Transport Stability Studies

Product: Rapid SARS-CoV-2 Antigen Test Card
Catalog No.: 1N40C5

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Xiamen Boson Biotech Co., Ltd.

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1. Purpose

Factors such as route, distance, time and conditions (temperature, humidity, vibration, etc.) during transport may have an impact on the condition of the product packaging (outer and inner packaging, etc.) and the performance of the product. To evaluate the transport stability of the Rapid SARS-CoV-2 Antigen Test Card by simulating extreme transport conditions, including temperature, humidity, vibration, and pressure.

2. References

	Document No.	Document
1	BS EN ISO 23640:2015	In vitro diagnostic medical devices Evaluation of stability of in vitro diagnostic reagents.
2	EP25-A	Evaluation of stability of in vitro diagnostic reagents；Approved Guideline

3. Personnel and Responsibility

Name	Position	Education	Responsibility
Haolong Shen	Management Representative	B.S.	Approval of study report
Zhijuan Jia	R&D Manager	M.S.	Review of study report
Kesai Liu	R&D Engineer	M.S.	Study implementation, recording, analysis of results, and report drafting
Mengjuan Wu	R&D Vice Manager	M.S.	Study implementation, recording, analysis of results, and report drafting

4. Materials

4.1 Evaluated Reagent

Rapid SARS-CoV-2 Antigen Test Card (1N40C5)		
	Lot Number	Manufacturer
1	H20061502	Xiamen Boson Biotech Co., Ltd.

4.2 Equipment

	Equipment	Model (No.)	Manufacturer
1	Refrigerated warehouse	/	Xiamen Boson Biotech Co., Ltd.
2	Shaker	MaxQ 6000	Thermo SCIENTIFIC

4.3 Corporate Controls

	Name	Lot No. (Catalog No.)	Notes
1	Limit of detection controls	Q20061902	Xiamen Boson Biotech Co., Ltd.
2	Positive controls	Q20061903	Xiamen Boson Biotech Co., Ltd.
3	Negative controls	Q20061904	Xiamen Boson Biotech Co., Ltd.
4	Repeatability controls	Q20061905	Xiamen Boson Biotech

			Co., Ltd.

5. Methods

5.1 Test Kit Storage

1) Store one batch of test kits (in the package for sale) under -20°C and a relative humidity of 80-90% for 7 days.
2) Transfer the test kits to 50°C shaker. Leave for 7 days on the shaking mode to simulate the transport.

5.2 Sample Testing

Testing the limit of detection, positive agreement, negative agreement, repeatability of products with limit of detection controls, positive controls, negative controls and repeatability controls after simulated transport.

5.3 Standard Requirements

5.3.1 Negative Agreement

Testing 20 negative controls (N1-N20) and the agreement rate for negative controls should be 20/20.

5.3.2 Positive Agreement

Testing 8 positive controls (P1-P8) and the agreement rate for positive controls should be 8/8.

5.3.3 Limit of Detection

Testing the limit of detection controls and the results should be consistent: S1 to S4 are positive, S5 and S6 are positive or negative.

5.3.4 Repeatability

Testing repeatability control J1 and each control were tested 10 times in parallel and the results were consistent and positive.

Testing repeatability control J2 and each control were tested 10 times in parallel and the results were consistent and positive.

6. Results

Table 1. Transport stability test results

Lot Number	Limit of Detection						Positive Agreement (+/+)	Negative Agreement (-/-)	Repeatability J1	Repeatability J2
	S1	S2	S3	S4	S5	S6				
H20061502	+	+	+	+	-	-	8/8	20/20	+	+

7. Conclusion

Rapid SARS-CoV-2 Antigen Test Card was placed at -20°C and 80-90% humidity for 7 days, and after shaking at 50°C for 7 days, all the performance indicators of the reagents could meet the proposed quality standards, indicating that the kit has good stability.