# Stability Study Report

<Product name: SARS-CoV-2 Antigen Test Cassette >

<Status: Controlled>

<Date of issue: 2021.12.22>

| Prepared by | | Checked by | |
|---|---|---|---|
| **Name** | Lingjie Bu | **Name** | Yangxia Li |
| **Signature** | Ling Jie Bu | **Signature** | Yangxia Li |
| **Date** | 2021.12.22 | **Date** | 2021.12.22 |

## Applicant: Jiangsu Mole Bioscience Co., Ltd.

## CONFIDENTIAL

## Chapter 1 Basis For Determining The Stability Research Method

Stability is a basic property of in vitro diagnostic reagents, and it is an important indicator to ensure that the product is safe and effective during use. Stability research is based on the physical and chemical properties of the product and reasonable stability research experimental projects are designed to investigate the main quality indicators of the product under different conditions with time, and to provide a basis for determining the storage conditions and expiration dates of the product.

## Chapter 2 Accelerated Stability Research Report

### 1. Test purpose

To verify the stability of the SARS-CoV-2 Antigen Test Cassette at 55℃.

### 2. Test compliance procedures

Please refer to the verification of finished products in the SARS-CoV-2 Antigen Test Cassette manufacturing and inspection procedures.

### 3. Test cassettes and batches

SARS-CoV-2 Antigen Test Cassette, batch numbers are M0120101, M0120105, M0120107.

### 4. Test instruments and samples

#### 4.1 Instruments

4.1.1 Timer

4.1.2 Pipette (2.5-1000μL)

#### 4.2 Samples

5 positive references (P1-P5), 10 negative references (N1-N10), three SARS-CoV-2 antigen sensitivity references (L1, L2, and L3), 1 repeatability reference (R).

### 5. Experimental methods

The three batches of products were placed in a 55℃ oven for 1 day, 3 days, 6 days, 9 days, 12 days, 15 days, 18 days, and 21 days, and then the performance of the kits were verified with the above-





6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

mentioned references, the results should meet the technical requirements.

## 6. Test items

### 6.1 Appearance inspection

The appearance should be smooth, materials should be firmly attached and the components should be complete.

### 6.2 Migration velocity

Liquid migration speed should not be less than 10mm/min.

### 6.3 Negative coincidence rate

Test 10 SARS-CoV-2 antigen negative references (N1-N10), and all test results should be negative.

### 6.4 Positive coincidence rate

Test 5 SARS-CoV-2 antigen positive references (P1-P5), and all test results should be positive.

### 6.5 Sensitivity

The detection results of three SARS-CoV-2 antigen sensitivity references (L1, L2, L3) requires that the reference L1 must be tested as negative, and the references L2 and L3 should be tested as positive.

### 6.6 Repeatability

Repeatedly test the repeatability reference (R) for 10 times, the color density of the test line should be uniform and consistent, and the results are all positive.

## 7. Result judgment

The quality of the kit meets the requirements only when the items 6.1-6.6 are all qualified.

## 8. Conclusions of accelerated stability test

The appearance inspection, migration velocity, positive coincidence rate, negative coincidence rate, sensitivity and repeatability of three batches of kits stored at 55℃ for 1 day, 3 days, 6 days, 9 days, 12 days, 15 days, 18 days, and 21 days respectively were all in line with the expectations. According to the routine comparison between the accelerated stability test data and the long-term stability test data, the kit is valid for 24 months under long-term storage.



www.molechina.com

6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

## 9. Annex

The following are the accelerated stability test records.

Table 1. Experimental data of Accelerated Stability (55℃) (lot: M0120101)

| Days | | Day 1 | Day 3 | Day 6 | Day 9 | Day 12 | Day 15 | Day 18 | Day 21 |
|---|---|---|---|---|---|---|---|---|---|
| Appearance inspection | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Migration velocity | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Positive coincidence rate | N=5 | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ |
| Negative coincidence rate | N=10 | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- |
| Sensitivity | L1 | — | — | — | — | — | — | — | — |
| | L2 | + | + | + | + | + | + | + | + |
| | L3 | + | + | + | + | + | + | + | + |
| Repeatability | N=10 | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ |

Note: "—" means negative result, "+"means positive result and "±"means critical state.

Table 2. Experimental data of Accelerated Stability (55℃) (lot: M0120105)

| Days | | Day 1 | Day 3 | Day 6 | Day 9 | Day 12 | Day 15 | Day 18 | Day 21 |
|---|---|---|---|---|---|---|---|---|---|
| Appearance inspection | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Migration velocity | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Positive coincidence rate | N=5 | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ |
| Negative coincidence rate | N=10 | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- |
| Sensitivity | L1 | — | — | — | — | — | — | — | — |
| | L2 | + | + | + | + | + | + | + | + |
| | L3 | + | + | + | + | + | + | + | + |
| Repeatability | N=10 | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ |

Note: "—" means negative result, "+"means positive result and "±"means critical state.





