after Opening	tomography velocity (mm/min)	7~10					
	Sample	L1	L2	L3	L4	L5	L6
	IgG	-	-	-	-	-	-
	IgM	-	-	-	-	-	-

Results show that the product is stable at Humidity: ≤65%, we suggest it used at one hour. When the humidity is >65%, the product must be used as soon as possible after it opened.

## 5. Conclusion

COVID-19 IgG/IgM Rapid Test Kit should be used within 1 hour of opening and, if in a high humidity environment, immediately.