6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

Table 3. Experimental data of Accelerated Stability (55℃) (lot:M0120107)

| Days | | Day 1 | Day 3 | Day 6 | Day 9 | Day 12 | Day 15 | Day 18 | Day 21 |
|---|---|---|---|---|---|---|---|---|---|
| Appearance inspection | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Migration velocity | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Positive coincidence rate | N=5 | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ | 5+ |
| Negative coincidence rate | N=10 | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- |
| Sensitivity | L1 | — | — | — | — | — | — | — | — |
| | L2 | + | + | + | + | + | + | + | + |
| | L3 | + | + | + | + | + | + | + | + |
| Repeatability | N=10 | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ |

Note: "—" means negative result, "+"means positive result and "±"means critical state.

## Chapter 3 Open Pouch Stability Research Report

### 1. Test purpose

To verify the open pouch stability of the SARS-CoV-2 antigen test cassette in different environments.

### 2. Test compliance procedures

Please refer to the verification of finished products in the SARS-CoV-2 Antigen Test Cassette manufacturing and inspection procedures.

### 3. Test cassettes and batches

Refer to the verification of finished products in the SARS-CoV-2 Antigen Test Cassette manufacturing and inspection procedures.

### 4. Test instruments and samples

#### 4.1 Instruments

4.1.1 Timer

4.1.2 Pipette (2.5-1000μL)

#### 4.2 Samples

5 positive references (P1-P5), 10 negative references (N1-N10), 3 SARS-CoV-2 antigen sensitivity references (L1, L2, and L3), 1 repeatability reference (R).





6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

**5. Experimental method**

To evaluate the open pouch stability of the kits, each performance of the test cassettes was verified with the above-mentioned references after the cassettes being stored in the three different environments with its aluminum foil pouch opened for 1 hour, 1.5 hours and 2 hours respectively. The three environments are as following: (1) 50% humidity, 25°C temperature; (2) 50% humidity, 37°C temperature; (3) 90% humidity, 37°C.

**6. Test items**

**6.1 Appearance inspection**

The appearance should be smooth, materials should be firmly attached and the components should be complete.

**6.2 Migration velocity**

Liquid migration speed should not be less than 10mm/min.

**6.3 Negative coincidence rate**

Test 10 SARS-CoV-2 antigen negative references (N1-N10), and all test results should be negative.

**6.4 Positive coincidence rate**

Test 5 SARS-CoV-2 antigen positive references (P1-P5), and all test results should be positive.

**6.5 Sensitivity**

The detection of 3 SARS-CoV-2 antigen sensitivity references (L1, L2, L3) requires that the reference L1 must be tested as negative, and the references L2 and L3 should be tested as positive.

**6.6 Repeatability**

Repeatedly test the repeatability reference (R) for 10 times, the color density of the test line should be uniform and consistent, and the results are all positive.

**7. Result judgment**

The quality of the kit meets the requirements only when the items 6.1-6.6 are all qualified.

**8. Conclusions of open pouch stability test**

The results of open pouch stability test show that the quality of the SARS-CoV-2 Antigen Test



www.molechina.com

6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

Cassette is stable within 1.5 hours in the specified environment (temperature 25°C, humidity 50%). The performance of kits starts to decline after 1.5 hours. The test cassettes become invalid faster when the temperature or the humidity goes higher. Therefore, the instructions suggest that the kit should be used as soon as possible (within 1 hour).

## 9. Annex

The following are the open pouch stability test records.

Table 4 The test card's open pouch stability (lot: M0120101)

| Environment | | Temperature 25°C, humidity 50% | | | Temperature 37°C, humidity 50% | | | Temperature 37°C, humidity 90% | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Time | | 1h | 1.5h | 2h | 1h | 1.5h | 2h | 1h | 1.5h | 2h |
| Appearance | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Migration velocity | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Positive coincidence rate | P=5 | 5+ | 5+ | 5+ | 5+ | 5+ | 4+ | 5+ | 4+ | 3+ |
| Negative coincidence rate | N=10 | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- |
| Sensitivity | L1 | — | — | — | — | — | — | — | — | — |
| | L2 | + | + | + | + | + | ± | + | + | — |
| | L3 | + | + | + | + | + | + | + | + | ± |
| Repeatability | N=10 | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 9+ |

Note: "—" means negative result, "+"means positive result and "±"means critical state.





6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

Table 5 The test card's open pouch stability (lot: M0120105)

| Environment | | Temperature 25℃, humidity 50% | | | Temperature 37℃, humidity 50% | | | Temperature 37℃, humidity 90% | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Time | | 1h | 1.5h | 2h | 1h | 1.5h | 2h | 1h | 1.5h | 2h |
| Appearance | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Migration velocity | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Positive coincidence rate | P=5 | 5+ | 5+ | 5+ | 5+ | 5+ | 4+ | 5+ | 4+ | 3+ |
| Negative coincidence rate | N=10 | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- |
| Sensitivity | L1 | — | — | — | — | — | — | — | — | — |
| | L2 | + | + | + | + | + | ± | + | ± | — |
| | L3 | + | + | + | + | + | + | + | + | ± |
| Repeatability | N=10 | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 9+ |

Note: "—" means negative result, "+"means positive result and "±"means critical state.

Table 6 The test card's unsealing stability (lot:M0120107)

| Environment | | Temperature 25℃, humidity 50% | | | Temperature 37℃, humidity 50% | | | Temperature 37℃, humidity 90% | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Time | | 1h | 1.5h | 2h | 1h | 1.5h | 2h | 1h | 1.5h | 2h |
| Appearance | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Migration velocity | | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified | Qualified |
| Positive coincidence rate | P=5 | 5+ | 5+ | 5+ | 5+ | 5+ | 4+ | 5+ | 4+ | 3+ |
| Negative coincidence rate | N=10 | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- | 10- |
| Sensitivity | L1 | — | — | — | — | — | — | — | — | — |
| | L2 | + | + | + | + | + | ± | + | + | — |
| | L3 | + | + | + | + | + | + | + | + | ± |
| Repeatability | N=10 | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 10+ | 9+ |

Note: "—" means negative result, "+"means positive result and "±"means critical state.





6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

## Chapter 4 Transportation Stability Research Report

### 1. Test purpose

To verify the impact of transportation on the SARS-CoV-2 antigen test cassette.

### 2. Test compliance procedures

Refer to the verification of finished products in the SARS-CoV-2 Antigen Test Cassette manufacturing and inspection procedures.

### 3. Test cassettes and batches

SARS-CoV-2 Antigen Test Cassette, batch numbers are M0120101, M0120105, M0120107.

### 4. Test instruments and samples

#### 4.1 Instruments

4.1.1 Timer

4.1.2 Pipette (2.5-1000μL)

#### 4.2 Samples

5 positive references (P1-P5), 10 negative references (N1-N10), 3 SARS-CoV-2 antigen sensitivity references (L1, L2, and L3), 1 repeatability reference (R).

### 5. Experimental method

Three batches of SARS-CoV-2 antigen test cassettes were shipped to Taizhou City, Jiangsu Province from Hangzhou City, Zhejiang Province at room temperature and then back to Hangzhou City in the simulated summer temperature. After the kits returned to Hangzhou, references were used to test the performance of the kits to verify the impact of transportation on the SARS-CoV-2 antigen test cassette.

### 6. Test items

#### 6.1 Appearance inspection

The appearance should be smooth, materials should be firmly attached and the components should



www.molechina.com

6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

be complete.

**6.2 Migration velocity**

Liquid migration speed should not be less than 10mm/min.

**6.3 Negative coincidence rate**

Test 10 SARS-CoV-2 antigen negative references (N1-N10), and all test results should be negative.

**6.4 Positive coincidence rate**

Test 5 SARS-CoV-2 antigen positive references (P1-P5), and all test results should be positive.

**6.5 Sensitivity**

The detection of 3 SARS-CoV-2 antigen sensitivity references (L1, L2, L3) requires that the reference L1 must be tested as negative, and the references L2 and L3 should be tested as positive.

**6.6 Repeatability**

Repeatedly test the repeatability reference (R) for 10 times, the color density of the test line should be uniform and consistent, and the results are all positive.

**7. Result judgment**

The quality of the kit meets the requirements only when the items 6.1-6.6 are all qualified.

**8. Conclusions of transportation stability test**

The appearance inspection, migration velocity, positive coincidence rate, negative coincidence rate, sensitivity and repeatability of the three batches of kits shipped back all meet the requirements, indicating that the transportation stability of the kits meet the requirements.

**9. Annex**

The following are the transportation stability test records.





6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com

**Table 7 Experimental data of transportation stability inspection**

| Batch numbers | | M0120101 | M0120105 | M0120107 |
|---|---|---|---|---|
| Appearance inspection | | Qualified | Qualified | Qualified |
| Migration velocity | | Qualified | Qualified | Qualified |
| Positive coincidence rate | N=5 | 5+ | 5+ | 5+ |
| Negative coincidence rate | N=10 | 10- | 10- | 10- |
| Sensitivity | L1 | — | — | — |
| | L2 | + | + | + |
| | L3 | + | + | + |
| Repeatability | N=10 | 10+ | 10+ | 10+ |

Note: "—" means negative result, "+"means positive result and "±"means critical state.

## Chapter 5 Conclusions

We have selected three batches of the test cassette to evaluate the stability of the product, the test results show that the test cassette performed well, and the specific conclusions are as follows:

1) Accelerated Stability: The kits have stable performance when stored at 55℃ for 21 days. According to the routine comparison between the accelerated stability test data and the long-term stability test data, the kit is valid for 24 months under long-term storage.

2) Open pouch stability: after the kit was open pouch, the performance was stable within 1 hour in the specified environment (temperature 4-30°C, humidity 40-90%).

3) Transport stability: the performance of the kit was stable within 3 days of transportation.





6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New&Hi-tech District,
Taizhou, Jiangsu Province, China
info@molechina.com